Health Ins Risks and Reforms

Massachusetts

Gary Fradin
2023

Table of Contents

Preface

I wrote this book as a text version of various lectures I gave to health insurance brokers over the past decade. It describes, briefly, the functions of health insurance then, in more detail, the problems we face implementing it in the US today and some possible solutions to those problems.

Each chapter addresses a stand alone issue or set of issues but these often overlap. I apologize for redundancy but, in health insurance, similar problems appear in different guises.

I continue to be amazed that benefits professionals understand so little about the impact of the benefits they provide. Health insurance brokers are generally expert at applying regulations and understanding financial concepts but weak at understanding how the benefits they sell actually affect people medically. I hope this book will address some of that deficiency.

I take the issues discussed here personally and seriously. As a child of the 1960s who, among other things, worked for CARE in Chad, Africa building primary schools and planting orchards - the latter in a leaper colony outside N'Djamena - I have a great passion for activities that improve people's lots in life. I have an equal passion for opposing destructive activities, with unnecessary medical care being a prime example.

I value reader feedback. If any of the ideas in this text stimulate your thinking, please let me know. I'm readily available at gfradin@HealthInsuranceCE.com. I promise to respond if you write to me!

I hope you find reading this book a worthwhile experience.

Gary Fradin

Introduction and Overview

Our healthcare system falls somewhere between a 'mess' [1] and 'insane' [2] costing $10,000 per person per year but putting us about 17th internationally among the 17 richest countries in the world, in life expectancy and infant mortality.

That the system works badly is clear. *Why* it works so poorly is hotly contested and *what* we can do to fix it administratively remain hotly debated topics, with the same basic positions restated consistently for almost a century.[3]

Some say we have *too much* government influence thus destroying the market's ability to deliver high quality services at reasonable costs. Others argue that we have *insufficient* government influence, allowing private companies and healthcare providers arbitrarily to provide too much or too little care thus raising costs without improving outcomes.

Hundreds, even thousands of commentators wax poetic about the problems (OK, generally not so poetically) and their own favored solution.

As I've read dozens of books and hundreds of articles, I've been impressed with a similarity among proposed solutions: 'If only we can get the payment and regulatory incentives right,' they seem to say, 'the system will work.' Virtually everyone in the healthcare commentary business focuses on the ***supply*** of medical services - how we distribute medical care in this country - and proposes a fix that fits his or her own orientation.

I disagree. If we could have gotten the incentives right, we would have gotten the incentives right - or at least *close* to right - given that we've worked on this for decades with ineffective reforms regularly emanating from both the federal and state governments and carrier plans increasing in complexity, in theory at least, to improve outcomes and reduce costs. I don't think we can create tremendous value by focusing on the supply side of healthcare.

Instead, I think the demand side offers greater opportunities to rein in costs, reduce waste and improve outcomes.

Let me state my position clearly: I don't see payment reforms, organizational changes or plan design modifications making our healthcare distribution system much more

---

[1] See Richmond and Fein, The Healthcare Mess, 2005. Both gentlemen were Harvard Medical School professors, with Richmond the US Surgeon General under President Carter.

[2] Regina Herzlinger of Harvard Business School, speaking at the Massachusetts Association of Health Plans convention in Boston, December 2014. My notes are unclear if she said 'crazy' or 'insane'. Apologies for any error here.

[3] See Thomas Miller's article 'Health Reform: Only a Cease Fire in a Political Hundred Year's War, Health Affairs June 2010 for the gory details

efficient, effective or valuable, with 'value' defined as better outcomes at lower costs. I base that conclusion on the past 50+ years of our healthcare reform experience defined by **new financing paradigms every 20 or so years** (from major medical to managed care to tax advantaged deductibles to private exchanges to public exchanges and now a mish-mash of everything), **cost growth averaging gdp + 3-5%** and **hard outcomes lagging behind other 1st world countries.**

No healthcare reform in the past 50 years has simultaneously improved access, reduced cost and improved outcomes, though some, most notably the Affordable Care Act, have improved access somewhat. Rehashing the same tired arguments strikes me as ineffective at best and insane – doing the same thing over and over but expecting a different result - at worst.

But that is what we have chosen to do.

Why we have the healthcare mess we have

Our healthcare system exists, I would argue, for two main reasons, the less important of which is to get people healthy.

The prima facie case here: we're not terribly healthy. We don't live as long as other populations, we have higher infant mortality rates than most developed countries and higher disease morbidity rates, unconscionably high hospital readmission rates (about 20% within 30 days), tragically high hospital infection and error rates and a utilization waste factor north of 30%, probably closer to 40 or 45% and maybe even **half of all medical care.** [4]

These situations simply would not exist if our system was primarily designed to get people healthy. We have too many smart and caring people working in healthcare. A country that can put a man on the moon, as they say, can fix these problems….if it wants to.

That we haven't fixed them, and maybe haven't even improved on them enough over the past decades, results from the primary reason our healthcare system exists: to pay participants. American healthcare is more a jobs program than a medical improvement one and it actually performs this function remarkably well.

Doctors get paid to perform their tasks, as do hospitals, X-ray technicians and MRI operators, orthopedists and chiropractors, psychiatrists and podiatrists, nutritionists and pharmacists, acupuncturists, art therapists and even lowly continuing education teachers, all extremely busy, most fighting with carriers and Medicare over codes and payments, none tying patient range-of-motion increases or pain reduction to their compensation.

[4] I'll explain in detail in the chapter on Price Transparency

Financiers loan money for medical equipment and hospital construction, lawyers draw up financing and leasing contracts and sue when doctors screw up and sometimes even when they don't. Insurance carriers provide confusing policies that average 15% gross profit on their $800 billion in annual premiums. Brokers shop for policies and benefits administrators explain them to employees who generally don't understand them, patient advocates help people navigate our nonsensical system that promotes quantity over quality while aiming to reduce utilization.

Pharmaceutical companies earn money making the drugs that lawyers sue over and advertising companies develop ads for those drugs that underwrite network TV news and sports but no one knows how well those drugs actually work or even if they work at all.

Compliance experts comply with mind-numbing paperwork and regulations designed to avoid the moral hazard related systemic abuse that runs rampant throughout our system. Software engineers write the codes that track all this stuff, administrators administer, managers manage, practitioners practice, consultants consult and so on and so forth for about $3 trillion annually, double or triple what other countries pay for better results, about half of which, I suspect, leads to ineffective or harmful care when tested. [5]

'Necessary' care in American healthcare *always* means that someone can bill for it and only *sometimes* that patients benefit from it.

As evidence of the 'jobs program' nature of our healthcare system, consider these statistics provided by Jonathan Bush, founder and former CEO of Athenahealth, a huge health information company: [6]

- In 1990 there were 10 hospital employees per physician
- Twenty five years later, *after* a hospital consolidation boom justified by greater hospital efficiency and *after* the computer revolution increased office efficiency throughout the developed world and *after* outsourcing took millions of jobs overseas, there were 16 hospital employees per physician, half administrators.

All these people working in our healthcare jobs program share one common perception: they're all overworked and think we need more of them for the system to work efficiently and create value.

If you don't believe me, just ask anyone in the industry. You'll get the same answer from brokers and lawyers, chiropractors and psychologists, primary care physicians and specialists, hospital bookkeepers and patient advocates: 'I provide really great services that save the system a ton of money. We need more people like me, doing what I do'

[5] See Vinay Prasad's insightful study A Decade of Reversal, Mayo Clinic Proceedings, 2013

[6] Bush, Where Does It Hurt, page 91. Jonathan is a 'Bush': his uncle and first cousin were presidents of the US.

which is another way of saving ‘pay other people less because they provide less value than I do’ unless, of course, we want to hire more of *everyone* which is probably the real goal of healthcare anyway.

How can *everyone* save the system money, given that healthcare inflation already outpaces gdp growth every year and we pay twice as much as other countries for poorer outcomes?

The answer is that healthcare exists to hire and pay people and all these various groups jockey and lobby for compensation to perform more of their tasks rather than competing over patient outcomes. A reasonable, rational healthcare system would compensate participants for getting patients healthier less expensively. Our system compensates people for lobbying and negotiating better.

We consequently have really good lobbyists and really lousy value.

My goal in this book: turning amateur patients into professionals

I don’t mean ‘professional patients’ in any pejorative sense as in ‘people who have learned how to overuse the medical care system so they spend excessive amounts of time with doctors.’ That’s not professional; it’s just dumb.

Instead I mean professional as someone whose education and training provide them with a particular knowledge base and skill set that allows them to excel in their chosen field.

A professional patient by my definition understands how well medical care actually works according to studies, which treatments are overused in real life, which care options he or she prefers and which providers perform those treatments the best. A heavy lift but a manageable one.

Consider an analogy with cooking or other routine human activities. Great cooks take cooking classes, good cooks read cookbooks and mediocre cooks rely on personal experience.

Ditto for artists, writers, musicians, craftsmen and more.

Today we get advanced training in lots of previously routine, ordinary activities. We’ve come to accept that the more training we get in a field, the better we get at it.

Except for the most important and dysfunctional thing we do, receive medical care.

Most important? Your life may depend on your decisions.

Most dysfunctional? We annually waste hundreds of billions of dollars on ineffective or harmful care.

No Patient 101 courses exist in high schools or colleges, no introductory educational programs in doctor’s offices, no patient training in hospitals, no overview modules from

HR in large self-funded companies, not even any specific training for doctors or nurses in medical schools.

What would a patient education course teach? What body of knowledge, in other words, would a great patient acquire? Here's a short list of topics I'd recommend:

- **How to choose care that works** i.e. benefits patients based on high quality scientific studies. Only some of medical care is based on science these days according to many estimates; the rest is guesswork and hunches.[i]

  That's why great patients routinely get opinions from different physicians with different treatment orientations.

- **How to avoid care that doesn't work** or doesn't work well based similarly on scientific studies, things like extended release niacin to reduce heart attack risks, joint lavage to reduce knee pain, beta blockers to prevent heart attacks and so one. I'll provide case studies of these and others in this book.

  Patients too often trust theories, not hard evidence, thinking 'it should work because the underlying biology says so.'

  Indeed, I've heard countless people in my classes say, when I present a case study showing a particular treatment doesn't benefit patients, 'the study must be wrong.'

  I'll explain what good, reliable scientific evidence, and show why relying on it can improve your outcomes and reduce your risk of harm.

  Not to mention reduce your treatment costs.

- **How to identify care that's overused** even if studies show that it works on a well-defined patient group, because we know that overuse accounts for about third or so of medical care in the US today,[ii] things like

  Imaging for eye disease, overused according to one large study about 74% of the time,[iii]

  Antibiotics for upper respiratory and ear infections, overused about 98% of the time,

  Cardiac stress tests, overused about 19% of the time and representing over $2 billion in annual waste, among others.

- **How to choose among care alternatives** because you have treatment options most of the time.[iv] Surgery or physical therapy? More aggressive surgery or less? Physical therapy or medications? Watch-and-wait or treat now? How does a wise patient decide?

  Studies consistently show that better informed patients – that means better informed about the likely outcomes and treatment options – tend to choose less invasive, less

risky and typically therefore less costly interventions more frequently than do less well-informed patients, the amateurs.

- **How to use screening tests effectively** because some tests generate unreliable information while others are tremendously beneficial. How does a wise patient decide which screening tests to have and how frequently?

  Related to this, at what test result should *you* do something, at blood pressure of 130/80 … or 145/85 … or 160/90 for example?

  I'll discuss how different organizations make different, sometimes contradictory recommendations but virtually all leave out critical mind-body or emotional factors. Should a happy, socially active, optimistic, financially well-off, athletic fellow take medications at the same blood pressure as a depressed, impoverished, lonely one? Read Chapter 3, consider the implications, then discuss your own situation with your doctor.

- **How to choose the best specialist and hospital** for fairly obvious reasons. I'll recommend a good, but not perfect, way to identify the best: *first* decide which treatment alternative you prefer, which specific type of surgery for example, and *then* determine which surgeons perform it the most. It's the best rule-of-thumb available for determining specialist quality, though it's not perfect.

  Read the first section of this book then consider how applying the lessons to your own physician and hospital decisions might benefit you.

- **How to understand a medical study, article or ad** because they're omnipresent in today's media and everyone relies on Dr. Google to some extent.

  As a quick introductory comment, it's way more difficult to read a medical article critically than most people think.

  And the headlines, the part that too many people rely on, may misrepresent critical nuances that can affect your own care outcomes.

My hypothetical Patient 101 course wouldn't focus on medical prices or insurance coverage. I've never heard anyone say 'I won't give my child necessary care until next Open Enrollment when we can switch to a plan that covers it.'

But I have heard people say 'I can't afford all this medical care so I'll only get some', which means they have to choose which to get and that takes us back to the care quality and wise patient issues.

Why well informed patients cost less

Wise patients – the professionals in my terms – know 3 things that amateur patients generally don't.

- How to identify and avoid unnecessary, ineffective and overused medical care,

perhaps 30% of all spending. [v]

- How to identify, explore and compare treatment options, available to patients about 85% of the time. [vi] Patients who explore and compare tend to choose less risky, less invasive and consequently less expensive care about a third of the time.
- How to identify and choose better quality providers. Better quality means fewer errors and hospital readmissions, shorter hospital stays and a quicker return to good health.

Each above leads to lower medical expenditures and *all three together* lead to much lower medical spending. That's why learning to get better care with less risk will save patients and payers money.

A message for CEOs and CFOs

Corporate attempts to control employee healthcare expenses over the past 40 years have generally failed. We know this because corporate healthcare premiums (employer + employee contributions + deductibles) have inflated much faster than the overall Consumer Price Index since the 1970s.

The fundamental reason is not necessarily inappropriate plan designs.

Instead, it's the attempt to solve clinical problems with financial or insurance tools, things like

- **Higher deductibles to reduce wasteful spending** but without defining waste or suggesting ways for your employees to differentiate high from low quality care.
- **Medical price lists**, to which amateur patients may respond 'I want the higher priced care because it's probably better'.
- **Wellness programs** that reward your current healthy employees financially but make the least well employees, i.e. your most expensive medically, feel badly so they don't participate.
- **Health risk assessments**, financially incentivized, meant somehow replace a primary care physician's advice.
- **Tax saving programs** – HSAs, HRAs, FSAs for example - that confuse participants and don't improve patient outcomes, and more.

We impose all this on employees who often lack critical medical decision making skills: some 88% of Americans are medically illiterate according to the US Department of Health and Human Services. [vii]

Illiterate means 'hasn't been trained' not 'stupid'.

'Medically illiterate' also means unable to estimate the likely benefits and risks of medical care.

Imposing financial incentives on this group can't possibly generate satisfying results either for you or them and it hasn't.

But there's an alternative approach: expanding employee medical literacy through a serious and well organized education program. Consider the potential impact on your utilization rates from this conclusion to the 2012 Patient Preferences Matter report, jointly authored by Dartmouth medical and business school professors: [viii]

> Well informed patients consume less medicine – and not just a little bit less, but much less.

And this observation from Dr. Sandeep Jauhar in his autobiographic book Doctored, largely a description of his years overtreating patients:

> Better informed patients might be the most potent restraint on overutilization.

To make your health insurance program work - reduce corporate medical spending, decrease unnecessary utilization and help your employees get or remain healthy – you need to include employee education about care quality.

Well informed vs. poorly informed patients

Many studies show that poorly informed people utilize medical care more, and consequently cost more, than well informed folks. Poorly informed patients typically assume that medical care works better than, in fact, it does. Poorly informed patients also typically think that higher technology and more invasive treatments are better than alternatives.

I'll suggest these definitions of well and poorly informed patients:

- Well informed patients focus on outcomes and risk likelihoods from more than 1 treatment alternative.
- Poorly informed patients focus on anatomy, physiology and biology and try to become mini-MDs in their attempts to understand their medical problem and determine how to proceed.

Patients who focus on outcomes tend to get better outcomes.

Patients who focus on bodily functions tend to get more care.

The task ahead

I see value creation – getting better outcomes for less money – as the fundamental future task of health insurance brokers. There's a vast opportunity and market for the most creative and forward thinking to participate and prosper in this endeavor.

I'll discuss that in this book.

I'll also discuss our various healthcare reforms – the Medicare Modernization Act of 2003 and its follow up, mainly the Trump healthcare reform proposals of 2017 – and the Affordable Care Act of 2010 and its follow up, mainly the Biden 2021 healthcare reform

proposals. And I'll discuss various other programs that may, possibly, transform American healthcare into the high quality patient care system that we all want.

Part 1: Health Insurance Risks

Risks, costs and causes

Chronic disease treatments consume about 85% of all healthcare spending with about half of Americans – that's roughly 160 million folks - having one or more chronic diseases. The number of chronic disease patients grows by 7 – 8 million every 5 years.[7]

The ten most common chronic conditions are arthritis, cancer, chronic obstructive pulmonary disease, coronary heart disease, asthma, diabetes, hepatitis, hypertension, stroke and weak or failing kidneys. These often – not always – have a lifestyle cause, a combination of excess body weight, suboptimal nutrition and insufficient exercise.

We have known about these chronic diseases, their costs and their causes for years, yet they continue and increase. Why? This chapter will suggest answers and focus on diabetes as a prime example of a lifestyle-caused chronic condition.

Diabetes occurs when your body produces too little insulin and results in you having too much sugar in your bloodstream. The disease comes in 2 basic forms: Type 1, an autoimmune disorder typically identified in kids for which there is no cure and Type 2, largely behaviorally based, in which your body doesn't use insulin well and can't regulate sugar in blood stream. About 95% of diabetic population has Type 2. It is largely preventable and potentially reversable. (Type 1 is neither.) We'll focus on Type 2 in this chapter.

Diabetes increases your risk of developing many of the chronic conditions listed above, perhaps most notably hypertension, failing kidney and heart disease. We might consider it a common cause of and link among America's epidemic of chronic diseases. That's admittedly an overstatement, though not a huge one.

Diabetes is defined by your number on one of 4 medical tests:

- Your A1C (aka hemoglobin A1C or HbA1c) above 6.5%
- Your fasting blood sugar above 126 mg/dL
- Your glucose tolerance above 200 mg/dL 2 hours after drinking a liquid. You need to fast the night before.
- Your random blood sugar above 200 mg/dL

About 37 million Americans have diabetes. It is the 7th leading cause of death and the #1 cause of kidney failure, lower limb amputations and blindness in the US. The number of diabetics has doubled in the past 20 years.

[7] The Relation of the Chronic Disease Epidemic to the Healthcare Crisis, Holman, American College of Rheumatology, Feb 19, 2020

Two syndromes / conditions predict a patient becoming diagnosed with diabetes: 'prediabetes' and 'metabolic syndrome'. Though overlapping in some ways, these are distinct. Both provide a warning to patients about their likely diabetes diagnosis future.

Prediabetes is a narrowly defined condition in which you have too much sugar in your bloodstream though not enough to have full blown diabetes. By the CDC's definition, you have prediabetes if tests determine the following about your blood sugar:

- Your A1C or hemoglobin A1C or HbA1c test is 5.7 and 6.4%.
    - Full blown diabetes is defined 6.5% or greater.
- Your fasting blood sugar test is 100 – 125 mg/dL.
    - Full blown diabetes is defined as 126 mg/dL or greater.
- Your glucose tolerance test is 140 – 199 mg/dL.
    - Full blown diabetes is defined as above 200 mg/dL.

Here's a summary chart.[8]

Result*	A1C Test	Fasting Blood Sugar Test	Glucose Tolerance Test	Random Blood Sugar Test
Diabetes	6.5% or above	126 mg/dL or above	200 mg/dL or above	200 mg/dL or above
Prediabetes	5.7 – 6.4%	100 – 125 mg/dL	140 – 199 mg/dL	N/A
Normal	Below 5.7%	99 mg/dL or below	140 mg/dL or below	N/A

About 96 million Americans have prediabetes including, according to Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy, about 1 in 4 American teenagers.[9] The condition increases your risk of developing Type 2 diabetes and suffering from all the problems associated with and resulting from it.

Metabolic syndrome, the other common precursor to full blown diabetes, is defined more broadly, again by the results of medical tests. It is a cluster of medical conditions occurring together, first identified in 1998. Though some researchers quibble about the exact numbers that define it, here is a generally accepted definition. [10]

- Obesity or having a BMI > 30.
    - Alternatively, males have a waist circumference >40 inches, females > 35.

[8] CDC Diabetes Basics https://www.cdc.gov/diabetes/basics/getting-tested.html

[9] Boston Globe, Nov 22, 2021 'The Obesity Pandemic Has Made Covid Much More Deadly'

[10] This definition comes from Harvard Health, Shmerling, Metabolic Syndrome is On the Rise, Oct 2, 2020 and AARP, Levine, Metabolic Syndrome

- Blood triglyceride levels above 150 mg/dL
- Low HDL (good) cholesterol, levels below 40 mg/dL in men or 50 in women
- High blood pressure, greater than 130/85 or on blood pressure medications.
    - For people over 60 years old, the American Heart Association suggests levels above 150/90
- Elevated blood sugar, having a fasting blood glucose level above 100 mg/dL, an A1C above 5.7 or taking diabetes medications.

Researchers seem to suggest that having 3 or more of these indicators defines someone has having metabolic syndrome.

Some 37% of Americans suffer from metabolic syndrome with the risk increasing as you age; some 50% of 60-year-olds have it including almost 60% of Hispanics over 60. [11]

People with metabolic syndrome are about 4x more likely to develop diabetes than healthy folks, 3x more likely to suffer a heart attack or have a stroke, and 55% more likely to develop kidney disease. In addition, according to the National Heart, Lung and Blood Institute[12], the syndrome increases your risk of developing

- Coronary heart disease
- Erectile disfunction
- Heart failure
- Inflammation and immune system problems – raise risks of complications from infections and Covid
- Organ damage esp pancreas, liver, gall bladder, kidneys
- Polycystic ovary syndrome (PCOS)
- Pregnancy complications such as preeclamsia, eclampsia, and gestational diabetes
- Problems with thinking and memory
- Sleep apnea and
- Certain cancers.

Metabolic syndrome, like prediabetes and diabetes itself, is largely preventable by maintaining a healthy weight, eating a healthy diet, exercising regularly and avoiding smoking.[13]

[11] AARP, Metabolic Syndrome, Levine

[12] National Heart, Lung and Blood Institute https://www.nhlbi.nih.gov/health/metabolic-syndrome/living-with

[13] Ibid.

This link between obesity, defined as having a Body Mass Index greater than 30, and diabetes is so strong that some researchers invented a new word for it: diabesity.[14] As the Cleveland Clinic put it in 2021:

> The pancreas creates insulin, which is a hormone that moves glucose out of your blood. Normally, insulin transports glucose to your muscles to use right away for energy or to the liver, where it's stored for later.
>
> But when you have diabesity, your cells resist letting insulin move glucose into them. To make matters worse, the area of your liver where excess glucose is usually stored is filled with fat. It's like trying to put furniture in a room that's already packed. With nowhere to be stored, the glucose remains in the bloodstream.
>
> Your pancreas becomes overworked, and as a result, it wears out. It starts producing less insulin. Diabetes develops and then quickly worsens if the fat resistance remains

The CDC calls diabetes the most expensive medical condition in the US, though no one knows for sure how much it costs because it affects so many other medical conditions. Should we include leg amputations as diabetes costs? The associated prosthetics? Unclear.

The CDC estimated direct diabetes costs and related reduced productivity at the lower end, $327 billion in 2017. That's about $500 billion today give a take a few dozen billion, about 14% of healthcare spending. That's the low estimate.

On the higher end, the American Diabetes Association claims that 25% of all US healthcare spending goes to diabetes and related treatments.[15] I don't know who's right here, but under either estimate, diabetes is a big deal and very expensive.

We know a lot about it, understand its causes and estimate its costs as high under any reasonable assumptions. Why can't we prevent it?

Why We Don't Prevent Diabetes
and cut healthcare spending while improving American's health

The classic advice for treating metabolic syndrome or pre-diabetes, the two typical precursors of full blown diabetes, is lifestyle modification. This traditionally has 2 components: dietary improvement and exercise increase. In short, eat a bit less of primarily healthier foods, and exercise a bit more.

---

[14] Cleveland Clinic, November 2021 'Diabesity: How Obesity is Related to Diabetes', slightly edited in the following quote.

[15] American Diabetes Association. Economic costs of diabetes in the US in 2017. *Diabetes Care.* 2018;41:917–928.

Easier said than done.

Let's put some numbers and costs into this advice. We'll use American males as our case study here simply to present an analytic framework. This will help us understand our dismal failure to prevent diabetes.

> We could have used American females instead of males – same methodology, just different numbers. Ditto for other socio-economic groups: Latino women, Appalachian residents, Appalachian single parent families, elderly urban men, etc. Same methodology, different numbers.

We'll first address the dietary part of that old 'diet and exercise' mantra and consider calorie **quantity** and **quality**.

In 2022, the average American male – we'll call him Joe - was 5 foot 9 inches tall, 38 years old, exercised 1 – 3 times per week and weighed 198 lbs.[16] He had a BMI of 29.2, almost obese. He gained about 1.5 pounds per year. According to online calorie consumption estimates[17], he needs to eat about 2650 calories per day; that's the amount necessary to maintain his 1.5 pound / year weight increase.

We'll assume that Joe is single for analytic ease.

Joe needs to reduce his daily calorie intake to 2237 to lose ½ a pound per week. That would get him down to 172 pounds in a year for a BMI of 25.4, slightly overweight but not nearly obese. It would probably get him out of the prediabetic or metabolic syndrome condition and help him avoid diabetes.

> I choose the ½ pound per week weight loss as a moderate amount; I didn't want to bias this analysis with a more aggressive number. Some research suggests that a faster weight loss, with the associated greater degree of daily discomfort /

---

[16] Average weight American male adult from healthline.com https://www.healthline.com/health/mens-health/average-weight-for-men

Average height American male adult from World Population Review https://worldpopulationreview.com/state-rankings/average-height-by-state

Average age Americans in 2022 from World Population Review https://worldpopulationreview.com/state-rankings/median-age-by-state

How Much Do Americans Exercise, Romero, Washingtonian, May 12, 2012

Daily calories to lose ½ lb / week from www.Calculator.net

Daily calories to gain 1.5 lbs / year from www.Calculators.net

Average American annual weight gain from Washington Post, 'Look How Much Weight You're Going to Gain' 1/29/2016

[17] In this case I used www.calculator.net.

hunger, leads to a quicker termination of this dietary program with the associated relatively fast rebound back to the original weight.

In other words, I want to stack the odds in Joe's favor.

We'll assume here that Joe spends 10% of his income on food. That comes from the US Department of Agriculture's 2021 estimate. [18]

We know that Joe earns $1,144 / week – that's $59,488 per year - thanks to various Bureau of Labor Statistics studies.[19] That means he has $16.34 available for food each day, 7 days / week, a combination of eating in and eating out. The BLS says we split this about 50/50.

If Joe was a Black or Hispanic male – an example of some specific socio-economic groups – he would only earn $820 / week ($42,640 per year) [20] meaning $11.71 available for food.

Or if Joe were a woman, a different socio-economic group, he would earn, on average, about 15% less and need about 10% fewer calories, than an average American male.[21]

Quick quantitative summary:

- Joe currently eats about 2650 calories per day. He gains about 1.5 pounds per year.
- He needs to reduce his daily caloric intake to 2237 to lose ½ pound per week or 26 pounds / year. That's 13% of his body weight.
- He has $16.34 available for food daily.

Let's turn now from calorie quantity to calorie **quality**. The most recent government recommendation is that our food plate consist of 50% fruits and vegetables, 25% grains – mainly whole grains – and 25% protein and dairy. That's a rough approximation of the

---

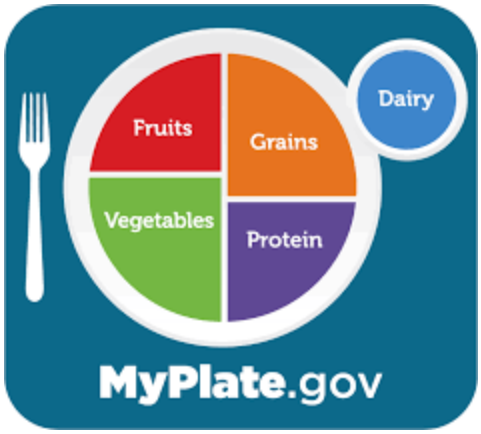
[18] US Dept of Agriculture estimate 2021, https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=76967#:~:text=In%202021%2C%20U.S.%20consumers%20spent,from%20home%20(5.1%20percent).

[19] Overall Median weekly earnings from BLS, wkyeng (5).pdf, July 29, 2022, 'Usual Weekly Earnings of Wage and Salary Workers Second Quarter 2022'

[20] Black and Hispanic male earnings from BLS, 'TED, The Economics Daily', Oct 25, 2021, https://www.bls.gov/opub/ted/2021/median-weekly-earnings-were-916-for-women-in-third-quarter-2021-83-3-percent-of-mens-earnings.htm#:~:text=Source%3A%20U.S.%20Bureau%20of%20Labor,End%20of%20interactive%20chart.&text=In%20the%20third%20quarter%20of%202021%2C%20median%20weekly%20earnings%20for,the%20median%20for%20White%20men.

[21] Earning estimates from various BLS studies. Calorie estimates from calculator.net; I simply substituted 'female' for 'male' using Joe's numbers. The calculator estimated 2008 calories / day for a woman instead of 2237 for Joe.

US Department of Agriculture's MyPlate, image below. You can google MyPlate.gov for more.



I don't like this graphic though. It's too cartoonish in my opinion and not detailed enough as a guide. I prefer the Canadian version, below. It's essentially the same – see the small dairy dish in the protein section as opposed to the small dairy circle in the American MyPlate version - but with more impactful graphics in my opinion. The Canadian version shows specific foods in each category. We'll use it in this chapter rather than the MyPlate image, again, only for presentation reasons. Feel free to disagree with my artistic taste.

The Canadian Food Plate

Water is the recommended drink.

You can quickly see the breadth and types of foods in each category and the approximate serving size of each.

> Proteins, for example, include nuts, beans, legumes and eggs, not just chicken, beef, pork, and fish and take up a quarter of your meal plate.
>
> Fruits and vegetables come in lots of different colors and flavors, with that variety apparently providing nutritional benefits.

This version seems to suggest that we eat lots of different vegetables, not just potatoes and tomatoes, the most commonly consumed vegetables in the US, which together dwarf all the others combined.[22]

Ditto lots of different fruits, not just apples and oranges, the most commonly consumed fruits in the US, which, along with bananas, dwarf the others.[23]

That's why I like this graphic: it's impactful and suggests what to eat simply and comprehensibly.

It also tells you what to avoid. Look at what's not on this plate:

- Corn
- Sugar
- Sweeteners
- Oils, salad dressing
- Refined, bleached flour
- Processed foods and snacks like chips, cookies & baked goods
- Sugary drinks
- Beer, wine & alcohol

We eat lots of these foods. Consider these summaries from a 2016 Pew study of American food and nutrition practices:[24]

> Baked goods, a $35 billion / year market segment not on the Food Plate, includes refined flour and sugar.
>
> Sweeteners, about 15% of daily calories for the average American, include sugar and corn based products (in addition to non-caloric options like aspartame). A can of regular Coke contains 140 calories for example. Americans consume

---

[22] Potatoes and tomatoes most commonly consumed vegetables, US Economic Research Service, Department of Agriculture, 2019 https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58340

[23] Apples and oranges are top US fruit choices, US Economic Research Service, Department of Agriculture, 2019 https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58322

[24] What's On Your Table: How America's Diet Has Changed Over the Decades, Drew Desilver, Dec 13, 2016

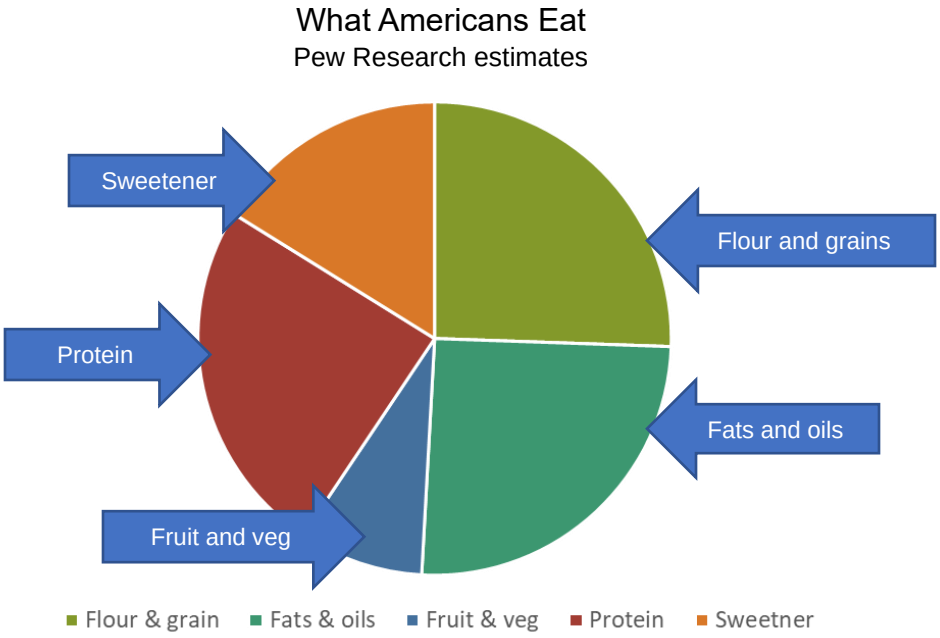
about 40 gallons of soft drinks per person annually, 72% non-diet.[25] Soft drink sales run about $318 billion per year. Not on the Food Plate.

Snacks, about 27% of children's daily caloric intake (remember Tufts School of Nutrition Dean Dr. Mozaffarian's estimate that 1 in 4 American teenagers is pre-diabetic?), mainly salty snacks, candy, cookies, and sugary drinks. Salty snacks, ice cream, candy and cookies are a $70 billion / year industry segment. Not on the Food Plate.

Oils for cooking, flavoring, and salad dressing, about 23% of our daily calories. On average. Americans eat about 36 pounds of these per year. Not on the Food Plate.

Processed foods including hydrogenated oils, HFCS, flavoring agents and emulsifiers used in foods like potato chips, sugary drinks & processed meat, not on the Food Plate. Processed foods tend to lead to higher weight gain than unprocessed.[26]

Instead of eating the high quality calories shown on the Food Plate above, here, according to the Pew Research folks, is what we really eat:



I find this estimate credible based on supermarket shelf space allocations and restaurant menus.

---

[25] Diet vs regular soda percent estimates from statistica.com https://www.statista.com/statistics/1133019/carbonated-soft-drinks-regular-vs-diet-volume-us/

[26] First randomized, controlled study finds ultra processed diet leads to weight gain, Clinical Center News from NIH, 2019 https://clinicalcenter.nih.gov/about/news/newsletter/2019/summer/story-01.html

Supermarkets allocate shelf space according to food sales, more to foods that sell the best. See, for example, the space allocated to salad dressing, cookies and sweetened breakfast cereal.

Restaurants offer meals that people request the most. See, for example, in moderate priced, popular restaurants - the large chains for example – the frequency of 'burger and fries' or 'chicken, potato and small vegetable of the day' or 'salad' generally consisting only of lettuce, tomato and carrot shavings doused in dressing (many restaurants offer more dressing options than vegetable variety). Compare to the frequency of fruit offerings.

Joe, our typical American male, thus faces 3 tasks in the attempt to improve his diet and thus avoid diabetes.

- Eat fewer calories.
- Eat higher quality calories.
- Stay within his $16.34/day food budget.

How might he accomplish all this?

Composite Daily Menus

Let's compare the daily costs of Joe's current diet and a healthier one designed to prevent diabetes. I've developed two sample day's meals – one called Food Plate based on the Canadian Food Plate above and the other called Typical based on the Pew analysis. I used food prices at my local Shaw's supermarket in Easton, Massachusetts in October 2022.

These diets are composites of what people *should* eat and what they often *in fact* eat. In designing these menus – particularly the typical one - I considered supermarket shelf space. I choose popular items meaning lots of people buy and eat them.

We have, of course, endless food options and combinations in this country. I present this analysis in part to show calorie and cost data and in part to show a methodology. Do a similar analysis yourself and see your own results. I suspect they will be close to mine below.

The healthier Food Plate diet below comes to 2237 calories for a day (our goal for Joe to lose ½ pound / week); the typical diet comes to 2648 calories (very close to our daily estimate of 2650 for Joe to gain 1.5 pounds / year).

Look at the cost difference.

Breakfast, Food Plate

- 1 whole wheat English muffin = 120 calories, $.88
- 2 tablespoons peanut butter = 190 calories, $.32
- 1 medium banana = 105 calories, $.24

- 1 large orange = 87 calories, $.73
- Black coffee = 2 calories, $.20
- 504 calories
- $2.37 at Shaw's, Easton

Breakfast, typical diet

- Shaw's honey bran muffin = 420 calories, $1.25
- Coffee = 2 calories, $.20
- Cream @ 35 calories per serving of Coffeemate = 35 calories, $.07
- Sugar @ 30 calories per serving of granular sugar = 30 calories, $.04
- 487 calories
- $1.56 at Shaw's, Easton

Lunch, Food Plate

- Spinach salad w/ tomato, carrots, yellow pepper, beets (130 cal total, $5.02)
    - 1 serving of fresh spinach = 20 calories, $1.71
    - Half a tomato = 45 calories, $1.50
    - Half a serving of carrots = 15 calories, $.16
    - Half a yellow pepper = 25 calories, $.85
    - Half a serving of beets = 25 calories, $.80
- Oil & vinegar dressing = 84 calories, $.22
- .33 lb chicken breast @ 748 calories per pound = 247 calories, $1.32
- 1 pita = 90 calories, $.37
- Apple = 95 calories, $.66
- 648 calories
- $7.62 at Shaw's, Easton

Lunch, typical diet

- Ham & cheese on sub roll with mustard & iceberg lettuce (538 cal total, $3.20)
    - Ham,.25 pound @ 885 calories per pound = 221 calories, $2.00
    - Cheese, 1 slice = 100 calories, $.30
    - Sub roll = 200 calories, $.50
    - French's mustard, 1 serving = 1 calorie, $.03
    - Iceberg lettuce .15 of a head = 16 calories, $.37
- Bag of chips from multi-bag box = 150 calories, $.52
- 3 Oreos = 160 calories, $.26
- Apple = 95 calories, $.66
- Coca Cola, can = 140 calories, $.23
- 1083 calories
- $4.88 at Shaw's, Easton

Dinner, Food Plate

- Basmati rice bowl with broccoli, summer squash, snap peas, green beans, .4 lb salmon, soy (873 calorie total, $8.48)
    - 2 cups Basmati rice @ 170 calories per cup = 340 calories, $.38
    - 1/3 pound of broccoli = 51 calories, $.66
    - 1/3 pound of summer squash = 24 calories, $.66
    - 1 serving of sugar snap peas = 35 calories, $1.00
    - ¼ pound of green beans = 25 calories, $.82
    - .4 pounds of salmon = 378 calories, $4.80
    - 1 tablespoon low salt soy sauce = 20 calories, $.16
- Blueberries (.6 pint) = 137 calories, $1.20
- Strawberries (.5 lb.) = 75 calories, $2.50
- 1085 calories
- $12.17 at Shaw's, Easton

Dinner, typical diet

- Pasta with sauce, ground beef, grated cheese (578 calories, $2.55 total)
    - Barilla pasta, 1 serving = 200 calories, $.37
    - Prego traditional pasta sauce, 1 serving = 70 calories, $.80
    - 80% ground beef, .25 pounds = 288 calories, $1.25
    - Grated Kraft parmesan cheese, 1 serving = 20 calories, $.13
- Green salad with dressing (150 calories)
    - Dole American salad bag, 2 servings = 30 calories, $1.50
    - Ken's House Italian dressing, 1 serving = 120 calories. $.25
- Canned peaches, 1 serving = 100 calories, $.50
- Friendly's vanilla ice cream, ½ serving = 105 calories, $.28
- Bottle of Budweiser beer = 145 calories, $1.38
- 1078 calories
- $6.46 total, food from Shaw's, Easton, beer from Walmart

You can see my spreadsheets at the end of this chapter for additional details. I encourage you to use this methodology with your dietary analysis. You can adjust the daily calorie targets to fit your own needs, then insert your foods of choice.

We learn from this process that 2237 healthier Food Plate calories cost $22.16 / day. Those are the foods Joe is supposed to eat, with meals designed to lose ½ pound per week. If Joe spends 10% of his salary on food as the Bureau of Labor Statistics suggests, then he needs to earn at least $80,000 per year to afford this menu.

But Joe only earns $59,488 per year. We learned that earlier in this chapter. He can't afford the healthy Food Plate!

> Imagine that Joe is a Black or Hispanic male. He'd only earn $42,640 per year making the Food Plate even more unaffordable.
>
> Try this with your socio-economic demographic of interest and see what you learn.

Now let's consider the 2648 calorie typical diet. It only costs $12.90 / day, making it affordable to people earning at least $47,000 per year. Joe earns that much. It is tasty and satisfying.

But he gains 1.5 pounds per year on it and risks prediabetes, metabolic syndrome and diabetes.

We're beginning to learn why we don't prevent diabetes by following the 'eat more fruits, vegetables and whole grains, less processed food, fat and sugar' mantra. It's too expensive.

This analysis only addressed foods prepared at home using one particular supermarket's prices and one daily food scenario. I ran a similar analysis on restaurants, comparing healthier and typical meals at Cheesecake Factory and D'Angelo's. It's methodologically easy; simply look up your items of choice on the restaurant's menu and nutritional guide – sometimes they're listed together on the menu - then divide.

Here's what I found, again all in October 2022.

> At the Cheesecake Factory, 'The Club' sandwich with turkey, bacon, bread, French Fries, lettuce, tomato and mayonnaise contains 1740 calories and costs $17.95. That's 1.0¢ per calorie.
>
> The Cheesecake Factory's Skinnylicious Factory Chopped Salad including dressing contains 530 calories and costs $15.95. That's 3.0¢ per calorie, 3x more per calorie than the Club sandwich.
>
> At D'Angelo's, the medium Italian sub contains 790 calories and costs $10.29. That's 1.3¢ per calorie.
>
> The D'Angelo's Garden Salad with small Pokket (pita bread) but without dressing contains 180 calories and costs 4.6¢ per calorie, about 3.5x more per calorie than the Italian sub.

As with our supermarket example above, eating the Food Plate healthier calories costs more. The oft-recommended 'fruits, vegetables and whole grains, not processed food, fat and sugar' diet is still too expensive.

How much more expensive? According to my supermarket food data above, eating healthier – meaning eating according to the Food Plate – costs about $9.12 more per

person per day. That's $3320 per year or, for the US average 2.6-person household, over $8300.

> A *single person* would need to earn $33,000 more annually to afford the Food Plate meals above. That's using the US Department of Agriculture's '10% of your income on food' estimate discussed above.
>
> An *average American household* would need to earn $83,000 more.

That's not the cost of eating but the *additional* cost of eating a healthy diet, the one designed to avoid or exit from, metabolic syndrome.

That's a significant economic disincentive to eat healthy foods and a significant economic incentive to stay the course.

Why do healthier foods cost more?

This chapter is not a discussion of food subsidies but the question often arises from astute readers. Here's a very short explanation:

Congress and various states subsidize food production.[27] In 2016, for example, the feds provided $13.9 billion in crop subsidies and insurance payments, equivalent to 25% of farmers income. Those subsidies generally went to the largest and best organized farm groups like huge companies that produce commodities - corn and soybeans for example. About 90 million acres – half our farmland – goes to those types of (heavily subsidized) products.

Food producers, in turn, then use those products in processed foods. That helps explain why corn sugar (a.k.a High Fructose Corn Sugar, HFCS and corn syrup) is included in so many of our processed foods. Just check the ingredients of your favorite jars or cans of food. We'll discuss this more in the section on food tastes, below.

> Subsidized corn sugar helps control the cost of real sugar, thus expanding the market for sweeteners, about 15% of American's typical daily calories.

Meanwhile, only about 10 million acres, or 3% of our cropland, goes to fruits, nuts and vegetables, products not typically included in the farm subsidy programs. They're more expensive for 2 reasons:

- Consumers pay the full price for their production since production costs are not subsidized
- There is no excess supply since their acreage is constrained by market forces, not supplemented by subsidies. Tighter acreage means less supply. The standard economics of price being determined by supply and demand factors then takes over.

[27] This analysis comes from Barth, Congress Finally Passed a New Farm Bill, January 7, 2019, Modern Farmer

We subsidize the foods we're not supposed to eat much of, and fail to subsidize the foods we're supposed to eat in abundance.

But wait, there's more

Let's now discuss some additional, non-cost problems of switching from our typical to a Food Plate diet. The problems fit into 3 groups: hunger, taste, and convenience. How much of a financial incentive would be required to induce people to overcome these problems? That's over and above the $3320 per person food cost difference.

Hunger: as people eat fewer calories, they feel hungry. That's the prime behavioral reason so many diets fail: people want that satisfying full feeling.

> I sometimes hear people claim, 'I lost 25 pounds and never felt hungry.'
>
> I rarely see these dietary results replicated on a large group of people over a long time period, making me dubious. Indeed, studies suggest that the vast majority of dieters regain all their weight within 2 years. I suspect hunger or related food cravings is a primary culprit.
>
> But when people claim to have lost weight without feeling hungry, I often respond 'Why doesn't everyone do that?'. That generally ends the conversation.

I can identify only 2 large groups of people who successfully lose weight by dieting and keep it off for a long time period: actors and athletes. (Apologies if I unintentionally missed a group.) Actors and athletes often / always have body weight requirements included in their employment contracts. That's a tremendous economic incentive, far exceeding anything that employers, insurance companies or the medical establishment can provide to employees or patients.

> A word about the long term issue facing of dietary incentives. Good food habits – eating certain foods, losing your taste for others, acclimating yourself to a certain 'appropriate' hunger – takes months if not years to develop. By appropriate' hunger, I mean accustoming yourself to feeling somewhat hungry much of the time and feeling only somewhat full immediately after meals. Most people, according to studies, need at least a few months to develop new food habits; other folks need much longer.[28] I needed a year when I lost 40 pounds in 2021 but that story comes later in this chapter.

How much of an economic incentive does Joe need to switch from his traditional 2650 calories per day to the Food Plate's 2237? Probably less than the $200,000 Matthew

---

[28] Grohol, Need to Form a New Habit? Give Yourself At Least 66 Days, PsychCentral, October 7, 2018 https://psychcentral.com/blog/need-to-form-a-new-habit-66-days ; UCL News August 9, 2009 Interview with Phillippa Lally https://www.ucl.ac.uk/news/2009/aug/how-long-does-it-take-form-habit

McConaughey earned for his 50 pound weight loss in Dallas Buyer's Club but I don't know how much less. Perhaps 3% of Joe's annual income? 5%? While I don't know the exact amount, I'm pretty sure that a calorie-restricted dietary program needs to address this issue.

Taste. Our Food Plate lacks many tastes common to the typical American diet – sugar, salt, salad dressings, mayonnaise, etc. People sometimes complain that healthy foods taste bland. They also sometimes describe food cravings, missing various tastes and sensations.

Food producers know this and have identified the 'bliss point', a combination of sweetness, saltiness and richness (generally some sort of fat) that people find satisfying. The right combination of these sends a jolt of endorphins to your brain causing a pleasure sensation and desire to do it again. That's why people like mayonnaise on sandwiches, salad dressing on their salads and cream and sugar in their coffee. It makes food more satisfying. How often have you heard 'I just couldn't drink black coffee'?

The combination of sweetness, saltiness and richness works better together than any one ingredient on its own. That's why a standard sized Hershey Bar contains 35 milligrams of sodium[29] and a Nestle Crunch Bar 66 milligrams[30] and why Jif peanut butter contains 2 grams of sugar per serving[31] and Barilla pasta 7 grams[32].

Fruits and vegetables lack the bliss point. There's infinitesimal salt in an apple or yellow pepper, infinitesimal sugar in spinach or kale. And no fat.

The good news is that people can adjust their tastes to become satisfied with non-bliss point foods. The bad news is that it takes time to develop the habit, likely that same as to adjust to the new 'slightly hungry' or 'no longer totally full' eating feeling. Again, programs aiming to help people eat fewer-but-healthier calories need to maintain their incentives for this lengthy time period.

Convenience. Joe's typical meals included a store baked honey bran muffin as opposed to the Food Plate home cooked eggs and toast. His ham-and-cheese sandwich lunch with a bag of chips and Oreos was quicker to make than the Food Plate made-from-scratch spinach salad with chicken breast. Not only quicker to make, but also quicker and easier to eat.

---

[29] https://www.hersheyland.com/products/hersheys-milk-chocolate-candy-bar-1-55-oz.html

[30] https://www.heb.com/product-detail/nestle-crunch-candy-bar/98268

[31] https://www.jif.com/peanut-butter/creamy/simply-jif

[32] https://www.heb.com/product-detail/barilla-traditional-sauce/1637428

And his industrially produced dinner Prego pasta sauce with canned peaches and ice cream for dessert was easier to prepare than the Food Plate home-made rice bowl.

Accessing these convenient foods is easy and relatively stress free – just open the can or package. Meanwhile, shopping for, cutting and preparing the less-convenient-but-healthier Food Plate meals is more difficult and time consuming, and therefore more stressful in our time compressed daily lives.

As one indication of convenience importance in our daily food decisions, consider the number of take-out food options now available. (I'm not sure if take-out counts as eating at home or out, but it doesn't much matter what we call it as long as people stay within their '10% of salary on food' parameter.) We had, for example, 71,856 pizza restaurants in 2012 but 78,092 in 2020.[33] That's almost a 9% increase in 8 years, not including other competitive take out options. All this suggests that increasing numbers of us order out to eat in, the definition of convenience.

How much should designers of wellness or diet programs incentivize people to eat more labor intensive / healthier foods as opposed to more convenient-but-less healthy? I don't know – sorry, not a program designer – but food convenience is one factor that such programs need to address. 'Address' here means 'provide economic incentives to do'.

Summary of the diet part of 'diet and exercise'

We have established so far that eating fewer-but-healthier calories costs more than eating more-but-unhealthier ones. The cost difference is about $9.12 per person per day or $3320 per year. Those are, of course, just estimates – take them with a grain of salt. (Bad pun.)

We have also discussed

- how eating fewer calories makes people feel hungry
- how eating non-bliss point foods diminishes taste satisfaction, and
- how consuming less convenient foods is more difficult and time consuming.

Overcoming those behavioral obstacles requires additional financial incentives for the 6-to-8 months – or more – necessary for the new dietary habits to get formed.

Remember our discussion so far: we want to help people avoid prediabetes, metabolic syndrome and diabetes. We have explored the 'diet' part of that standard 'diet and exercise' recommendation. We learned that eating healthier foods is more expensive, less tasty, less convenient and less comfortable. The dietary goal is, therefore, difficult to achieve.

[33] Number of pizza restaurants in the US, Statistics https://www.statista.com/statistics/377597/number-of-pizza-restaurants-us/

> Tons of real world evidence shows this, including increasing rates of obesity and diabetes in the past 20 years.

Let's switch focus and turn to the exercise side now, to see if that holds more promise for success.

Exercise

The April – May 2004 issue of Harvard Magazine summarized some then-current research at Harvard University and Medical School as follows (lightly edited for context):

> [Researchers are developing] a pill, a marvel of modern medicine that will regulate gene transcription throughout your body, helping prevent heart disease, stroke, diabetes, obesity, and 12 kinds of cancer—plus gallstones and diverticulitis.
>
> Expect the pill to improve your strength and balance as well as your blood lipid profile. Your bones will become stronger. You'll grow new capillaries in your heart, your skeletal muscles, and your brain, improving blood flow and the delivery of oxygen and nutrients.
>
> Your attention span will increase. If you have arthritis, your symptoms will improve.
>
> The pill will help you regulate your appetite, and you'll probably find you prefer healthier foods. You'll feel better, younger even, and you will test younger according to a variety of physiologic measures.
>
> Your blood volume will increase, and you'll burn fats better. Even your immune system will be stimulated.[34]

There is just one catch. There's no such pill.

The prescription instead is exercise.

Everyone knows that exercise is good for you. The Harvard quote makes the point poignantly. But touting the overall benefits of exercise is not our aim here. Instead, our focus is diabetes prevention and, more specifically, the impact of exercise on people with prediabetes or metabolic syndrome. How does exercise impact these groups?

Several papers address this, mainly metabolic syndrome patients. I'll quote 3 below.

One study by the Norwegian University of Science and Technology Faculty of Medicine in 2008 found that 36% of patients with metabolic syndrome reversed the condition with 4 months of exercise.[35] "The study shows that shows that exercise in general, but

---

[34] The Deadliest Sin, Harvard Magazine, April – May 2004

[35] https://norwegianscitechnews.com/2016/08/exercise-to-combat-metabolic-syndrome/

especially interval training, is able to partially or completely reverse metabolic syndrome," according to lead author Arnt Erik Tjønna.

Second, a 2017 meta-review of 16 studies was, according to the authors, the "first to compare the effects of aerobic, and combined aerobic and resistance, exercise on clinical outcome measures in people with metabolic syndrome".[36]

The authors concluded that

- BMI was significantly reduced in exercise versus control groups.
- Fasting blood glucose was significantly reduced in exercise compared to control groups.
- Triglycerides were significantly improved, and LDL cholesterol was significantly improved in exercise versus control participants.
- HDL cholesterol was unchanged in exercise versus control participants.

Third, a 2019 metastudy, published in Nutrients suggested that "physical activity as a treatment for metabolic disease remains underutilized." [37] Among their findings

> In one component study "exercise training resulted in marked improvements in the metabolic profile of the participants, including triglycerides, HDL cholesterol, blood pressure, fasting plasma glucose, and waist circumference. Of the 105 participants with the metabolic syndrome at baseline, 30.5% (32 participants) were no longer classified as having the metabolic syndrome after training."
>
> A different component study found "strong support the use of aerobic exercise for patients with the metabolic syndrome who have not yet developed diabetes."
>
> A third component study totaling 77,000 patient hours of exercise for folks with metabolic syndrome found "In analyses comparing aerobic exercise training versus control groups, there were reductions in BMI, waist circumference, systolic blood pressure and diastolic blood pressure, fasting blood glucose, triglycerides and low-density lipoprotein."

The authors concluded that "achieving the minimal physical activity guidelines (at least 150 minutes per week of moderate-intensity activity or 75 minutes per week of vigorous intensity activity) has been consistently demonstrated to have significant benefits on metabolic risk" and "Among subjects who meet the criteria for the metabolic syndrome, health outcomes are significantly improved by aerobic or resistance training, or their combination."

---

[36] Ostman et al, The effect of exercise training on clinical outcomes in patients with the metabolic syndrome: a systematic review and meta-analysis, Cardiovascular Diabetology, 2017

[37] Myers et al, Physical Activity, Cardiorespiratory Fitness, and the Metabolic Syndrome, Nutrients, July 19, 2019

Terrific benefits to people suffering from metabolic syndrome. Unfortunately, Americans don't exercise much or enough.

The CDC recommends that adults get 2.5 to 5 hours of moderate cardio exercise per week and 30 minutes of muscle strengthening exercise. Only 23% of us meet these targets, skewed toward higher income folks.[38] Lower income folks, those most likely to find switching to the Food Plate diet more economically difficult, tend to exercise the least.

How much might it cost to incentivize people to exercise? An old economic rule-of-thumb suggests that people value their free time at 1/3 the amount they normally earn. Our hero Joe, earning the US male average of $1,144 / week, gets $28.60/hour and would therefore values his free time at $9.44/hour. He would, according to this economic theory, exercise in his free time if someone paid him $9.44 / hour or more.

Joe probably should exercise about 4 hours / week – that's conservative, the mid-point of the CDC's weekly recommendation. I exercised about 7 hours / week during my own weight loss period, mainly brisk walking, but again, that discussion comes later in this chapter. Joe's 4 hours / week would cost $37.76, or $1964 in annual incentives. I don't know who pays this – an employer, insurance company, hospital, TPA or other. At this point, I only want to suggest what the incentive would be. I focus here on why we fail to prevent diabetes and invite others to figure out the rest.

The Context of our Failure to Treat Metabolic Syndrome and Prevent Diabetes

Two socio-medical factors underly our failure to treat patients suffering from metabolic syndrome and to prevent diabetes. I'll briefly address each in turn.

Television. Americans watch, on average, about 3 hours of TV each day.[39] The states in which people watched the most TV correlate closely with states having the highest percent of obese people – West Virginia, Alabama, Arkansas and Mississippi. Obesity often leads to diabetes. We begin to see the television link

"The best single behavioral predictor of obesity in children and adults is the amount of television viewing," according to Harvard School of Public Health's Professor Steven Gortmaker.[40] "The relationship is nearly as strong as what you see between smoking and lung cancer." Wow.

---

[38] Only 23% of adults meet guidelines, Time Magazine, Ducharme, June 28, 2018.

[39] Hubbard, Outside of Sleeping, Americans Spend Most of Their Time Watching TV, US News, July 22, 2021. Also Statistica, Average Daily Time Spent Watching TV, https://www.statista.com/statistics/186833/average-television-use-per-person-in-the-us-since-2002/#:~:text=Estimates%20suggest%20that%20in%202022,hours%20watching%20TV%20each%20day .

[40] The Way We Eat Now, Craig Lambert, Harvard Magazine, May-June 2004

Unpack this:

> TV watching is non-weight bearing, non-aerobic, entirely sedentary activity that generates no metabolic system benefit or weight loss.
>
> TV watching exposes viewers to (generally less healthy) food products. That advertising leads to sales, otherwise companies wouldn't continue. Products advertised rarely include the fruits and vegetables that are supposed to account for half our food plate.
>
> > The average American child sees over 40,000 TV commercials per year according to estimates by the American Psychological Association.[41] That's a lot of low-quality food message reinforcement!
>
> TV watching, according to anecdotal evidence, is associated with munching less healthy foods. People report eating salty snacks, buttery popcorn, sugary baked goods and similar while watching TV; fewer (none?) report over-indulging in broccoli or kale.

The take-away about television watching: if you want to create an obese, diabetic population, get them to watch a lot of TV. Our bountiful viewing options including streaming services, seem ideally suited to this task.

Cholesterol treatments. Our typical diet, referenced in the meal case study above, leads to high blood cholesterol, with statin prescriptions a primary treatment. About 1/3 of American adults currently take a statin.[42]

Statins, it turns out, may *increase* your risk of developing type 2 diabetes.

Statins prevent the buildup of fatty deposits in blood vessels and reduce the inflammation that occurs when arteries are blocked. This lessens your risk of having a heart attack, but it may also make cells more resistant to insulin, the hormone that helps regulate glucose levels in blood. The net effect according to various studies:[43]

- Statins increase your risk of developing diabetes by about 9% on average, but
- The higher the statin dose, the higher the diabetes risk, and

---

[41] Protecting Children From Advertising, American Psychological Association, June 2004 https://www.apa.org/monitor/jun04/protecting#:~:text=The%20average%20child%20is%20exposed,a%20year%2C%20according%20to%20studies.

[42] The 1/3 estimate is extrapolated from the trend. https://consumer.healthday.com/general-health-information-16/misc-drugs-news-218/number-of-americans-taking-statins-keeps-rising-cdc-694895.html or https://www.ahrq.gov/data/infographics/statin-use.html

[43] This analysis comes from Madhusoodanan, NY Times, October 25, 2022 Ask Well 'Do statins increase the risk of type 2 diabetes?'

- The higher your blood sugar levels when you start taking the statin, the more likely you are to develop diabetes.

That means sicker people, taking higher statin doses, are more likely to develop diabetes, exactly the people most at risk.

One study found that, on average again, 1 in every 255 people who take a statin for 4 years will develop diabetes[44] but older patients especially those suffering from multiple health problems are at higher risk that younger, healthier people.[45]

Note the caveat here: though changes in blood sugar caused by statins are 'pretty modest' according to Dr. Jill Crandall, an endocrinologist at the Albert Einstein College of Medicine in New York, they may be enough to tip someone from prediabetes to full blown diabetes.[46]

Let's tie all this together:

- Diabetes and related medical costs account for up to 25% of all healthcare spending, with diabetes rates rising
- About 90% of diabetes is type 2, caused by lifestyle behavior
- The standard 'lose weight and exercise to avoid diabetes' prescription is both unaffordable and unpalatable to most of us; diets generally fail within 2 years
- The economic incentives required to keep people on their diet and exercise programs are unaffordable to employers, insurance carriers or similar
- One common behavioral response to our high stress lifestyles – TV watching – may exacerbate the diabetes problem
- Medical treatments for other behaviorally related health problems, i.e. statins to lower cholesterol, may also exacerbate the diabetes problem.

Is there a medical solution?

Semaglutide

Semaglutide developed by Novo Nordisk, apparently treats obesity and diabetes quite well.

In one large random controlled study, for example, patients taking 2.4 milligrams of semaglutide lost an average of 6% of their body weight by week 12 and 12% of their body weight by week 28. That's impressive.

Other studies have suggested similar successes.[47]

---

[44] Sattar, Statins and risk of incident diabetes, https://www.ncbi.nlm.nih.gov/books/NBK78906/

[45] Madhursodanan, op cit

[46] Ibid.

[47] Weghuber et al, One-Weekly Semaglutide in Adolescents with Obesity, NEJM, Nov 2, 2022

In February 2022, the British National Institute for Clinical Excellence (NICE), the UK's medical rationing agency, approved Wegovy, Novo Nordisk's brand name for semaglutide to treat obesity. In the vernacular, NICE approval means the drug works; it has a higher approval bar than the US Food and Drug Administration.

> Eli Lilly has developed a competitor weight loss drug called tirzepatide, not yet approved as of time of writing. I assume other companies have already, or will, similarly design competition to semaglutide.

NICE's stringent use guidelines for semaglutide illustrate some underlying issues with the drug.[48]

- It is approved for people with at least 1 weight related medical issue and a BMI of 35 or more, or, only exceptionally, for people with a BMI between 30 – 34.9
- It can only be prescribed as part of a specialist weight management program including supervised weight loss coaching. This has implications for the US where only 1% of physicians are trained in obesity medicine.[49]
- Semaglutide can be prescribed for 2 years, maximum.

Novo Nordisk also sells semaglutide it for diabetes treatment under the brand named Ozempic.

But the pricing:

- Ozempic, semaglutide for diabetes, lists for $894 for 4 weeks in the US. Insurance companies normally cover it for diagnosed diabetics.
- Wegovy, semaglutide for weight loss, lists for about $1,350 per month. Insurance companies normally don't cover it, at least not without a fight.
- Saxenda, basically Wegovy lite also by Novo Nordisk, also lists for $1,350 per month. Ditto on the insurance coverage front.

This creates confusing incentives. In the US, having a high BMI does not necessarily quality a patient for Wegovy or Saxenda as in the UK. American doctors must wait until their patient becomes diabetic. Patients 'only' suffering from obesity and metabolic syndrome don't have access so must settle for less robust, older medications, often with unpleasant side effects. As the New York Times reported, one doctor 'finds herself rejoicing when patients have high blood sugar levels'[50], i.e., becomes diabetic and therefore eligible for treatment.

We don't yet know the long term effects of semiglutide because the it's too new:

---

[48] Much of this discussion comes from 'NICE approves Wegovy for obesity', European Pharmaceutical Review, February 10, 2022 https://www.europeanpharmaceuticalreview.com/news/168431/nice-approves-wegovy-semaglutide-for-obesity/

[49] Kolata, The Doctor Prescribed and Obesity Drug; the insurance company called it vanity, NY Times, May 31, 2022. Much of the following discussion comes from this source.

[50] Ibid.

- Does a patient who loses 12% of their body weight in 7 months then keep it off?
- What happens when, in the UK situation, semaglutide's prescription runs its full 2-year course: does the patient regain the weight or not?
- Is 2 years long enough for the patient to develop good eating habits?
- Can the patient afford to stay on the healthier diet?
- What is the medical cost difference between staying on Wegovy for life and returning to obesity and diabetes?

We also can't yet answer the most important economic question: how do semaglutide treatment costs compare with medical treatment costs over time? We can only, today, guess at the answer.

Semaglutide and, perhaps, Novo Nordisk's competitor's drugs, may be the light at the end of the obesity-to-metabolic syndrome-to-diabetes tunnel. Or they may be the proverbial headlight of an oncoming train. I certainly don't know which, but the future looks murky to me. At best.

Case study
My own experience with metabolic syndrome

My doctor diagnosed me with metabolic syndrome in August 2020 based on various numbers from my annual physical.

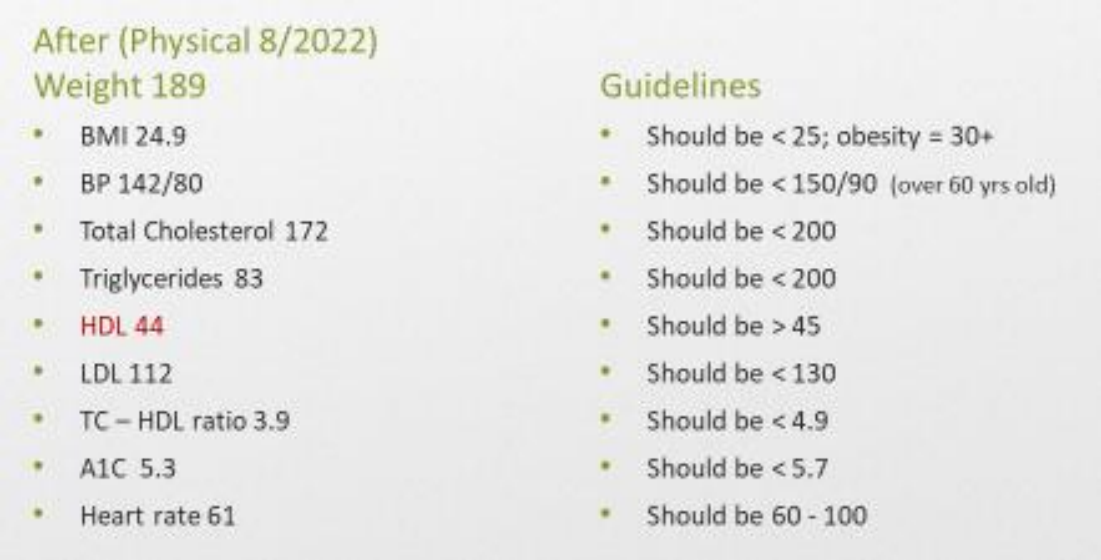
> A quick word on numbers and annual physicals. I consider these equivalent to a half-semester report card in high school, a rough indication of your academic health and direction. You might be a good student having a bad semester for some ephemeral reason. You might have a serious intellectual disease. Or you might be going in a bad academic direction, through lack of effort for example. Your half semester report card doesn't tell which.
>
> A series of report cards over time might though. Consider a student with an A average in 8th grade, an A- average in 9th grade, a B average in 10th grade and a C- average on the first half semester report card in 11th grade. We see a trend. The report card suggests need for an intervention by the school, parents, community, or others to identify and address some issue or other.
>
> Similarly, my 2020 annual physical numbers suggested an issue. What is was – lifestyle, individual biology or something else – remained to be determined.
>
> Add to that my own idiosyncratic personality: I don't like to receive failing grades. I found myself annoyed more than concerned and determined to do something about it. I self diagnosed – always a bad idea – my problem as lifestyle and decided to lose weight, exercise more and see what happened.

My August 2020 numbers compared to the metabolic syndrome guidelines:

I put myself on diet-and-exercise program and lost about 40 pounds in a year. See the addendum to this chapter for details.

But the big question facing me: would the healthy habits, developed over a year, maintain themselves and keep me at a healthy weight at the 2 year anniversary? I know the 2 year failure rate of weight loss programs, well over 80% with some estimates as high as 97%. Also, what would that metabolic profile look like 2 years later?

Here are the results from my August 2022 physical:



And here's the side-by-side comparison of all those numbers two years apart to show the remarkable impact of weight loss and exercise increase in one relatively easy-to-read chart.

Diet and exercise worked well to get me out of the metabolic syndrome.

It's a shame that cost, convenience, and other factors keep so many others from enjoying this success and the related good health / low healthcare costs.

Chapter summary

Diabetes accounts for up to 25% of all healthcare spending. Its incidence grows over time, along with the underlying causes: obesity, low quality caloric food consumption and insufficient exercise afflict many of us, perhaps a majority of Americans, perhaps a large majority.

Many afflicted folks progress through metabolic syndrome and / or prediabetes to full blown diabetes. Efforts to intervene behaviorally - typically referred to as lifestyle changes involving dietary improvements and exercise increases - generally fail, by some estimates up to 97% of the time.[51] They're

- Too expensive for average income Americans
- Too uncomfortable to maintain for years
- Too inconvenient
- Too dissonant with our normal lifestyles, TV watching for example.

New, promising medications are too expensive for widespread use, with 'widespread' meaning the 70 million currently obese Americans. Insurance companies balk at the cost.

[51] The Weight of the Evidence, Harriet Brown, Slate, March 24, 2015 https://slate.com/technology/2015/03/diets-do-not-work-the-thin-evidence-that-losing-weight-makes-you-healthier.html.

I don't see a hopeful path forward. Instead, I see our diabetic population growing along with the associated healthcare costs.

A pessimistic end to a pessimistic chapter.

My calorie and cost spreadsheets

All data from Shaw's, Easton Massachusetts, October 2022. I made several trips to gather data.

In case you have trouble reading the spreadsheets below, the column headings are

- Item name
- Cost / package. The store publishes this.
- Servings / package. This is on the nutritional label of all packaged foods, or you can google it for fruits and vegetables.
- Calories / serving. Again, on the nutritional label. Google provides this information about other foods - calories / pound of apples for example, or calories in a medium apple.
- Cost / calorie. This is a simple division: cost / package divided by number of servings / package divided by number of calories / serving.
- # servings per meal. That's how much you put on your plate. You may choose 2 servings of spinach for example, or ½ serving of ice cream.
- Total calories = Again a simple calculation: the number of calories / serving times the number of servings on your plate.
- Total cost = the cost / calorie for each food times the number of calories on your plate.

Item	Cost / package ($)	Servings / package	Calories / serving	Cost / calorie	# servings	Total # calories	Total cost ($)
Healthy breakfast							
2 jumbo eggs - range free	7.99	12	90	0.007398148	2	180	$ 1.33
2 pieces Arnold Multigrain toast	5.29	16	110	0.003005682	2	220	$ 0.66
Butter (Land o Lakes)	4.79	30	50	0.003193333	1	50	$ 0.16
1 banana	0.69	3	100	0.0023	1	100	$ 0.23
Black coffee	19.99	100	2	0.09995	1	2	$ 0.20
Total						552	$ 2.58
Healthy lunch							
Spinach salad	5.99	3.5	20	0.085571429	1	20	$ 1.71
Tomato	2.99	1	90	0.033222222	0.5	45	$ 1.50
Carrot	3.49	11	30	0.010575758	0.5	15	$ 0.16
Yellow Pepper	1.7	1	50	0.034	0.5	25	$ 0.85
Beets	3.99	2.5	50	0.03192	0.5	25	$ 0.80
Olive oil - Bertolli	7.49	33	120	0.001891414	0.67	80.4	$ 0.15
Balsamic vinegar - Filippo Berio	6.99	33	11	0.019256198	0.33	3.63	$ 0.07
.3 lb of chicken breast	3.99	1	748	0.005334225	0.3	224.4	$ 1.20
1 pita	2.99	8	90	0.004152778	1	90	$ 0.37
Apple	1.99	3	95	0.006982456	1	95	$ 0.66
Total						623.43	$ 7.47
Healthy dinner (Rice Bowl)							
2 cups brown rice	20.99	111	170	0.001112348	2	340	$ 0.38
Broccoli	1.99	1	154	0.012922078	0.33	50.82	$ 0.66
Summer squash	1.99	1	74	0.026891892	0.33	24.42	$ 0.66
Snap peas	2.99	3	35	0.02847619	1	35	$ 1.00
Green beans	3.29	4	25	0.0329	1	25	$ 0.82
Salmon	11.99	1	944	0.012701271	0.4	377.6	$ 4.80
Low salt soy sauce	3.29	20	20	0.008225	1	20	$ 0.16
Blueberries	2	1	229	0.008733624	0.5	114.5	$ 1.00
Strawberries	4.99	1	149	0.033489933	0.5	74.5	$ 2.50
Total						1061.84	$ 11.97
Total Daily Calories & Cost						**2237.27**	**$ 22.02**

Item	Cost / package ($)	Servings / package	Calories / serving	Cost / calorie	# servings	Total # calories	Total cost ($)
Typical breakfast							
Honey bran muffin (Shaw's)	$5.00	4	420	0.00297619	1	420	$ 1.25
Coffee	19.99	100	2	0.09995	1	2	$ 0.20
Cream (Coffeemate)	4.49	63	35	0.002036281	1	35	$ 0.07
Sugar (Domino's granular)	1.99	54	30	0.001228395	1	30	$ 0.04
Total						487	$ 1.56
Typical lunch							
Ham	7.99	1	885	0.009028249	0.25	221.25	$ 2.00
Cheese (20 slices / lb)	5.99	20	100	0.002995	1	100	$ 0.30
Sub roll	2.99	6	200	0.002491667	1	200	$ 0.50
Mustard (French's)	2.49	79	1	0.031518987	1	1	$ 0.03
Lettuce - ice berg	2.49	1	105	0.023714286	0.15	15.75	$ 0.37
Bag of chips	21.99	42	150	0.003490476	1	150	$ 0.52
3 Oreos	5.49	21	160	0.001633929	1	160	$ 0.26
Apple	1.99	3	95	0.006982456	1	95	$ 0.66
Coca cola	2.79	12	140	0.001660714	1	140	$ 0.23
Total						1083	$ 4.88
Typical dinner							
Regular pasta (Barilla)	2.99	8	200	0.00186875	1	200	$ 0.37
Pasta sauce (Prego traditional)	3.99	5	70	0.0114	1	70	$ 0.80
Ground beef - 80%	4.99	1	1152	0.004331597	0.25	288	$ 1.25
Grated cheese (Kraft parm)	5.99	45	20	0.006655556	1	20	$ 0.13
Green salad - Dole American	3	4	15	0.05	2	30	$ 1.50
Italian dressing (Ken's house)	3.99	16	120	0.002078125	1	120	$ 0.25
Canned peaches	3.49	7	100	0.004985714	1	100	$ 0.50
Ice cream (Friendly's)	4.99	9	210	0.002640212	0.5	105	$ 0.28
Beer (Bud) Walmart	8.27	6	145	0.009505747	1	145	$ 1.38
Total						1078	$ 6.46
Total Daily Calories & Cost						2648	$ 12.90

****

Addendum: My battle with metabolic syndrome

A version of this is available from www.lulu.com as Gary's Guide to Weight Loss.

Foreword

Dr. David Mudd

Gary asked me to write a forward to his book while we were kayaking together. I told him I would be honored to do so.

I have worked for 30 years as a primary care physician in a mixed urban / suburban environment. Over these years obesity rates have skyrocketed. I have seen it in my own practice: young and old patients, blue and white collar, it doesn't matter. Far too many of my patients are heavier these days causing other health conditions to become more prevalent including diabetes, hypertension and heart disease.

I have had countless people come to me complaining of their inability to lose weight. The complaints are the same and the accounts of their food intake and exercise eerily similar. "I hardly eat anything" or "I eat the same amount I always have." Lacking hard data, I wonder about this.

When I ask about their activity level, they usually respond “I try to walk.”

They typically want to have their thyroid checked, assuming that there is a medical explanation for their weight gain and fatigue.

My message to them is always the same: “you need to cut back on your calories and become more active”. Unfortunately, we never have enough time together for me to understand their lifestyles, dietary norms and physical activity habits in enough detail. Invariably they return frustrated and unsuccessful.

Fewer than 1/10 patients actually make the changes necessary to lose weight and keep it off.

Patients such is Gary Fradin are few and far between but a joy to work with. Gary is the rare patient who understands nutrition and exercise and actively takes control of his own health. He formulated a plan to cut his calories and increase his activity level and enjoyed spectacular results, losing over 40 pounds and getting himself into good physical shape as well.

Gary summarized the process in this readable and informative book. His recommendations are science based, useful and appropriate. I heartily recommend it.

In fact, I plan to give this book to my own patients. Enjoy it and good luck!

Dr. David Mudd
Easton, Massachusetts
May, 2021

Preface

After Covid struck, after our lives turned upside down, after my business revenues fell by 50%, after all normal routines disappeared, my doctor told me I had metabolic syndrome and to lose weight.

I told him I was fit and healthy.

He repeated his order.

How to lose weight? Diet options ranged from A (Atkins) to Z (Zone). All claimed dramatic successes.

But all almost certainly fail over time. Research suggests that 97% of people regain their weight within about 3 years.[52] Here, for example, is Traci Mann from UCLA summarizing her group's study:

> "You can initially lose 5 to 10 percent of your weight on any number of diets, but then the weight comes back. We found that the majority of people regained all the weight, plus more."[53]

I didn't want to be one of the failures.

My doctor offered a nutritionist referral, which I postponed; I didn't like the odds, hate scheduling medical appointments and feared entering the modern diet culture even under the guise of organized medicine.

Instead, I decided to try on my own. I figured I could achieve at least the same dismal long- term weight loss result myself, and possibly do even better.

This chapter describes how.

The program isn't a unique, novel or brilliant but it's straightforward, practical and honest. You can easily adapt it to your own situation.

Just follow the steps, modify it to your own needs and give yourself time.

The Camera Adds 20 Pounds
Me, fit-and-healthy pre-weight loss

[52] The Weight of the Evidence, Harriet Brown, Slate, March 24, 2015 https://slate.com/technology/2015/03/diets-do-not-work-the-thin-evidence-that-losing-weight-makes-you-healthier.html.

[53] Dieting Does Not Work, Stuart Wolpert, UCLA Newsroom, April 3, 2007 https://newsroom.ucla.edu/releases/Dieting-Does-Not-Work-UCLA-Researchers-7832

Introduction

I’m not a doctor, nutritionist, dietician or exercise physiologist. I have no medical training.

Instead, I’m an economist. I measure things. Weight loss strikes me as a measurement problem:

- If you eat more calories than you burn, you gain weight.
- If you eat fewer calories than you burn, you lose weight.
- As you eat less, your metabolism slows so you need to exercise more.

Sustained, long term weight loss also incorporates a fourth, behavioral consideration:

- Do this all slowly enough to develop new habits. That increases your chance of long-term success.

This program incorporates all those issues.

As background, I’m a 68-year-old, 72-inch-tall man. I weighed 225 pounds in my doctor’s office on August 13, 2020.

I followed this program for 9 months and weighed 185 at my Sunday morning weigh-in April 4, 2021. I had lost 40 pounds over 36 weeks, about a pound per week on average.

It wasn't very difficult – more a task to accomplish than a mountain to climb - but I was hungry much of the time, especially at the beginning. That feeling dissipated as my new eating habits became ingrained and my body adjusted to its new setpoint. Dissipated but didn't disappear.

I'm optimistic about long-term success, optimistic that my habits have changed enough to maintain my new weight for years to come. Cautiously optimistic that is, not blindly. After all, 97% of people who lose weight ultimately put that weight back on.

We'll see. The future is a long time.

Step 1: Calculate your daily calorie needs.

There's a weight loss mantra 'eat 500 calories less each day and lose a pound a week'.

Maybe true – I don't know - but I needed a starting point. 500 calories less ***than what***? No idea. I hadn't tracked my previous consumption.

I initially tried cutting cream from my morning coffee and dessert from lunch and dinner. But I didn't use the same amount of cream every day. Nor did I eat dessert every day but when I did, the type and size varied. Did that cut 500 calories? No idea.

I tried eating smaller portions. Small enough? Too small? Again, no idea. I only knew that I felt hungry. I worried that if I felt hungry without seeing results, I'd get frustrated and stop.

I needed a plan.

So instead of eating 500 calories *less* than some unknown number, I decided to calculate how many calories I *should* eat each day to lose a pound a week, an absolute number.

I googled 'calories per day to lose weight' and found lots of websites that base their estimates on age, height, weight, gender and daily activity level. Most suggested roughly the same amount – 2300 calories per day to lose a pound a week from that 225 pound starting point. (Your own amount will vary.)

The agreement among websites gave me a reasonable degree of confidence.

I aimed for 2200 calories per day, slightly below the 2300 estimate to allow for measurement errors.

Interestingly, 2200 calories per day isn't a starvation diet. Far from it. In fact, the US Department of Agriculture estimates that the average American consumed 2234

calories per day in 1970.[54] My 2200 calorie target simply mimicked America's pre-obesity food consumption level.

Three thoughts on eating according to your daily calorie estimates and watching the impact on your weight:

1. Remember to recalculate as you lose weight. Your calorie needs drop.
2. Set reasonable weight loss goals – neither too fast nor too much – to avoid frustration.
3. Weigh yourself on the same scale, at the same time, every week. This generates the most consistent data, necessary to keep you on track. I choose Sunday mornings, first thing. Those are the weights I show in the **Results and Lessons** chapter.

I started thinking 'if I can get down to 215, I'll be successful'. Then, upon reaching 215, I wondered about losing another 5 pounds. Then I aimed for 200, a nice round number. Then 195, a 30-pound loss and enough to write a book. Maybe others could benefit from this program?

But losing 40 pounds sounded better than 30, so I aimed for 185 and made it. Low enough! My doc said to stop here.

Remember that my initial goal wasn't 185. It was 215. Try to define success for yourself as a goal you can reasonably reach in a relatively short period, something that will make you feel proud. Then let the future take care of itself as you gain confidence through success.

Step 2: Divide your daily calorie target into 3 meals and a snack.

I used this rule-of-thumb for my initial 2200 calorie per day program.

Breakfast - 400 calories (18% of total daily calories)

Lunch - 600 calories (27%)

Dinner - 800 calories (36%)

Snacks or dessert - 400 calories. You can add these to your breakfast, lunch or dinner.

Your own calorie target and meal amounts may differ.

[54] Wells and Buzby, US Food Consumption Up 16% Since 1970, Economic Research Service US Department of Agriculture, November 1, 2005 https://www.ers.usda.gov/amber-waves/2005/november/us-food-consumption-up-16-percent-since-1970/

You'll find calorie estimates for specific foods on packages or online. Simply google 'calories in a medium potato' or 'calories in a cup of blueberries' or whatever. It's easy and close enough for our purposes.

Meal timing: I ate according to the clock throughout this program and expect to in the future:

- Breakfast at 9:00
- Lunch at 1:30
- Dinner at 6:30. Regular as clockwork.

Try not to eat whenever you feel hungry because those feelings come and go. Stick to the clock. It's honest, reliable and will keep you on track.

See the discussion of hunger below, for more on this.

Food choices: I learned several things through trial and error about my own reaction to food groups. You probably will too, though perhaps different lessons.

First, I feel fuller, longer eating vegetables probably because of their high fiber and water contents. I eat lots of vegetables these days.

Second, I prefer healthy food tastes. I look forward today to my English muffin, peanut butter and banana breakfast as enthusiastically as I had previously anticipated pancakes with syrup or eggs with bacon, sausage and toast.

In fact, I no longer want those overly-sweet, overly-salty, overly-filling, low-fiber meals, not because they're so high in in calories but because they make me feel lousy afterward. They sit like a rock in my stomach and leave me stuffed and thirsty, then surprisingly hungry relatively quickly.

Third, I don't miss those previously routine, calorie-rich tastes, things like cream in my morning coffee, cheese and crackers between meals or rich desserts after dinner. I now prefer blueberries, raspberries or strawberries for dessert, sometimes with a drop of honey on top. Berries are sweet and delicious, and I feel good after eating them.

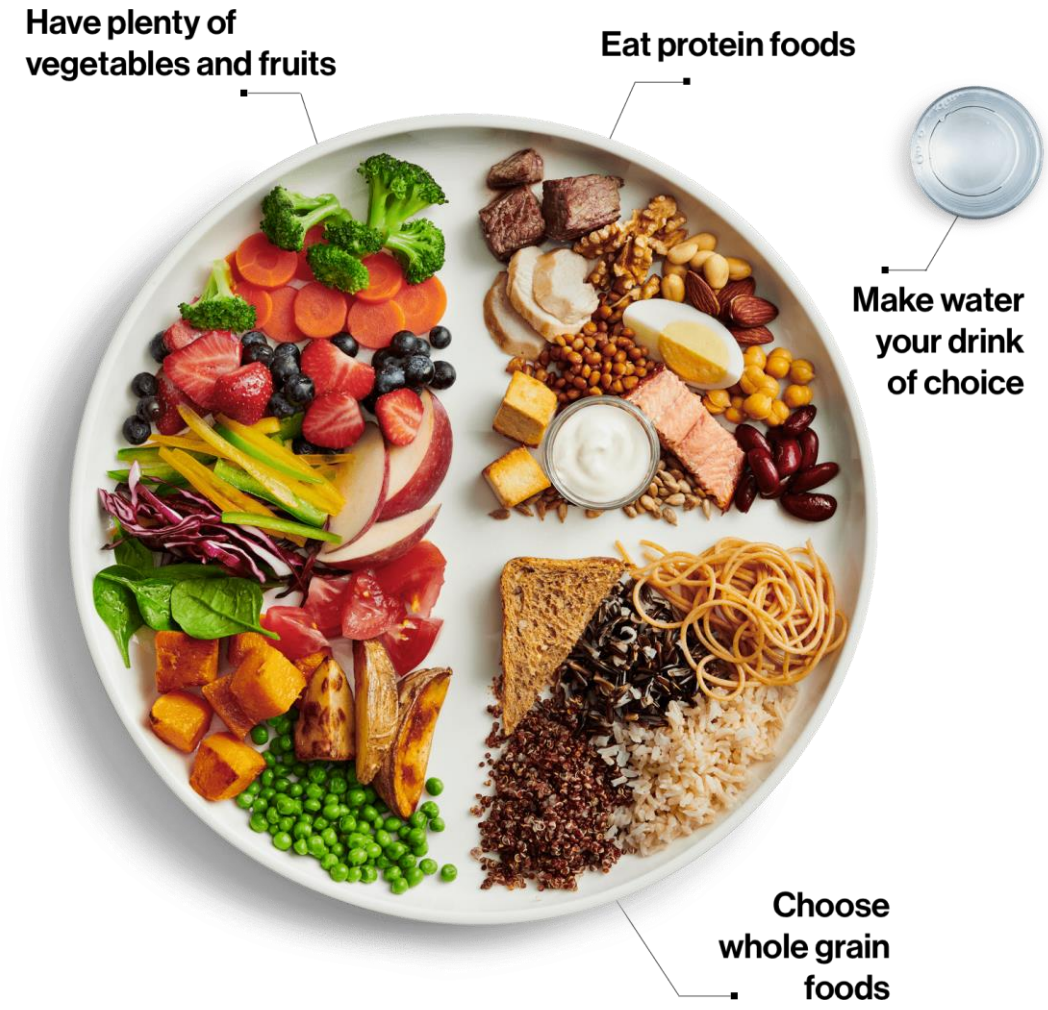
Plus I don't have that sugary thirst like I used to after eating cookies or cake.

My experiences mirror recommendations from 2 thoughtful sources. Michael Pollan, New York Times contributor, best-selling author, and Berkeley professor famously advises people to "Eat food. Not too much. Mostly plants." Consider each phrase.

- **"Eat food"** means eat real, identifiable farm products like fruits, vegetables, whole grains, meat and fish. Avoid ingredients you can't pronounce and foods your grandmother wouldn't recognize.
- **"Not too much"** means stick to your daily calorie limit.
- **"Mostly plants"** means lots of fruit and vegetables.

The Canadian Food Plate, photo below, suggests the proportion of each food group – plants, grains and proteins – to eat daily. Remember that nuts, beans and legumes count as proteins.

About half your plate should be fruits and veggies – aim for lots of different colors - a quarter protein and another quarter whole grains.



Eat food. Not too much. Mostly plants.

Tastes and habits: When people say, ‘I can’t drink coffee without sugar’ or ‘I can’t eat an egg without salt’, I wonder if they remember what got them into their overweight situation in the first place.

Changing eating habits is a process, both challenging and rewarding. The good news is that you really can change.

The bad news is that it takes time. Most people require at least 2 months for a new taste preference to become fully automatic though some people take up to 8 months

according to research.[55] Understand and accept this. Give yourself time to change your habits.

This habit development process may suggest why our modern diet industry so often fails people. It operates within two mutually exclusive constraints.

- First, it has to deliver weight loss results quickly enough that people don't drop out and post negative reviews online.
- But second, long term sustained weight loss and new habit creation takes a long time.

You can't generate fast results slowly! That's why I didn't want to get involved with it. I wanted a program without commercial or time pressure.

Hunger. Eating fewer calories per day makes you hungry. That's simply reality. I learned to differentiate three types of hunger.

*** Hunger as not feeling completely full.** I had previously enjoyed eating until I was 'pleasantly satisfied'. I don't get that feeling anymore.

Instead, I feel 'full enough' these days, not exactly hungry but not completely full either. I could happily eat an additional muffin at breakfast, a bigger sandwich at lunch, an extra helping at dinner or a second bowl of fruit in the evening. But I don't.

I've learned to embrace feeling 'full enough' when I reach my calorie limit per meal. It's my new normal, my new habit. Today it feels right.

You can adapt to this new feeling too. Just give yourself time. And remember your goal.

*** Hunger as deprivation**, actual physical need. This is sometimes called 'belly hunger' as opposed to 'head hunger', below.

I wasn't worried about physical deprivation as long as I ate every 4 – 5 hours. I knew that my 2200 calorie per day program was sufficient for good health; the 1970 era US food experience proved that. Two hundred million Americans ate that way every day. End of story.

Some people, of course, might have special nutrition or health issues. I can't speak to those. Still not a doctor.

***** Head hunger differs from **belly hunger**. Head hunger goes away when you think about something else. Belly hunger does not.

---

[55] Grohol, Need to Form a New Habit? Give Yourself At Least 66 Days, PsychCentral, October 7, 2018 https://psychcentral.com/blog/need-to-form-a-new-habit-66-days ; UCL News August 9, 2009 Interview with Phillippa Lally https://www.ucl.ac.uk/news/2009/aug/how-long-does-it-take-form-habit

Try this thought experiment to understand the difference: visualize a delicious burger or juicy steak or moist chocolate cake or juicy mango. Imagine the taste. Picture it. Anticipate the sensation as you bite in.

Hold that thought.

Feel hungry? It's head hunger.

Now think of an IRS audit or root canal surgery. Visualize it. Hold onto it. Lose the hungry feeling?

Head hunger is a mental state. You can feel it equally few hours after either a big or small meal. When you feel it, think about something else. Easier said than done of course.

Food costs. Vegetables, per calorie, cost more than most other food groups due to various food subsidy and tax programs. Understand this and be prepared for a food budget increase.

Restaurants pose a problem for calorie restricted diets. Here are four suggestions that might help:

- Split a main course with someone and complement each portion with a side salad.
- Ask the restaurant to bring a doggie-bag containing half of your meal ***when they serve it***. I find this works better than attempting to estimate and eat half first, then asking for a doggie bag later.
- Stick with salads and protein toppings. Careful with the dressing. This option might make the restaurant experience less special, but it will make your calorie intake more predictable.
- Pay attention to drinks, both alcoholic and non. Wine has about 120 calories per glass, beer 150, gin and tonic 170, Long Island iced tea 280 and Margaritas up to 450.[56] Coca-Cola classic has 140 calories per 12 ounces, orange juice about 110 per cup and chocolate milk about 200. Those all count toward your daily total.

Cheating: Try not to. You'll only sabotage your progress and depress yourself at your next weekly weigh in. Be honest with your measurements and anticipate that you'll be on this program for several months at least, maybe for life (maintenance period).

Summary: Eat according to the clock and follow your grandmother's advice: eat the foods she would approve, don't eat foods she wouldn't recognize and control your portions.

Allow yourself time to develop new habits.

[56] Best and Worst Booze While Dieting, Carolyn Williams on cookinglight.com
https://www.cookinglight.com/healthy-living/weight-loss/best-alcohol-drink-on-diet

****

I invented some recipes, unexpected food combinations that satisfied me. Several became my new habits. If you like any, use them. Feel free to invent your own!

Breakfasts

Toasted English muffin with peanut butter plus a banana with almond butter. I eat this most frequently, perhaps 5 times per week. Cut a whole wheat English muffin (100 calories) in half and toast both halves. Then spread one tablespoon of salt-free peanut butter – about 100 calories – onto the 2 halves, about half a tablespoon per half. I don't add jam because I don't like very sweet tastes for breakfast, but that's just me.

Then cut a ripe banana, about 100 calories, in half and spread one tablespoon of almond butter – about 100 calories - onto it, again half a tablespoon per half. I prefer almond butter to peanut butter with bananas but again, my own preference.

Poached eggs on oatmeal. Instead of 2 scrambled eggs and 2 pieces of toast for breakfast, I substituted 2 poached eggs over oatmeal with a splash of ketchup, again my own taste preference. Oatmeal instead of wheat, one grain for another. Make it thick. One-third cup of steel cut oats is 170 calories, two jumbo eggs total 180.

Sometimes I add tomato slices or steamed broccoli. Tasty. Other times I melt Swiss cheese into the oatmeal, then put one egg on top. Delicious!

Plenty of other breakfast options exist within that original 400 calorie constraint. You're only limited by your imagination.

Lunch

I often eat leftovers for lunch, generally vegetables with some protein and fruit for dessert. Sometimes I add peanuts, cashews or butter beans - I really like butter beans - depending on our refrigerator's contents. Remember to estimate your calories honestly when you do this.

Here are some creative combinations that I enjoyed.

Tuna fish sandwich with pickles and a chocolate banana smoothie. I use chunk light tuna, only 90 calories per can, oilier than solid white so requiring less mayonnaise; add about ½ tablespoon, 50 calories. Then 2 slices of bread @ 100 calories each, a tomato slice and lettuce with a side of pickles for a 360 calorie, filling sandwich. Maybe add a splash of mustard (!) for flavor.

Then, assuming your taste buds require (mine generally do), make a frozen banana smoothie. One cup of skim milk (100 calories), a banana (another 100) and 2

tablespoons of Ovaltine (40 calories). I prefer Ovaltine to other chocolate syrups, but again, that's just me. Total about 240 calories, making your tuna sandwich plus smoothie a tasty 600 calorie lunch.

Beans or mussels in tomato sauce over steamed vegetables. One 8-ounce packet of frozen mussels (I use PanaPesca) contains 175 calories; 3 cups of broad beans about 150 calories. One cup of tomato or marinara sauce has about 120 calories depending on the brand. Put this modified bolognaise sauce over steamed zucchini, broccoli or cauliflower and sprinkle with parmesan cheese for a delicious and filling 300 calorie lunch. Enjoy a couple pieces of fruit for dessert.

I sometimes substitute chicken, garbanzo beans or left-over steak.

And I sometimes, though rarely, put this over a cup of pasta, about 200 calories.

Plenty of options to try.

A word about vegetables and salad. Per volume, vegetables contain fewer calories than most other foods. It's hard to overeat spinach or broccoli!

Try mixing three cups of raw spinach (25 calories) with a cup of raw beets (45 calories), a large tomato (25 calories), left over veggies from your refrigerator and any other vegetables you have on-hand. Then top with your favorite cheese, nuts or protein.

Careful with the dressing though. I limit myself to 1 tablespoon, generally of Italian or Greek dressing, 50 - 75 calories depending on the brand. Sometimes I make my own, mixing olive oil, vinegar and mustard or horseradish.

A word about fruit. I normally eat at least 3 pieces of fruit every day in addition to my frequent morning banana. I'm partial to apples, oranges, clementines, strawberries, raspberries and blueberries. We're not, in my family, big melon, pineapple or mango people but if we were, I'd include those too. It's a matter of taste again.

Dinner

We enjoy broiled vegetables at almost every dinner during the winter and grilled veg in the summer, generally broccoli, cauliflower, green beans, Brussels sprouts or eggplant. I char them slightly and sometimes sprinkle lightly with salad dressing. ('Lightly' means about a tablespoon per pound of veg.)

We typically eat this as a side dish with grilled meat, chicken or fish, most often fish. Sometimes my wife and I split a sweet potato too, about 80 calories per half. That adds natural sweetness to the meal.

Remember to control your portions! Steak has more calories per pound than chicken; salmon more than white fish.

We also try more creative dinners too.

Tomato sauce with turkey or beans and vegetables. This becomes a stand-alone stew; no pasta required. We use low fat ground turkey, a low calorie / low salt pasta sauce (read the labels) and add broccoli, cauliflower, peas, onions, mushrooms, peppers or fresh tomatoes. Then flavor with red wine.

We sometimes substitute butter beans for the turkey.

One issue with this meal: estimating calories accurately, especially leftovers. I generally add up all the calories in the entire batch, then estimate portion size – a quarter, a third, etc. Close enough for our purposes. Overestimating your portion today leads to underestimating it tomorrow or vice versa.

I then label the leftover calories in the fridge because I forget otherwise.

Baked feta and vegetables. Cut a block of feta cheese into 300 calorie chunks then bake or broil with red onions and cherry tomatoes. Sprinkle lightly with Greek salad dressing. Add a glass of chilled white wine, about 100 calories.

We sometimes add or substitute tofu for feta. Same idea but a different flavor.

Homemade oatmeal muesli, a sweet, Swiss-themed change from veggies and protein. Mix together 1/2 cup of steel cut oatmeal (255 calories), ½ cup of unsalted cashews or peanuts (320 cal.) or almonds (414 cal), a cup of blueberries (85 cal.), a cup of strawberries (50 cal.) and a banana (100 cal.). Total about 800 calories depending on your specific ingredients. Top with yogurt or honey, another 70 calories or sprinkled coconut. Eat hot or cold.

Snacks and Deserts

Some of my favorite quick-and-easy snacks include:

- Baked apples with cinnamon
- Blueberries or raspberries. 85 cal. per cup each + 1 tablespoon honey, 70 cal. equals 155 calories total
- Yogurt with Ovaltine. ½ cup fat free, sugar free yogurt, 60 cal. + 2 tablespoons of Ovaltine, 40 cal. = 100 calorie version of chocolate mousse. OK, not *exactly* mousse but it's pretty good. I sometimes double this if I'm ahead on my daily calories. (Haven't tripled it yet.)

You'll invent your own recipes. Write everything down so you remember which worked best for you.

Step 3: Go for a daily brisk walk.

or get some other form of daily exercise

Our metabolisms slow down as we eat fewer calories. To counter this, exercise every day. I normally enjoy a brisk daily walk, equal emphasis on **brisk** and **daily**. 'Brisk' means you can *just barely* keep a conversation going. Walk with a friend to find your

own speed using this metric. (Check with your doctor to make sure you're healthy enough first.)

Our frighteningly unfashionable hero in his winter walking outfit, 2021

I average about 420 minutes – 7 hours – of brisk walking per week. I measure minutes of exercise per day instead of steps or total walking distance to allow for variety - swimming, bike riding, exercise classes, weight-lifting, cross country skiing or similar activities.

Interestingly, both the CDC and British National Health Service recommend *at least* 150 minutes per week of brisk exercise for everyone. More is better. That weekly 420 minutes of brisk walking helped keep my metabolism from slowing down as I ate fewer calories. The simple form at the end of this book helped me stay on track. Try it yourself.

Daily exercise – walking in my case - like everything else in this book, becomes a habit. You miss it on days you don't go. Allow yourself time for this habit to develop.

I like to measure both my daily exercise time and walking distance. The goal is to maintain at least, and hopefully increase, both. Various smart phone apps can help.

One day, early in this program, I walked 4 miles in 70 minutes, about 17.5 minutes per mile, finishing tired and certain I couldn't go farther or faster. Six months later, on a mid-February walk, I averaged 15:30 per mile for 5 miles, equally certain that I couldn't go faster … but pretty sure, this time, that I could go farther. (I actually went 7 miles a week later though at a slower 16:30 pace.)

Some people prefer to track total daily mileage or total daily steps. These are different ways to measure the same thing. I prefer exercise minutes since I can plan and control these, but again, just my preference. As long as you walk briskly during your exercise minutes, any measure can work.

One trick that keeps me motivated, even enthusiastic about walking every day: I listen to novels, generally long ones that keep me engaged. I prefer historical fiction and mysteries but again, personal preference.

I've walked with Winston Churchill during the Blitz of London, young Nigerian intellectuals as they navigate life, Sherlock Holmes, seafaring merchants, unscrupulous criminals, clever detectives and many others. I look forward each day to reconnecting with my audio friends and often – oddly – feel sad when each book ends. Listening while walking has become another habit, one that I increasingly enjoy.

Confessionary addendum: I know that I should add strength training to my exercise regime. I keep meaning to start but, truth be told, I never enjoyed lifting weights or doing sit-ups. Maybe I'll start tomorrow.

Probably not.

Step 4: Write *everything* down.

Write down your food consumption after every meal and snack, and your exercise time (or whichever exercise metric you choose) every day. That keeps you on track to achieve your goals.

The forms below can help. Completing them becomes another habit. It takes a minute or so. I expect to continue this for years since I plan to stay in the 185 pound weight range for a long time.

Writing down your food consumption each meal also makes you think twice about what you eat. It acts as a speed bump, forcing you to ask 'Do I really want to use this many calories on this food?' I found it a useful exercise.

Weight I weigh myself first thing every Sunday morning, always on the same scale. That's my 'official' weight though I confess to checking more frequently. I worry, slightly, that daily weigh-ins will drive me crazy, or, more likely, my wife. I'm already obsessive enough!

Beware of salt and water retention at your weigh-ins. Eating a salty evening meal – feta cheese or pasta sauce for example – can increase my weight by 2 to 3 pounds the next morning. Factor this into your calculations and, perhaps more importantly, watch your daily salt consumption. Harder to do than say unfortunately.

Meals You can use the attached simple form to track your daily calories. You'll see patterns emerge pretty quickly. Plus this will keep you from overeating in response to

head-hunger. I've inserted a week of meals simply as an example. You can set up these forms very easily in Excel and design your own meals.

Date	Breakfast	Lunch	Dinner	Snack(s)	Total
Sun	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Salad bag (50) Tomato (30) Chicken left overs (300) Italian dressing (75) Apple (100) Total 555	Turkey stew (ground turkey, pasta sauce and veg) (750) Salad and dressing (100) Pineapple (120) Total 970	3 Clementine (105) Yogurt & Ovaltine (100) Blueberry + honey (150) Total 355	2280
Mon	Oatmeal (170) 2 jumbo eggs (180) Ketchup (20) Total 370	Cauliflower left overs (75) Butter beans (150) Dressing (75) Chicken (150) Apple & cashew butr (190) Total 640	Salmon (300) Broccoli (100) Salad (50) & Dressing (75) Wine (100) 3 clementines (105) Total 730	Bana & Alm butr (100) Blueber & honey (150) Yogurt & ovaltine (200)	2190
Tues	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Broad beans (200) Steamed veg (150) Dressing (75) 2 sm oranges (180) Total 605	Cod & panko (450) Salad & beans (200) Dressing (75) 1 slice bread (100) Total 825	Blueberries & Activia (220) Orange (100) Apple (100) Total 420	2250
Wed	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Impossible burger (270) 2 x Bread (200) L & T, mustard, pickle (30) Apple (100)	Oatmeal (170) Cashews (320) 2 cups frozen fruit (140) Honey (70) Total 700	Baked apple & cinn (200) Yogurt & Ovaltine (200) Total 400	2100

		Total 600			
Thurs	Eng Muffin (100) Pnut butter (100) Banana (100) Almond butter (100) Total 400	Tuna (90), mayo (50) 2 x Bread (200) Pickles, L & T (40) Skim milk & banana (200) Ovaltine (40) Total 640	Swordfish (400) Broccoli (200) Green beans (100) Dressing (75) Blueberries (85) Total 860	Apple (100) Orange (100) 2 x Clem (70) Total 270	2170
Fri	Oatmeal (170) 2 jumbo eggs (180) Ketchup (20) Tomato (30) Total 400	Broccoli (100) Green means (50) Swordfish (200) Dressing (50) Pear & orange (200) Total 600	Baked feta (300) Tomatoes, onions (50) Broccoli (100) Potato (200) Wine (100) Total 750	Blueberries & honey (180) Yogurt & Oval (200) Clem (100) Total 480	2230
Sat	Oatmeal (170) Swiss cheese (100) 1 egg (90) Ketchup (20) Total 380	Tuna (90), mayo (50) Eng muffin (100) Pickles, L & T (40) Skim milk & banana (200) Ovaltine (40), Apple (100) Total 580	Beans (200) Rice (200) 1/3 cup cashews (250) Salad and dressing (150) Blueberries (100) Total 900	Baked apple & cinn (200) Yogurt & Oval (100) Orange (100) Total 400	2260

Exercise Use this form to track your daily exercise, total mileage or steps. If you track exercise minutes, focus on brisk walking minutes, the time your heart beats more quickly than normal so you can just barely keep a conversation going.

Exercise minutes per day, mileage or steps

	Sun	Mon	Tues	Wed	Thurs	Fri	Sat	Total
date								
date								
date								

Results and Lessons

This program worked for me. It may also work for you. No promises but I hope so.

If you decide to try, give it an honest effort. Stick with it for at least 6 months, long enough to develop new food habits.

You'll likely be pleased with the results.

Below, a sample of my own experience over 3 months, enough to make the point.

Weekly Food Consumption, Exercise and Weight Change
4th quarter, 2020

Week Ending Date	Average Calories Consumed per Day	Total Minutes Walked per Week	Sunday Morning Weight	Weight change, pounds, rounded
Oct 4	2120	465	207	
Oct 11	2020	535	206	-1
Oct 18	2230	465	204	-2
Oct 25	2110	550	203	-1
Nov 1	2300	360	202	-1
Nov 8	2019	475	201	-1
Nov 15	2087	455	200	-1
Nov 22	2657 (Thanksgiving)	580	198	-2
Nov 29	2069	540	199	+1
Dec 6	2157	320	196	-3
Dec 13	2452	485	195	-1
Dec 20	1999	340	197	+2
Dec 27	2400	410	196	-1
Jan 3, 2021	2332	600	195	-1
Averages over 14 weeks	2210	470		-.9 **lb. per week**

Part 2: The Health Insurance System

Employer Based Health Insurance
Part 1: Overview

The US is the only advanced industrialized country to finance medical care primarily through employment. Most other countries use employer based financing either to supplement a national healthcare system (e.g. the United Kingdom) or ban it from competing with the national system (Canada).

About 160 million Americans receive health insurance from work. That's about half of our population. The other half either receives health insurance through a government program – Medicare, Medicaid for example – from a state exchange or is uninsured. About 30 million Americans are medically uninsured.

Employers who offer health insurance worry about the costs. They need to balance their firm's financial health with their employee's medical health so provide plans that are good enough to comply with the various state and federal regulations and provide satisfactory employee coverage without costing too much. It's a delicate and confusing balance.

Employees should also worry about their employer's health insurance costs but too few actually do. Most employees think health insurance is a 'benefit' – a freebie that the employers offer. Labor economists virtually universally reject this assumption. They claim that the actual cost of each employee is the total of salary plus benefits, so if the employer pays less in benefits, the employee will receive more in salary.

In other words, the employee actually pays for employer-based health insurance via foregone wages.

Employer based health insurance has set the paradigm of healthcare financing in this country. We rely on 1 year long insurance policies to finance medical care even though 70% of healthcare spending goes to chronic disease treatment, i.e. treatments that take longer than 1 year. This sets up a fundamental inefficiency, treating long term problems with short term financing, a mismatch resulting in higher costs and, apparently, poorer outcomes than optimal.

Other healthcare financing systems, most notably Medicare, follow this one year long policy format. I'll discuss this in more detail below.

Three structural problems with employer based healthcare financing
#1: Moral hazard

Our employer based system finances all medical care with **insurance** rather than **payment plans** probably for historical reasons that we'll discuss shortly.

This confuses *insurance* (protection against financial harm caused by random events) with financing normal, routine and expected medical events like flu shots and knee replacements.

Compare health insurance to auto insurance. Auto insurance pays for ***un***expected events, like crashes; it doesn't pay for expected events like oil changes, tire rotations or transmission rebuilds. Yet we expect health insurance to cover all medical events, from the most routine and predictable to the most random and unpredictable. This leads to enormous inefficiencies because, many argue, insurance is the wrong financing mechanism for routine medical events.

- Insurance pools risk inefficiently based on timing; those *not having* medical events this year pay for those having.
- This suppresses any market mechanisms from pooling more efficiently and developing better, more targeted, more actuarially based medical financing products - orthopedic payment plans for example, or pediatric immunization payment plans.

  We can imagine lots of medical payment programs, underwritten and priced for individuals or banded for groups. Middle aged men might buy 5 or 10 year orthopedic and urologic plans but not birthing; younger women the opposite.

  This kind of program pools need more efficiently than blanket insurance plans that cover every possible medical situation, for all people, that might occur this year. 'Insurance' then provides a safety net for the unexpected or random events not covered by specific payment plans.[57]

A fundamental problem using insurance to finance all medical activities is **moral hazard**. Insurance programs *always* face concerns about moral hazard. Moral hazard is the phenomenon in which people get more care than they need because it appears free to them. Insurance financing that includes this moral hazard component is a great foundation for a healthcare jobs program but a poor one for an efficient medical care financing system.

The moral hazard concept originated when home fire insurance was developed centuries ago. Underwriters were concerned that people with 'poor moral character' would burn their houses to collect the insurance proceeds then rebuild a less expensive house and pocket the difference. This translates in the health insurance arena to people having tests and treatments because –why not? It's free to me and may offer some benefits.

[57] Regina Herzlinger has written extensively and creatively about this type of program. See especially her book Who Killed Healthcare.

Medical care providers understand this issue and can generate income from it: 'let's send you for another test just to rule something out. Don't worry – it's covered by insurance' and medical testing and treatment industries develop. Dr. Sandeep Jauhar, Director of the Heart Failure Program at Long Island Jewish Medical Center, has written eloquently and painfully about this. Consider these various quotes from his 2014 book Doctored:

> Bob and Joe and Dave have an unwritten agreement to call one another when patient issues arise outside their scope of expertise. If Bob, the nephrologist, sees a patient, he finds a cardiac and a gastrointestinal issue and consults the other two specialists and vice versa…a mutual scratching of backs…**Insurance companies can restrict medications, tests and payments. But they still cannot tell us who or when we can ask for help.** (page 97, emphasis added)
>
> A large percentage of healthcare cost is a consequence of induced demand – that is, physicians persuading patients to consume services that they would not have chosen if they were better educated. (page 107)
>
> [Describing one particular physician] …he was doing a plethora of tests – eye exams, audiometry, pulmonary function tests, even Holter monitoring – to generate revenue … he avoided the high-risk cases… 'Those we would send to a cardiologist' …[and, quoting a gastroenterologist] 'If a doctor doesn't do excess testing, forget it, he isn't going to be able to live.' (page 167)

Dr. Jauhar's unsettling conclusion about the impact of moral hazard:

> In our healthcare system, if you have a slew of physicians and a willing patient, almost any sort of terrible excess can occur. (page 94)

Others have, of course, also written expansively about the impact of moral hazard on our healthcare system. My point in this discussion: by relying on insurance to finance all aspects of healthcare, the employer based model exacerbates, rather than ameliorates, this problem. By basing our entire healthcare financing system on and around the employer model, the moral hazard problems permeate all aspects of American healthcare financing, creating more healthcare jobs and less healthcare value.

While we can't calculate an exact cost of moral hazard in our healthcare system, credible research suggests that 30% + of all medical spending is wasted on unnecessary care. That's generally estimated at about $700+ billion annually or $2500+ per employer based policy. The Dartmouth researchers primarily responsible for that estimate, though, are quick to note that we 'view these as an underestimate given the

potential savings even in low cost regions' [58] meaning that even they have no real solid idea how much moral hazard exists in our system.

But they and others admit that it's a lot.

A very lot.

Structural problem #2: Disconnecting payers from users

Payers in the employer based model are employers, often acting through their benefits department. Payers decide what network size employees want, what deductible levels, what drugs to include in the formulary and what copayments to have. This is particularly true in small companies covering the bulk of American workers that may offer only 1 policy to all employees.

Consider the impact of payer's decisions. A company opting for a wide provider network decides that each employee would prefer *paying more for health insurance* to *having more disposable income available* (and using a smaller network).

Or a company opting for a smaller network decides that employees prefer *more disposable income* to *having the most expensive doctors and hospitals available in-network.*

Employees, though, are the consumers and each may seek different things from our healthcare financing system. One may want higher deductibles or lower, wider networks or smaller, bigger drug formularies or not. Each facing his or her own specific medical issues can reasonably have his or her own set of preferences.

We call this 'consumer sovereignty' meaning that the most efficient economic distribution system is one in which consumers express their desires through purchases. We have seen this work quite effectively in other markets for hundreds of years.

Take the grocery market for example. A typical supermarket has thousands of products available because some people like expensive cuts of meat while others are vegetarians. Some people like ice cream while others are lactose intolerant. Some people like rye bread, others white bread and still others prefer bagels. And so on, for canned foods, soups, fruit and many other food products.

Our food distribution system is 'efficient', or so goes the argument, because individual consumers, casting their own dollar-votes, decide which products should be available and how much shelf space stores should allocate to each product. As consumers demand more soup, the store supplies more soup. Ditto for apples, mangoes and bread.

[58] Dartmouth Atlas of Healthcare, Reflections on Variation, answer to the question 'The Atlas is often cited as a source for the estimate that 30% of the nation's spending is unnecessary --- what is the evidence? http://www.dartmouthatlas.org/keyissues/issue.aspx?con=1338

Imagine the impact on our food choices if these decisions were made by your employer! 'Apples are good for my employees, so stock a lot. Cut down on cookies and fatty meats. And, since more and more people are lactose intolerant, switch to carrying more skim milk.' (As if your employer had any interest in making those decisions. Your employer wants to make and sell widgets, not decide what you should eat. Hmmm, sounds like healthcare, doesn't it?)

Restrictions on consumer sovereignty lead to higher prices, less choice and sometimes poorer quality. Would apple producers focus as much energy on their product quality if they knew that all stores had to buy more apples from them? Maybe – or maybe they'd focus more on quantity and price.

In the employer based health insurance model, consumers have far less sovereignty than many would like, since benefits administrators make many of their key consumption decisions. But remember the economic axiom: the more consumer sovereignty, the more efficiency. And vice versa.

Structural Problem #3: One year long policies

Some 70% of healthcare expenditures go toward chronic, long term and on-going medical care as opposed to episodic, acute care. A chronic condition is, for example diabetes and an on-going care example might be post-operative cancer treatment. Dozens more examples exist. The best outcomes result from continuity of treatment from the same provider. Medically, thus, *long term financing programs* tend to generate the best outcomes, generally at the lowest costs since care discontinuities can lead to errors, which add treatment costs.

Employers, however, oppose funding multi-year health insurance policies. Business conditions may change they reason, their employee census may change, prices may fall – why encumber themselves with long term liabilities? Employers like 1 year long policies so they can change the program if business conditions warrant.

This creates a conflict between *employee medical needs* and the *employer's business considerations*. We have, nationally, adopted the employer's position as the basis of our healthcare financing system, not the medical need position. Financing medicine based on anything other than medical concerns adds inefficiencies (costs) to the system without any related benefits or value increases.

The employer financing model forces health insurance carriers to compete on short term medical cost controls rather than long term patient outcomes. I'll explain how all this works and some impacts later in this chapter.

These three structural problems – financing routine medical care through insurance, disconnecting payers from users and embracing 1 year health insurance plans - lead to an inefficient system with skewed incentives. Good for healthcare jobs growth but bad for system value creation.

But that's what we get with employer based financing as the core of our national healthcare financing system.

Three consequences of employer based health insurance

Uwe Reinhardt, professor of healthcare economics at Princeton, suggests 3 consequences of placing employer based health insurance at the center of healthcare financing. [59]

First, it is tremendously expensive. In 2021, for example, the average family health insurance annual premium was $22,221 [60] up about $17,000 from $4,969 in 2011.[61] This compares to a median annual family income in 2021 of about $79,900. That's 28% of the average annual family income going to health insurance. Under what definition of 'affordable' does this make any sense?

Reinhardt wonders how any employer who finances employee healthcare, carrier that designs plans or broker who implements benefit programs can take pride in his/her work product. So do I.

Second, having employment at the center of our healthcare financing system requires lots of 'fill in' programs for people unable to obtain employer based insurance. Each of those programs – Medicare and Medicaid, for example, or SCHIP – develops their own regulations, licensure requirement, codes and prices resulting in overlapping and confusing payment categories.

We have, as a result:

- One healthcare system for fulltime, employed people. This system has its own access rules, reporting rules, prices and payment rules.
- A second healthcare system for elderly people, with its own (different) access rules, reporting rules, prices and payment rules.
- A third healthcare system for very poor, unemployed people who (for lots of bureaucratic and political reasons but no medical ones) must *also* be either i children, ii blind or disabled, iii elderly, iv mentally ill, v pregnant or vi mothers. [62] This system, as the two previously mentioned, also has its own access rules, reporting rules, prices and payment rules

[59] This section based on Reinhardt's lecture at the Pioneer Institute in Boston, 2014. I updated the premium numbers in this text but his core argument remains valid.

[60] KFF.org 2021 Employer Health Benefits Survey

[61] How much does health insurance cost, Nov 2, 2011, eHealth news release

[62] Ezekiel Emanuel makes this point in Redefining American Healthcare, page 47

- A fourth healthcare system for slightly poor, partly employed people (we sometimes call this ‘non-group’, a financial distinction but not a medical one)
- A fifth system for children not otherwise accounted for
- A sixth system for military veterans, but only if they’re also either old or accessing medical care as a result of combat injuries, or both, and finally
- A seventh system for people with kidney disease, provided it’s end-stage.[63]

Inefficient and irrational are two polite ways to summarize this chaos: nuts might be more appropriate. Having all these overlapping, irrational categories creates confusion and complexity that makes our system far less efficient and effective than we would like or hope for, leading to more jobs, higher costs and, unfortunately, poorer outcomes than patients would hope for.

I wonder if that’s the system goal.

These different categories exist, again, because of the employer basis of healthcare financing. We needed to develop all these programs to address groups left out of the employer coverage model.

And **third**, having all these different categories has led to different prices for the same service. [64]

- The **List Price** exists though is rarely paid. It’s reserved for rich foreigners and uninsured Americans. It’s the highest price hospitals charge.
- The **Medicare rate**, completely transparent, is stipulated by Medicare. It’s generally about 80% of hospital costs, meaning hospitals must overbill some other category of patients to remain financially solvent.
- The **Commercial Insurance rate**, higher than Medicare and lower than List Price, varies by carrier based on their market clout and negotiating skills. It tends to run about $135% of hospital costs though this can vary significantly.

  One reason for the high price and variation: market clout. A carrier with 8% of the market generally negotiates relatively ineffectively with a hospital network that controls 60% of the beds.

[63] We also have the Indian Healthcare System which, you’ll be pleased to read, is funded under the Indian Healthcare Improvement Act, signed by President Obama in 2010 and which is included in the Affordable Care Act. Probably others too, but that falls outside my area of expertise.

[64] This section comes from Ezekiel Emanuel’s book Reinventing American Healthcare, pages 72 -76. It follows from Reinhardt’s analysis.

- The **Usual and Customary rate** is the rate hospitals charge carriers with which they don't have a contract – a Colorado hospital that treats Florida insureds who injures themselves while skiing for example.
- The **Medicaid rate** is typically the hospital's lowest rate, often quoted as a percentage of Medicare's rate.
- The **Actual Cost** of providing the service is generally unknown. Many medical professionals interact with each patient, requiring detailed time-and-motion studies which are expensive to produce.

Note that in other – efficient – parts of our economy, the service provider determines his/her price for the service and then sells it to anyone who will buy with, perhaps, some quantity discounts to account for scale. But in medical care, the same service varies in price by patient and the same patient can switch from category to category, thus inducing different prices from the same providers for the same care. See why I suggested this is nuts?

This huge, complex, irrational and inefficient system exists, again, because of the employer centric structure of our healthcare financing system.

Two problems that employer based health insurance fails to address
#1: Unnecessary Care

Unnecessary care, defined as care that does not improve patient health, is the largest single category of medical spending in this country. Credible estimates, as from the Dartmouth Atlas of Healthcare and Dartmouth Institute for Health Policy, suggest that up to about 1/3 of all healthcare spending or some $700 billion annually is unnecessary. I think this a low estimate, but at 30% of medical spending, it trumps

- Heart disease, about 10% of medical spending
- Diabetes and cancer, about 5% of medical spending each.

In fact, according to Jonathan Bush, founder and CEO of Athenahealth, 'unnecessary care is part of the hospital business model'. [65]

The interesting question for this section: who, in the employer financing model, tackles unnecessary care as a function of his/her job?

- **Does the benefits administrator care?**

  Probably not. The benefits administrator generally wants to keep premium inflation around 'trend', the industry definition of healthcare inflation.

[65] Jonathan Bush, Where Does It Hurt?

If his/her company's premiums inflate at trend, then he or she can take a CYA approach: 'I did my job. Our premiums reflect trend.'

If his/her company's premiums inflate faster than trend, then alter plan designs, generally by increasing deductibles and copayments and shrinking the provider network.

Engaging with carriers and providers to reduce unnecessary care is time consuming, a task for which the benefits administrator probably doesn't get paid and is probably ill-equipped. It will likely be an unsuccessful effort anyway. That's why most benefits people tend to take the CYA approach and settle for the 'we're at trend' justification for mediocrity.

- **Does the CFO care?**

  Again, probably not. The CFO is busy, responsible for the company's financial health and less interested in the internal operations of a hospital. As long as premiums inflate at an 'appropriate' rate, then the CFO will focus on his/her company's core business, making widgets for example, and generate profit on those.

  CFO's lacks both the time and expertise to work with doctors and hospitals on reducing unnecessary care. A huge company CFO might have the time and interest to work with a select group of providers on this issue. But hospitals that engage with this particular large company may well then turn around and bill other, smaller companies more to make up the difference.

- **Does the employer care, especially the small and mid-sized ones?**

  Again, probably not. Most economists argue that employers simply reduce wage increases to fund health premiums. (See below). If premiums rise quickly, wages rise more slowly.

  The employer corporation doesn't care – economically – if it pays employees wages or premiums. It's only concerned with the total employee costs.

#2: Underfunded Social Programs

Among developed countries, the US has the highest rates of diabetes, sexually transmitted diseases, teen pregnancy and auto mortality. We also have the second highest rates of heart and lung disease and lose more years of life before age 50 to drug and alcohol abuse. [66]

[66] For Americans Under 50, Stark Findings on Health, Tavernise, NY Times, Jan 9, 2013

Are sexually transmitted disease and teen pregnancy the *employer's* problem? The patients typically don't work for the employer but the employer pays for treatments through 'trend'.

We know that social and behavioral factors affect more than

- 70% of colon cancer and strokes.
- 80% of coronary heart disease
- 90% of adult on-set diabetes, and
- Probably most leg amputations (we lead the developed world)

But the underlying social and behavioral factors exacerbating these problems are not addressed by employer based health insurance. These are 'social' problems, appropriate for some government agency or non-profit to address – or so believe many employers and benefits administrators.

Perhaps as a result, we spend far less on social determinants of health (housing and rent subsidies, training programs for poorly educated or unemployed folks, disability cash benefits and social services in general) and far more on medical treatments after someone gets sick than do most other developed countries.

In fact, though we're #1 in medical spending per capita in the world, we're #13 in 'medical and social spending' combined. We have the ratios reversed from most others. The OECD average is about 2/3 of combined 'medical and social spending' going to social and about 1/3 going to medical; we're the opposite, joining only Korea and Japan as spending the majority of 'medical and social' on medical. [67]

This situation developed largely because employers lobbied more successfully for health insurance premium tax breaks than did social service agencies for funding. (More on this below when we discuss the history of employer based health insurance.)

How well do employers negotiate for their employees?

In 1964, the average wage in this country was $2.53/hour and the average health expenditure $197 per person per year, requiring the average person to work about 78 hours (2 weeks) to pay for healthcare. [68] Divide $197 by $2.53 to see this.

[67] See The American Healthcare Paradox by Bradley and Taylor for more on this. I only summarized their research here.

[68] This example comes from Philip Longman's excellent book on the Veteran's Administration Healthcare system, Best Care Anywhere

In 2019, the last year before Covid, the average wage had risen to $22.98 / hour, healthcare cost to about $11,500 per person, requiring the average person to work 500 hours (12.5 weeks) to pay for healthcare.[69]

This strikes many as a pretty poor track record. One wonders if individuals, negotiating for their own policies, might have done better than employers and brokers working together. [70]

'But my employer pays 75% of my premiums'

This misconception pervades the employer based health insurance model. Let me explain what most people believe first, and then show the real costs. [71]

Consider Mary, a single woman who earns $35,000 a year. In this hypothetical example, the company's single premium is $649/month ($7791 annually) of which Mary pays 27% or $2112 per year. She also pays a $250 annual deductible and has 4 office visits at $25 each.

Mary thinks her healthcare costs about $2462, or roughly 7% of salary. Not too bad.

There's only one problem with this analysis: it's completely wrong. Not even close to correct.

Here's what Mary actually pays:

- The entire **$7791** premium in foregone wages. Remember that her employer doesn't care if Mary receives compensation as salary or benefits. The employer only cares about the total annual cost of employing Mary.
- $1276 in state taxes at a 3.6% state tax rate. Since states average spending about 10% of their budgets on healthcare costs for employees and Medicaid, Mary pays about **$128** in healthcare costs to the state.
- $3827 in Federal taxes, about 11% of her income. Since 20% of the federal budget goes to healthcare, Mary pays another **$765** here.
- Medicare taxes (1.45%) plus the employer match (foregone wages again), another **$1015**.

---

[69] Wage estimates from the Bureau of Labor Statistics 'Usual Weekly Earnings of Wage and Salary Workers, Third Quarter 2019'

[70] See in particular David Goldhill's Catastrophic Care. Philip Longman compares cost inflation in the Veteran's Healthcare Administration system to the employer based system in his book Best Care Anywhere. The VHA did a better job controlling costs while, according to Longman, generating better outcomes.

[71] This analysis comes from David Goldhill's 'Catastrophic Care', chapter 2 'The Hidden Beast'. I've adjusted the numbers slightly and changed the woman's name to Mary, though unclear exactly why.

Mary actually spends about **$10,000** on healthcare annually, not $2462. See why all the healthcare system inefficiencies we've been discussing really matter?

Part 2: How Employer Based Health Insurance Developed
An historical accident

Let's consider two historical themes to understand both why we have an employer-centric healthcare financing model and why it works so poorly.

First, remember that healthcare and social services evolved independently and differently. Healthcare was a profitable industry, supported by powerful special interests; social services were not but, but rather were disorganized, politically weak and stigmatized for helping the 'undeserving'. [72]

Consider this story from Bradley and Taylor's book The American Healthcare Paradox about Joe, a 28 year old, very low income diabetic: [73]

- His poor diet, including very little fresh food, exacerbates his condition
- He wears old, holey shoes that keep his feet constantly damp.
- His doctor admonishes him to eat better, take his insulin and keep his feet dry, but he can't afford to do these things often enough
- Last year he had 2 toes removed costing $7000 and next year likely two more for $14,000
- His doctor discussed the possibility of a foot amputation ($18,000) plus rehab (total medical costs about $30,000), plus a wheelchair ($1000). This would make finding a job far more difficult, reducing Joe's chance of earning much income and consequently paying taxes (more or less paying for the social welfare of others). A leg amputation might permanently relegate him to surviving on government benefits, not a job.

Perhaps the most ironic or depressing part of this story: new shoes cost $75 and an apple costs $1 per day. Our (underfunded, disorganized) social services can't manage these minimal costs while our (well funded, powerful) medical system racks up tens of thousands in fees by implementing medical solutions to social problems.

Second, our healthcare financing system evolved inefficiently, from a vertically integrated 'financing + care provision' system to a non-vertically integrated one.

- Vertical integration means medical care and medical financing are the same entity with salaried physicians. Both the financing arm and medical care arm

[72] See Bradley and Taylor, The American Healthcare Paradox for a longer explanation of this point.

[73] Ibid. page 1

work together to generate the best patient outcomes at the lowest cost, at least in theory.

'Managed competition' is competition among vertically integrated healthcare providers. Those generating the best outcomes at the lowest costs will gain customers; those operating at higher costs and generating poorer outcomes will lose. [74]

Vertically integrated healthcare entities compete with each other on *value*: outcomes per dollar spent, since they control their own income (i.e. the premiums they charge customers.)

- A 'non-vertically integrated system' has separate companies handling financing and medical care. Today we call financing companies 'insurance carriers' and medical care provision companies 'providers', generally hospitals and physician groups.

  In this system, financiers always want to pay service providers less and service providers always want to bill more. The relationship between the two is 'war' - according to Atul Gawande, professor at Harvard Medical School and staff writer for the New Yorker – 'every step of the way'. [75]

  In a non-vertically integrated system, carriers and hospitals argue over payment formulas since hospitals do not control premiums. A very different focus from the vertically integrated model above.

How Employer Based Healthcare Started

(This section comes from an edited transcript of my lecture on Employer Based Health Insurance delivered at the Health Services Administrators in Braintree, Massachusetts on September 29, 2008. A version of this appeared in my book Understanding Health Insurance published in 2010. GF)

The myth – or perhaps truth - is that it started in Dallas around 1929 as a reaction to the stock market crash and financial meltdown. [76] The business problem for Baylor University Hospital in Dallas was that it didn't have enough money to pay its bills.

[74] Alain Enthoven of Stanford University, perhaps our greatest managed care theorists and proponent, has written widely about this which is somewhat outside the scope of this particular chapter. See his seminal article The History and Principles of Managed Competition for more. http://elsa.berkeley.edu/pub/users/webfac/held/157_VC2.pdf

[75] See Gawande's second book 'Better', chapter entitled Piecework

[76] This suggestion comes from Richmond and Fein, The Healthcare Mess, page 30.

Prior to the stock market cash, hospitals raised funds in two ways. First they had paying customers who were billed for services rendered - a fairly modest percentage of the population because most people didn't have a lot of money. Second, the community chest, the charitable organizations - the wealthy would donate to the hospital because it was a good place to donate your extra money. Charity made you feel good and was good for the community.

But with the stock market crash, the wealthy didn't have as much money to donate, unemployment increased (reducing the number of patients able to pay), and the hospital faced a difficult financial landscape. So Baylor University Hospital made a deal with the Dallas School System. They said, "School system, you raise money from taxes. You always have money. Pay us $.50 every other week, $.25 a week, for each of your employees and when they get sick, they come to us and we'll take care of them." Employer based health insurance arrives.

A few comments about this.

First, it's a nice deal. It's a nice deal for the hospital because they stay in business. They don't have to worry about going out of business. They don't have to worry about turning people away as long as they get the numbers right (which apparently they did), $.50 per employee every other week. That was the true cost. The school system payments protected the hospital's cash flow, so the hospital stayed in business.

Second, this was very efficient. The hospital signs one contract with one employer group and received back enough money to stay in business. Sweet. That's a pretty good incentive to look for more large employer groups.

Third, there was no prevention or provider choice, but theoretically the teachers and other employees of the school system were happy because they got medical care essentially for free.

Fourth, this was for hospitalization only. There was no outpatient doctor's coverage.

Fifth, community rating. The Dallas School System paid $.50 per person every other week, regardless of individual medical status. There was no medical underwriting.

Sixth, there were no quality controls, no outcome based incentives, no holdbacks for poor hospital performance. Health insurance began simply to save the financial health of the hospital.

This was a vertically integrated system, almost textbook variety. And it exhibited the classic flaw of vertically integrated healthcare system: lack of consumer choice. As developed initially with Baylor University Hospital, the Dallas school system employees could only go to one hospital. This has advantages and disadvantages.

Advantages:

1. Lower Costs

2. Reasonable medical care from a small number of ‘in-network’ providers

Disadvantage:

1. Little provider choice as few hospitals ‘in-network’

The Baylor Hospital / Dallas School System deal worked so well that other hospitals soon copied it. Different hospitals looked for different large employers, offering the same kind of deal. Large manufacturers, the Dallas Morning News, and others. What problem begins to arise?

The Choice Problem

Consumers (school system employees or manufacturing workers, for example) wanted to chose among various hospitals. ‘What do I know about Baylor University Hospital? I only know one thing. I know someone who went there and didn’t get good treatment, so I want to go somewhere else.’ Someone always knows of someone else who had a negative experience there. So you want to go somewhere else - consumers want choice.

Remember vertical integration, where finance and service provision are the same company? Once you introduce choice, then you have one group handling finance and another handling service provision. You have a split and you lost vertical integration. (More on this coming up soon.)

Back to Dallas. The hospitals are cranking along with the employer based financing model. They’re very happy. They’re making money. And then one of the Blues brothers comes along – Cross or Shield, I don’t remember which – and offers to provide financing for lots of Dallas hospitals. ‘Dallas teachers’ they might have said, ‘you can sign up with Baylor University Hospital only, or, for just a little more money, sign up with us and we’ll give you the choice of many hospitals in Dallas. We contract with lots of hospitals. We have a large network.’ Sounds pretty appealing, right?

Doctors looked at this and said, “Hey, we want in on this too.” They organized a second Blues brother so doctors could get paid because the same depression was affecting all medical providers, both hospitals and physicians. Blue Cross for your doctor’s bills and Blue Shield for your hospital bills (or maybe the other way around. Wikipedia didn’t say when I looked it up.) Both organized to protect provider incomes.

And both – conceptually, if not in real life – competed with vertically integrated hospitals, like Baylor University Hospital was at the beginning with the Dallas School System.

The Blues developed a couple of very clever ideas in the 1930s. First, from a marketing point of view, they offered this very attractive provider choice option. Very appealing to many consumers.

Second, they began searching for the healthiest subscribers. An interesting business idea: if they could find the healthiest people, they could offer lower priced policies and gain a competitive edge vs. their vertically integrated competitors signing up large employers at a fixed price per person.

Underwriting vs. Community Rating

The Blues figured that they would underwrite better than the competition so people would join them because their premiums would be a little bit lower. The community rating folks faced higher premiums because they took all employees.

Underwriting serves the economic interests of the carriers. It doesn't improve healthcare outcomes. It doesn't improve the healthcare system. It doesn't differentiate medical quality. It doesn't create patient value. It only makes one carrier lower cost than another carrier by having sick people pay more. The healthy pay less, the sick pay more but there's no value created: the total medical costs remain the same. But some people win and others lose.

This financing system has little to do with getting people healthy, or creating value. That was not its intention. It was designed to protect physician and hospital income. That was the original Baylor idea. Then carriers came along to make a profit on consumer demand for choice. The demand for choice leads to the Split.

The Split and the Provider Payment Problem

Once you split finance from service provision, you have a wider consumer choice and you have to figure out how to pay doctors and hospitals. We're still, today, trying to get this one right.

The original and still most popular payment mechanism is fee-for-service. The doctor gets paid $100 for treating each broken arm and $350 for each rotator cuff surgery.

As soon as you split finance and service provision there's an incentive on me, the doctor, to do more treatments. You're paying me by treatments, so I will do more treatments. 'That guy's got a sore shoulder that's probably due to a rotator cuff tear, so I'll operate on his rotator cuff.' Fee for service provides an incentive for doctors to do more procedures and hospitals to admit more people.

You, on the other hand, the carrier, want to limit the number of treatments. You want to ask if I have to do that procedure. We fight all the time. My clinical judgment (influenced, perhaps – at least psychologically – by the fee-for-service payment formula) vs. your financial judgment (influenced, perhaps – at least psychologically – by the same fee-for-service formula. You don't really trust my clinical judgment.) That's the conflict between healthcare payers and medical service providers.

Let's remember where we are. We're still in the 1930's and we're talking about the growth of the employer based system. Little cost control. We've developed the split

between finance and service provision. Finance people will say, “You really don’t need to do that procedure,” and the service provider says, “Yes I do. Yes I do.”

The Problem of Measurement in Fee for Service Medicine

There’s a related problem in fee-for-service medicine – the problem of measurement. How well does a particular physician treat his/her patients? How well does a particular hospital perform certain surgical procedures? How well does a particular treatment work?

These are enormously difficult questions to answer. We do not even today have good measurement criteria or good data – and we had even poorer criteria and data in the 1930s. The data that we can measure might not be the most important. Remember that our healthcare goal is to extend life or improve life quality. We do not yet fully understand which treatments today will lead to longer lives in 30 or 40 years. Nor do we fully understand which treatment qualities will lead to long term life quality improvements.

We can only measure some aspects of medical treatments – surgical mortality rates, hospital infection rates, 30-day hospital readmission rates, for example. These may not always be the most significant outcome data, though they may be useful for some patients.

Whose interests are served by measuring or publicizing this information? Not the providers. They get paid fee-for-service for the *quantity* of medical care, not the *quality*. Publicizing outcome data may harm them economically. Thirty day hospital readmission rates may show that Hospital A provides poorer patient treatments than Hospital B. Or that Surgeon Z has a higher mortality rate than Surgeon X.

The risks of either inappropriate or unflattering outcome data becoming public were so great during the inception of our employer based system that providers fought against its release. The fee-for-service system suited their interests far better than any outcome based payment mechanism.

The fee-for-service / component payment structure suited their interests in a different way also. Absent good data collection, each physician – responsible only for his/her specific tasks – can argue ‘I did my job correctly. The fault lies elsewhere.’ Physicians act as subcontractors, narrowly defining their individual tasks, rather than as general contractors responsible for the life of the patient. This follows directly from payment systems that developed from the Split between finance and service delivery.

Fee-for-service / component financing serves provider interests, is inflationary and expensive, and is not designed to improve patient health. It’s only designed to reward providers, which it did quite well historically. We, in the US, have traditionally performed more procedures / 1000 of population than similar developed countries around the world. Things today like spinal fusion surgery, hip replacements, knee replacements,

coronary bypass surgeries. The Split between finance and service provision led us down this road.

The Impact of World War II

Let's continue with our historical / conceptual history of employer based health insurance.

During World War II, or perhaps as a function of it, more and more people got insured, most notably people in the military. They continued with insurance coverage after the war. In the relatively short post-war period we get lots more Americans covered for hospitalization insurance.

1942: 10 million hospital insurance / health insurance subscribers

1946: 32 million

1951: 77 million [77]

World War II plays an important role in our story for three main reasons.

First, the soldiers who received health coverage while in the military wanted to continue with it afterward. They saw the advantages of having health coverage. They married and wanted their families to receive coverage also. This created demand for health insurance.

Second, our wartime economy devoted significant resources to medical technology improvements. Perhaps most significant was the introduction of sulfa drugs to combat infections. These helped turn hospitals from infection breeding institutions into patient treatment and improvement centers. Other technological innovations followed. These improved the quality of medical care, or the supply.

Third, the Federal wartime wage and price freezes fostered the development of 'fringe benefits' such as health insurance. These reduced the cost of insurance to the individual consumer and further helped stimulate demand. It's a pretty interesting story just how these developed.

The government decided during the War to freeze wages and prices - to avoid domestic economic difficulties and help focus our economy on war production. Employers could not raise wages to attract new workers or to reward their best employees. The government controlled this aspect of employee compensation very tightly.

But the government allowed employers to offer fringe benefits such as health insurance. This was how employers could attract new talent and retain their current employees. The concept of 'fringe' meant 'outside the normal compensation' and 'benefits' meant 'advantages of working here'. Employers couldn't simply raise wages – the traditional

[77] Richmond and Fein, The Health Care Mess pages 30 - 38

way of attracting labor – as that was illegal during the war. Fringe benefits were simply a mechanism to get around the wartime wage freeze.

As we grew in 9 years from having 10 million to 77 million insurance subscribers in this country, the health insurance industry developed and gained political power. It lobbied Congress for favorable legislation. It applied political pressure. It acted, in short, just like all other powerful industrial groups.

The Hill Burton Act and IRS decisions strengthen hospitals

Congress, just after World War II, passed the Hill Burton Act to fund hospital expansion. This increased the number of hospital beds in this country by about 40%, from 3.2 per 1000 people to 4.5. It also made hospitals the centerpiece of our medical care system; the travelling doctor who made house calls started to disappear.

Shortly thereafter, in 1953, the IRS decided that fringe benefits were exempt from federal income tax: those became *tax deductible to the employer* but *not income taxable to the employee.* **This was essentially a government subsidy for hospital care,** since that's what health insurance ultimately financed. The government stimulated sales of employer based health insurance by subsidizing the price through the tax exemption.

To understand how this is a subsidy, let's look at both the employer and employee tax situations. The employer buys a $100 insurance policy for an employee, and, prior to the IRS regs, pays corporate income tax on the $100 ---- let's say that was 50%. So the employer's total cost was $150: $100 for the policy and $50 for the income tax on that $100.

By making the payment tax deductible to the employer – that means by foregoing the corporate income tax on that $100 - the government reduced the cost. Health insurance now only costs the employer $50; the employer takes a 50% tax deduction on the $100 payment. That's a big savings compared to the previous $150 expense.

The employee received this $100 employment benefit. Prior to the IRS regulatory change, he/she would have paid their marginal tax rate on this income --- let's say 30%. By making this tax free to the employee – that means by foregoing the personal income tax on the $100 – the government contributed $30. In other words, the government subsidized the employee who received health insurance by $30.

An interesting note from the employee point of view. $100 in benefits is more valuable than $100 in salary. The $100 in salary is taxable, so nets only $70. Remember our discussion above that 'My employer pays 75% of my premium.' I suggested that the employer doesn't care if he/she pays salary or benefits – the employer only cares about the total cost.

But the employee, according to many economists, does care. The employee prefers benefits since they're not taxed. The employee's foregone salary, according to this

argument, is more valuable than benefits since it's not taxed. (I'm not sure I buy this argument completely but it does give me pause to consider.)

This subsidy for health insurance was so effective that the rate of Americans with hospital coverage skyrocketed. In the mid-1950s, about 45% of Americans had hospital insurance. By 1963, 77% had hospital coverage, and an additional 50% had some form of physician coverage.[78]

The favorable tax treatment of fringe benefits led to healthcare inflation from higher *hospital* prices – because more people could afford to use hospitals.

Over this time period two strange incentives evolved in our healthcare marketplace: an *excessive hospitalization* incentive and an incentive to *cover the unemployed*. These two conditions merged in the late 1960s and 1970s. Their combined effect became clear by the 1980s as our health insurance costs skyrocketed and our employer based financing model became even more firmly entrenched.

Excessive Hospitalization Incentives

By the mid-1960s over three quarters of Americans had hospitalization insurance, paid for by employers and subsidized by the government. Hospitalizations became essentially free to patients, creating, in the words of Harvard Professors Richmond and Fein a 'not-so-subtle perverse incentive to hospitalize individuals.'

This was the case even for diagnostic tests that could have been performed on a less costly outpatient basis, they say. Over time the hospital became all the more important and central to the delivery of healthcare services.

This increased the need for health insurance:

Since medical care became more costly, insurance became more useful (indeed, necessary). In turn, the presence of insurance helped underwrite a buildup of resources and an upgrading of technology that added to costs and made insurance even more valuable. [79]

Remember the incentives here.

- Employees liked the system because it appeared free to them;
- Carriers liked the system because the government subsidized their product (health insurance policies);

[78] Enthoven and Fuchs, 'Employment Based Health Insurance: Past, Present and Future' Health Affairs, Nov/Dec 2006

[79] Richmond and Fein, op. cit., pages 38 - 39

- Hospitals loved the system because they received patients and insurance payments – a wonderful recipe for making money.
- Employers objected somewhat to this system, but not terribly strenuously. After all, the government was subsidizing their health insurance payments, so they felt the pain only partially.

Our healthcare system was hospital based – not really interested in preventive care (hospitals couldn't charge much for that); not really interested in public health (the field was only just developing); not really interested in outpatient or chronic care. Providers focused on hospital care because that's where the money was.

Hospital insurance stimulated the excess use of hospitals, which created more need for hospital insurance. Three byproducts:

- First, we used hospitals for almost all medical care, even if less expensive setting existed;
- Second, we developed fewer outpatient, home based, preventive or non-hospital types of medical care;
- Third, we continued to underfund social program. All this hospital growth and funding (largely from government programs and tax subsidies) crowded out social service investments.

Yet this third issue was tremendously important. Let me quote Professors Richmond and Fein on the relative importance of hospital investment and public health investments. [80] And remember: these were two highly respected Harvard Medical School professors. Richmond, in fact, was US Surgeon General in the Carter administration.

- 'A growing professional consensus holds that the health gains since WWII were largely **the consequence of applying our knowledge of health promotion and disease prevention rather than improved clinical care…' (**i.e. public health investments**)**
- 'The revolution in biology subsequent to World War II, a revolution that had brought many advances to clinical care, as yet **had only marginal effects on improving our vital statistics'**

Social spending had a bigger impact on our national health gains than did hospital investments! We invested the wrong way (assuming our healthcare investments were aimed at promoting health).

How Could Employers Afford Health Insurance Premiums after World War II?

[80] Richmond and Fein, op cit, pages 92 and 94

What set of circumstances allowed this system to develop? Why was the employer based system healthy and growing until the late 1900's, then in decline?

It turns out that for a number of years, this 40 year period more or less, many countries were (a) recovering from World War II or (b) gaining independence and expanding their educational systems. They were not economic threats to the United States – countries like Japan, India, Korea, China, or Western Europe. We dominated economically.

Our big firms in particular were very profitable. They didn't have much foreign competition. They could afford to pay for employee healthcare. They could raise prices because nobody was competing with them to keep prices low. That's the trend that you see from World War II to about the 1980s or so. Big firms could set the standard and then small businesses filled in the holes. All competed for labor based on offering attractive 'salary + benefits packages' and all could because the big firms were managing the world economy.

This allowed the U.S. to have an extra cushion of money available for healthcare benefits. Even though people complained, the economy could support the excess premiums. Regulated industries - for political and various other reasons - were able to pass on the cost because our economy was stronger than any other. Unions were strong. They could demand health insurance and the big firms could afford it.

The key factors that fostered employer based health insurance post World War II all changed in the 1980s and 1990s:

<u>World Economy, 1945 – 2000 +/-</u>

Little foreign competition for American manufacturers;

Japan and Western Europe needed time to rebuild;

US manufacturers could keep prices high and afford health benefits

<u>Importance of Large Firms, Regulated Industries and Unions</u>

GM, US Steel, ALCOA, etc – profitable with little foreign competition. Able to share profits with employees as benefits;

Regulated industries (AT&T) – regulated monopolies were able to pass health insurance costs to consumers; they had little or no competition;

Unions were relatively strong, could bargain effectively for benefits

All these conditions changed in the 1980s and 1990s. Our ability to generate excess profits, if you will, to afford for the employers to pay for healthcare starts to disintegrate as foreign competition gets going. From World War II until about 1980 or 1990 we could afford employer based health insurance and there was no significant political group that was lobbying or arguing against it.

Medicare and Medicaid Remove Potential Political Threats to Employer Based Insurance

One major potential political threat to our employer based health insurance system could have come from the unemployed – that significant percent of the population that is too old to work or unable to find full time work with benefits. This is potentially a very potent political force that could have lobbied in favor of single payer healthcare, universal coverage or something like that – like in other countries.

By introducing Medicare and Medicaid in the 1960s, this political force goes away. People are happy. They're not under pressure. They're not demanding universal coverage because they've got coverage. Where are politicians going to find a block of supporters who are going to argue for single payer systems, universal healthcare? They don't exist because Medicare and Medicaid took the potential block off the table.

Here is an estimate of the population size that these two entitlement programs satisfied. I'll use Medicare, because this covers the elderly who vote in particularly high numbers and in particularly important electoral states like Florida. This large voting bloc could have become a potent political force for universal coverage. Instead it became satisfied with Medicare.

Medicare Enrollment 1970 – 2000

Year	Number Medicare Enrollees	% of US population
1970	20 million	10%
1980	28 million	12%
1990	34 million	13.5%
2000	39 million	13.8%

Medicaid covers about the same population size.

The argument is that Medicare and Medicaid are key supporters of our employer based health insurance system. They allowed the system to grow and become entrenched nationally in the second half of the last century.

The employer based system reaches its peak of 165 million people in 2000 and then it starts to decline. Why did it decline? Because the international economic conditions changed. American firms could no longer pass on benefit costs to their customers.

At the same time, the hospital lobbies and related groups had done such a good job of protecting their constituencies that healthcare became hugely expensive. Healthcare grew from about 4% of US GDP in 1950 to 14% in 2000 to about 19% today.

Lower cost alternatives to large general hospitals – freestanding outpatient clinics, for example – never took hold, presumably due to hospital lobbying efforts. Similarly,

specialty hospitals – local diabetes clinics, for example – also failed to establish themselves, again presumably, for the same reasons. The Affordable Care Act, for example, didn't actually prohibit establishment of physician-owned specialty hospitals, but placed such burdensome requirements on their establishment as to destroy this as a potential market force.

By the early 2000s we had developed a perfect storm for healthcare system financial catastrophe. Our healthcare costs – primarily hospitalizations due to the government subsidies of fringe benefits – rose far faster than GDP. Meanwhile, American businesses' abilities to pay for their employee's health coverage diminished in the face of foreign economic competition.

Mandates

As healthcare became increasingly costly, carriers (reflecting employer's interests) tried denying services to patients. This spurred a political reaction, pitting patients and medical provider interests against employers. Perhaps the most impressive display of patient and special interest power presented itself by the growth of healthcare mandates.

The number of state mandated services grew from 7 in 1965 to 1961 in 2008. These reflected the political power of special interests to protect the incomes of their members. Chiropractors lobbied for chiropractic to be included as a benefit in insurance policies. Nurses lobbied for minimum nurse-to-patient ratios. Voters generally supported mandates as protection against insurance carrier abuses.

Mandates raise prices. This increases the need for insurance but makes insurance less affordable, which increases the need for government subsidies (tax breaks and, in some states like Massachusetts, premium supports), which reduces the amount of money available for social programs and 'health promotion and disease prevention' activities (in the words of Richmond and Fein [81]) which in turn medicalizes social problems and raises costs.

But perhaps most disappointing of all, mandates don't improve patient health much. Consider this graph comparing American life expectancies to French and Canadian as we increased the number of healthcare mandates between 1965 and 2010. You can see how our life expectancy rates fell slightly below the trend line of the French and Canadians even as we required more healthcare services for our patients.

Instead, healthcare mandates are political reflections of the economic power of various healthcare groups. They have, apparently, little impact on health. But they ensure that the various medical interest groups get paid.

[81] Richmond and Fein, The Healthcare Mess, page 92

Consumer Driven Healthcare to the rescue (or not)

The first major attempt to adapt employer based healthcare to these new economic realities was CDHC or Consumer Driven Health Care. The term 'consumer driven health care' arose primarily from the Medicare Modernization Act of 2003 which established Health Savings Accounts.

'Consumer driven products' are high deductible health insurance policies with certain tax benefits. Each consumer spends the deductible as he/she sees fit – for physician visits, medications, tests, therapies etc – more or less employing the consumer sovereignty idea we discussed earlier in this chapter. Only after satisfying the deductible does insurance pay. Then, depending on the specific plan design, insurance pays all or part of additional medical expenses.

Problems equating high deductibles with consumerism in healthcare

Unfortunately, CDHC policies as 'consumer sovereignty light' fail in healthcare for two main reasons.

First, an annual $1000 deductible (or even $3000) is too small to act as a real medical spending brake. Once satisfied, and depending on the specific plan design, all other medical care is free.

A patient might satisfy that deductible hurdle in January and then enjoy lots of excessive and unnecessary medical care for free during the next 12 months.

Or the deductible has little impact on a patient facing an expensive procedure. What's the difference to this patient if the procedure costs $45,000 …. $50,000….$60,000 or $100,000? Once the deductible is satisfied, the rest is free. 'Consumerism' fails to affect patient behavior in these expensive cases.

This fundamental flaw in the 'high deductible = consumer driven healthcare' thesis exists because the vast majority of healthcare spending goes to a very small group of high cost patients. Here's spending by percentage of the population. These numbers have remained remarkably constant for the past several years.

Healthcare Consumption by % of Our Population [82]

1% of our population accounts for about 24% of medical spending

5% of our population accounts for about 49% of medical spending

10% of our population accounts for about 64% of medical spending

50% of our population accounts for about 97% of medical spending

[82] Yu, et al, 'Medical Expenditure Panel Survey Statistical Brief #81', May 2005, Agency for Healthcare Research and Quality

So the healthiest 50% of our population accounts for only about 3% of medical spending. These are typically the folks who purchase CDHC products and who often spend less than $1000 annually. Cutting their spending by 20 or 30% would have *virtually no impact* on *overall* medical spending or trend.

Here's the same chart using 2010 spending data. In 2010, total US healthcare costs reached about $2.7 trillion for the approximately 310 million of us. Though the 2010 average annual healthcare spending per person was about $8,700,

The 1% heaviest users (3.1 million people) averaged about $209,000 each;

The 5% heaviest users (15.5 million people) averaged about $85,000 each;

The 10% heaviest users (33 million people) averaged about $52,000 each;

The 50% lightest users (155 million people) averaged about $500 each

Very few of the 10% of users who account for about 2/3 of all medical spending will change their medical choices based on a $1000 (or even $2500 or $5000) deductible. *Whatever* the deductible, their medical care needs far exceed it.

Second, medical consumers have little meaningful quality information, and even if they have it, they rarely know how to use it. This makes medical decisions different from, say, car purchasing decisions. The car buyer can compare the quality of various cars before deciding which to purchase. Large or small, good gas mileage or poor, lots of luxuries or few, high resale value or low, etc.

But the medical purchaser generally has very little similar information. Which doctor has the best outcomes? Which hospital? How effective is this medication compared to that one? We generally lack detailed answers to these questions.

For these two reasons – unequal healthcare spending and lack of medical quality information / well educated medical consumers - so-called Consumer Driven Health Care had only a small impact on medical trend which has run at our gdp growth rate plus 3 – 5% annually for years. CDH policies became the vogue in the early 2000s. They pretty much ran their course within about a dozen years.

Americans continue to spend about twice as much on healthcare as other developed countries without getting any value for the excess spending, just as we did prior to CDHC policy introduction. Here are the estimates for 2019, the last year before Covid hit and altered these statistics with a unique set of circumstances. (I don't know if or how Covid is representative of 'normal' healthcare trends so try to leave that out of this analysis.) [83] I could have included more countries but you get the idea from this limited comparison.

[83] OECD Health Data statistic updated annually https://stats.oecd.org/Index.aspx?ThemeTreeId=9

2019	Annual spending / capita	Life expectancy at birth
US	$10,855	78.8
Canada	$6,730	82.3
France	$4,014	83
Spain	$2,412	84
UK	$3,334	81.4

We clearly haven't figured out how to generate good value for our healthcare system costs.

Three additional problems with having employer based health insurance as the centerpiece of our healthcare financing system

Price structure: Today's health insurance policies are priced at 'employer contribution + employee contribution'. Losing your job may lead to a quadrupling of your health insurance premiums, assuming that your employer pays 75% of the premium.

Labor market distortions: Some employees either choose jobs or remain on their jobs for the health insurance. Two main reasons for this are

- cost – employer contributions reduce employee costs, and
- access – pre-existing conditions traditionally made health insurance unavailable to some people if they changed from their current jobs, though the Affordable Care Act has changed much of this.

One research paper estimated that employer based insurance reduced job mobility by 25 – 40% [84] at least until the ACA impacts work their way through our healthcare system.

Impact on the Federal budget: Tax breaks for employer based health insurance (not income taxable to the employer or employee) constitute the biggest tax break / loophole in the federal budget, an estimated $260 billion annually. [85] This is roughly 3x the mortgage interest tax deduction.

[84] Gruber & Madrian, 'Health Insurance, Labor Supply and Job Mobility' Workng Paper 8817, NBER, March 2002

[85] Health Affairs *Health Policy Brief*, August 1, 2013 'Premium Tax Credits', http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=97

This tax break is regressive: higher income people with expensive policies are subsidized by lower income people with less expensive policies.

Many on Capitol Hill seek to reduce this tax break. Here, for example, is Representative Paul Ryan who ran for Vice President in 2012 with Mitt Romney. The tax deductibility of employer based health premiums

> tilts the compensation scale toward ever-greater (tax free) benefits and away from higher (taxable) wages. This isn't just a big driver of runaway healthcare costs, as more dollars chase the same amount of services. It's also a big reason why too many Americans haven't seen a raise in a long time. [86]

Ryan, among other things, echoes my suggestion that employers pay premiums by withholding wage increases from employees. $1 of benefits is worth more to the employee than $1 of wages since the wages are taxed.

Paul Starr, Princeton Professor of Sociology who normally sits far to the left of Ryan, agrees with him on this point, saying the employer based premium tax exclusion has

> long been the target of criticism on both distributive and allocative grounds: it provides the biggest subsidies to higher income employees with the most generous insurance, and it contributes to America's inflated health spending by obscuring the true costs. Nixon and Clinton considered limiting the exclusion, but each rejected the idea because of political opposition.[87]

Summary: Employer Based Health Insurance

Employer based insurance provides some 160 million Americans with health coverage. But it does so remarkably poorly.

- By setting powerful employer business interest groups against far weaker population health interest groups, it's a key cause of underfunding our various (health related) social services
- The employer based structure harms **employers** by putting an unnecessary (for widget production) economic and administrative burden on them.
- It harms **employees** by reducing their medical care options
- It harms **patients** by locking our system into one focused on short term cost control rather than long term outcome improvement, or, in economic terms, value creation

---

[86] Turner, Capretta, Miller and Moffit, Why ObamaCare is Wrong for America, Forward

[87] Paul Starr, Remedy and Reaction, page 258

- It harms **carriers** by reducing their ability to develop high value products and by forcing them to satisfy employer needs rather than patient, and
- It harms **providers** – doctors and hospitals – by reducing their ability to focus on long term outcomes and treatment excellence, but rather on short term costs, carrier and network referral requirements and associated administrative tasks aimed at reducing moral hazard.

Where will this take our healthcare system? Stanford Business School Professor Alain Enthoven summarizes in prophetic terms. Our employer based model, he suggests, will unfold 'like a Shakespearean tragedy: known, tragic flaws taking their inexorable toll.' [88]

Or, as Lady Macbeth might put it,

> *The employer based healthcare financing system simply doesn't work. Bandaids and piecemeal reforms cannot not fix this fundamentally flawed model.*

(I've admittedly taken some pretty generous poetic liberties here. Lady Macbeth actually said 'Here's the smell of the blood still. All the perfumes of Arabia will not sweeten this little hand'. It's not easy ending a chapter on employer based healthcare financing with a Shakespearean quote!)

[88] Health Affairs, Forum on Employer Sponsored Health Insurance, 2006
http://content.healthaffairs.org/content/25/6/1537.full

Review Questions

Answers on next page

1. This chapter suggested that Moral Hazard is endemic to health insurance. What is moral hazard?

a. People get more care than they need because it appears free to them
b. People with poor moral standards get more care than appropriate because they are greedy
c. There is a close correlation between high morals and low healthcare costs
d. 'Moral hazard' addresses the mind-body relationship. Basically moral people sleep better so remain healthier than lose moral people who more typically suffer from sleep disorders

2. This chapter suggested that disconnecting health insurance payers from healthcare users leads to inefficiencies. What does 'disconnecting health insurance payers from users' mean?

a. Payers are employers but users are employees
b. Payers are generally government entities that pass rules and legislation but users – who must implement those rules – are employers
c. Payers are, in reality, tax payers who fund most healthcare in this country even though employers are the biggest cohort of users
d. Payers are carriers who actually pay doctors and hospitals for their services while 'users' are all the entities that make up the bills, like pharmaceuticals, device manufacturers etc

3. This chapter suggested that having 1 year long health insurance policies leads to systemic inefficiencies. Why?

a. Carriers and providers try to control short term spending to keep renewal increases low, while some 70% of spending goes to patients with chronic diseases that require a long term focus.
b. Renewing annually creates far more paperwork, and therefore costs, than a more efficient system would have
c. Most employers would prefer longer term policies – 10 or even 20 year long policies – so they could plan and cut overhead
d. One year long policies opens the door to expanded lobbying on Capitol Hill from groups that offer the 'newest and greatest' short term health insurance fixes

4. This chapter suggested that having employment as the core of our healthcare financing system leads to underfunding social programs (that often have a major impact on health). Why is that?

a. Many of the social causes of medical problems – poor nutrition or poor housing, for example – are not the employer's financial responsibility. As such,

they are often left out of our health insurance discussion, since carriers and employers focus so intently on the next year's policy renewal price.
b. Social programs, as many studies have shown, have little to no impact on medical care or spending
c. Employers lobby aggressively to cut social spending programs which might, if they worked well, increase the employer's premium costs
d. Employers, brokers and carriers combine to develop fully comprehensive insurance plans. Anything not included in those plans, virtually by definition, is not relevant to promoting good health.

5. Who pays health insurance premiums?

a. The employee by foregoing wages
b. The employer by foregoing profits
c. The government by crediting the premiums equally to the employer and employee
d. Hospitals by undercharging for their service

6. Why do we have healthcare mandates in this country?

a. To improve care quality. Since the introduction of mandates our 30 day readmission rates have fallen almost to zero
b. To improve care outcomes. Since the introduction of mandates, our average longevity at birth has increased by almost 100 years
c. To reduce infant mortality. Since the introduction of mandates, our infant mortality rates have fallen to the lowest in the world
d. To reward lobbying by influential groups like nurses (who lobby for nursing mandates), chiropractors (who lobby for chiropractic mandates), pharmaceuticals (who lobby for pharmaceutical mandates) and similar.

7. Which country exhibits the shortest life expectancy at birth?

a. US
b. France
c. Canada
d. Britain

8. Which country uniquely bases healthcare financing on employment?

a. Britain
b. Canada
c. US
d. France

9. About how much medical care is 'unnecessary' according to scholars at Dartmouth and other research institutions?

a. 1%
b. 30%
c. 90%
d. 95%

10. Who actually pays the employee's premiums in our employer based system?

a. The employer
b. The employee via foregone wages and the government via foregone taxes
c. The insurance carrier
d. The primary care doctor

11. How does our employer based healthcare financing system affect job mobility?

a. It has no impact on job mobility
b. It increases job mobility
c. It reduces job mobility because people may be reluctant to switch insurance types and coverage because the switch may lead to provider and treatment differences
d. It increases job mobility in the public sector but reduces it in the private sector

12. Which is the biggest tax break allowed by the IRS?

a. Employer based healthcare premiums
b. State sales taxes
c. Foreign travel
d. Home office deduction

Review Questions

Correct answers in bold

1. This chapter suggested that Moral Hazard is endemic to health insurance. What is moral hazard?

a. People get more care than they need because it appears free to them
b. People with poor moral standards get more care than appropriate because they are greedy
c. There is a close correlation between high morals and low healthcare costs
d. 'Moral hazard' addresses the mind-body relationship. Basically moral people sleep better so remain healthier than lose moral people who more typically suffer from sleep disorders

2. This chapter suggested that disconnecting health insurance payers from healthcare users leads to inefficiencies. What does 'disconnecting health insurance payers from users' mean?

a. Payers are employers but users are employees
b. Payers are generally government entities that pass rules and legislation but users – who must implement those rules – are employers
c. Payers are, in reality, tax payers who fund most healthcare in this country even though employers are the biggest cohort of users
d. Payers are carriers who actually pay doctors and hospitals for their services while 'users' are all the entities that make up the bills, like pharmaceuticals, device manufacturers etc

3. This chapter suggested that having 1 year long health insurance policies leads to systemic inefficiencies. Why?

a. Carriers and providers try to control short term spending to keep renewal increases low, while some 70% of spending goes to patients with chronic diseases that require a long term focus.
b. Renewing annually creates far more paperwork, and therefore costs, than a more efficient system would have
c. Most employers would prefer longer term policies – 10 or even 20 year long policies – so they could plan and cut overhead
d. One year long policies opens the door to expanded lobbying on Capitol Hill from groups that offer the 'newest and greatest' short term health insurance fixes

4. This chapter suggested that having employment as the core of our healthcare financing system leads to underfunding social programs (that often have a major impact on health). Why is that?

a. Many of the social causes of medical problems – poor nutrition or poor housing, for example – are not the employer's financial responsibility. As

such, they are often left out of our health insurance discussion, since carriers and employers focus so intently on the next year's policy renewal price.

b. Social programs, as many studies have shown, have little to no impact on medical care or spending

c. Employers lobby aggressively to cut social spending programs which might, if they worked well, increase the employer's premium costs

d. Employers, brokers and carriers combine to develop fully comprehensive insurance plans. Anything not included in those plans, virtually by definition, is not relevant to promoting good health.

5. Who pays health insurance premiums?

a. The employee by foregoing wages

b. The employer by foregoing profits

c. The government by crediting the premiums equally to the employer and employee

d. Hospitals by undercharging for their service

6. Why do we have healthcare mandates in this country?

a. To improve care quality. Since the introduction of mandates our 30 day readmission rates have fallen almost to zero

b. To improve care outcomes. Since the introduction of mandates, our average longevity at birth has increased by almost 100 years

c. To reduce infant mortality. Since the introduction of mandates, our infant mortality rates have fallen to the lowest in the world

d. To reward lobbying by influential groups like nurses (who lobby for nursing mandates), chiropractors (who lobby for chiropractic mandates), pharmaceuticals (who lobby for pharmaceutical mandates) and similar.

7. Which country exhibits the shortest life expectancy at birth?

a. **US**

b. France

c. Canada

d. Britain

8. Which country uniquely bases healthcare financing on employment?

a. Britain

b. Canada

c. **US**

d. France

9. About how much medical care is 'unnecessary' according to scholars at Dartmouth and other research institutions?

a. 1%
b**. 30%**
c. 90%
d. 95%

10. Who actually pays the employee's premiums in our employer based system?

a. The employer
b**. The employee via foregone wages and the government via foregone taxes**
c. The insurance carrier
d. The primary care doctor

11. How does our employer based healthcare financing system affect job mobility?

a. It has no impact on job mobility
b. It increases job mobility
c. **It reduces job mobility because people may be reluctant to switch insurance types and coverage because the switch may lead to provider and treatment differences**
d. It increases job mobility in the public sector but reduces it in the private sector

12. Which is the biggest tax break allowed by the IRS?

a**. Employer based healthcare premiums**
b. State sales taxes
c. Foreign travel
d. Home office deduction

Issue 2: Components of a Health Insurance Premium

Health insurance premiums broadly reflect the law of large numbers with premiums, in aggregate, approximately equal to healthcare expenses. As healthcare trends rise, in other words, so do health insurance premiums. We can state this differently: as demand for healthcare rises, i.e. as people need more healthcare services to stay alive, premiums also rise.

Prior to discussing premium components, let's briefly take a more holistic view. We purchase health insurance / healthcare to become healthier. That's both obvious and axiomatic, but that statement assumes medical care will make us healthier. Is that true? How much impact can medical care have on a population's health? In other words, does an extra $100 billion spent on medical care make us healthier than

- $10 billion for cleaner air
- $20 billion for better housing
- $30 billion for nicer public parks and
- $40 billion for better public transportation systems?

Probably not. In fact Bill Frist, former Republican US Senate Majority Leader and a cardiac surgeon claimed

> Health is not health services. Health is behavior, it's genetics, it's socio-economic status, it's disparity, it's environment.
>
> Health services has about a 15 – 20% impact. [89]

Frist's in a good position to know as he addresses the issue from both a public policy and medical professional point of view.

The Massachusetts Health Policy Commission's 2013 Cost Trends Report – consider this just one of dozens of government reports that study the same issues and arrive at the same conclusions – agrees with Frist's assessment, stating

> Research shows that [medical] outcomes are driven largely by social and behavioral factors, along with public health policies, while **health care services delivered account for only 10 percent** of general variation in health status. [90]

[89] CNBC Meeting of the Minds: The Future of Healthcare, broadcast July, 2009

[90] 2013 Cost Trends Report, Massachusetts Health Policy Commission, p 22, direct quote with emphasis added

Academic researchers agree too. Consider the observations by of Harvard Medical School Professors Jules Richmond and Rashi Fein that our phenomenal health gains since World War II

> were largely the consequence of applying our knowledge of health promotion and disease prevention rather than improved clinical care**…**the revolution in biology subsequent to World War II, a revolution that had brought many advances to clinical care, as yet had only marginal effects on improving our vital statistics. [91]

Let's not quibble about medical care's actual percentage impact but agree that it's probably somewhere between Frist's and the Massachusetts Health Policy Commission estimates, probably around 15%. This means other issues – behavior, genetics, socio-economic status, disparity and environment – account for 85% or so of a population's health status.

Our question becomes: knowing that medical care only has a minor impact on good health, why do we substitute expensive healthcare (i.e. health insurance) for less expensive and more effective mechanisms to achieve good health?

Understanding *Demand* for Healthcare

In broad terms, demand for medical services comes from two sources: population age and population health. Let's look at population aging briefly first, then focus on the far more interesting issue of population health.

The US population median age has increased annually from 28 in 1970 to 38.1 in 2019. As we age, we cost more medically. One estimate broke this down by age group using 2004 data. [92] Consider the spending *ratios* in the chart below rather than *exact costs.*

These ratios remain approximately the same over time even as healthcare costs rise per capita.

[91] Richmond and Fein, The Healthcare Mess, pages 94 and 92

[92] "U.S. Health Spending By Age, Selected Years Through 2004." By Micah Hartman and others. *Health Affairs*, November 2007.

Age Group	Annual Spending / capita	% of average
0 – 18	$2,650	50%
19 - 44	$3,370	64%
45 - 54	$5,210	99%
55 - 64	$7,787	147%
65 - 74	$10,778	204%
75 - 84	$16,389	310%
85+	$25,691	487%
Average	$5,276	

Though demographers can extend this analysis in several interesting ways, I propose simply to accept that we, as an aging population, will spend more money on healthcare over time annually simply because our population ages, though we can discuss the efficiency and effectiveness of that medical spending, which I do elsewhere in this book.

I want to focus instead on our population's health, primarily obesity and physical fitness and discuss some government programs affecting these. While we can't do much to affect aging (except extend it) but we can do quite a bit to affect population health.

Consider these data:

- Average daily caloric consumption per American grew from 2200 in the 1970s to about 2700 in the early 2000s [93] - and to 3600 in 2017.[94]

[93] See the USDA's Agriculture Fact Book, Chapter 2 'Profiling Food Consumption in America' for example http://www.usda.gov/factbook/chapter2.pdf. See also the USDA's Dietary Guidelines for Americans, published and updated about every 5 years

[94] Several articles refer to a Business Insider study that suggested 3600 calories per day. I've seem lots of references to this study but can't find the actual study online. Seems both a squishy and reasonable estimate though.

- The greatest caloric gains came from fats, oils, milk and milk byproducts and sweeteners. [95]
- Some 42% of Americans are obese according to a 2017 CDC study.
- Only about 48% of American adults meet the 2008 Physical Activity Guidelines of 150 minutes of moderate exercise per week. Inactive adults have a higher risk for early death, heart disease, stroke, type 2 diabetes, depression, and some cancers. [96]
- Adults with more education are more likely to meet the 2008 Physical Activity Guideline for aerobic activity than adults with less education. [97]
- Adults whose family income is above the poverty level are more likely to meet the 2008 Physical Activity Guideline for aerobic activity than adults whose family income is at or near the poverty level. [98]

Obesity, caused largely by dietary and exercise behaviors, increases healthcare costs. Here are some examples courtesy of US government researchers: [99]

- 81 million Americans suffer from cardiovascular disease. Major risk factors include high levels of blood cholesterol and other lipids, type 2 diabetes, hypertension (high blood pressure), metabolic syndrome, overweight and obesity, physical inactivity, and tobacco use.

  Cardiovascular disease treatment costs about $300 billion annually or 7% of all healthcare spending.

- Approximately 116 million Americans—about 1 out of every 2 adults — suffer from hypertension.[100] Hypertension is a major risk factor for heart disease, stroke, congestive heart failure, and kidney disease. Dietary factors that increase

---

[95] Dietary Guidelines for Americans 2010, US Department of Agriculture and US Department of Health and Human Services, page 11
http://www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf

[96] See the CDC's webpage Facts about Physical Activity
http://www.cdc.gov/physicalactivity/data/facts.html . The 2008 Physical Activity Guidelines for Americans articulates the types of physical activities recommended along with suggested weekly time for each.
http://www.health.gov/paguidelines/pdf/paguide.pdf

[97] http://www.cdc.gov/physicalactivity/data/facts.html

[98] http://www.cdc.gov/physicalactivity/data/facts.html

[99] Dietary Guidelines for Americans, op cit. page 3

[100] Estimated Hypertension Prevalence, Treatment and Control Among US Adults,
https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html#:~:text=Nearly%201%20out%20of%202,modifications%20only%20(24.3%20million).

blood pressure include excessive sodium and insufficient potassium intake, overweight and obesity, and excess alcohol consumption.

- 37 million Americans suffer from diabetes. That number has doubled in the past 20 years. The majority are type 2 diabetics, which is heavily influenced by diet and physical activity.

  Diabetes cost estimates vary from $250 billion annually - about 5% of our healthcare spending – to up to 25% of all healthcare spending if we include related treatments.[101]

Let's state this differently: obesity raises healthcare costs about as much as does 20 years of aging, according to one estimate.[102] An obese 40 year old, in other words, costs medically about the same as a healthy weight 60 year old. Remember that as we age, we require more medical care. Here the aging and obesity trends converge: we have both an aging population and an increasingly obese one.

According to a 2021 study, obesity increases medical treatment costs, on average, by $2500 per person as compared to a normal weight person, with costs increasing according to the degree of obesity.[103]

> The effects of obesity raised costs in every category of care: inpatient, outpatient, and prescription drugs….In 2016, the aggregate medical cost due to obesity among adults in the United States was $260.6 billion.

The OECD expands on obesity's impact:

> The lifespan of an obese person is up to 8-10 years shorter (for a BMI of 40-45) than that of a normal-weight person, mirroring the loss of life expectancy suffered by smokers. [104]

Obesity, some studies suggest, is contagious with its spread patterns mimicking infectious diseases. In one particular study researchers found that

> a person's risk of becoming obese was 2% per year, **but the risk rose another 2% for every five obese social contacts they had**. [105]

---

[101] American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018;41:917–928.)

[102] Strum 'The Effects of Obesity, Smoking and Drinking' Health Affairs, March 2002

[103]

[104] Obesity and the Economics of Prevention, Fit not Fat, © OECD 2010
From Executive Summary

[105] Hill, et al, Infectious disease modeling, PLOS Computational Biology, November 4, 2010, emphasis added

Bill Walczak, Executive Director of Boston's Codman Square Health Center put this in lay terms:

> In lower-income communities, there is an expectation that when you get older, your hair gets gray and you get diabetes, because it's so common. [106]

Metabolic Syndrome, a step toward diabetes

Metabolic Syndrome was initially conceptualized in the late 1990s to describe a common, though not universal, road to diabetes. It afflicts some 47 million Americans, about 1 in 6 of us.[107] Syndrome sufferers aren't actually sick and don't actually have diabetes but they're getting close. MS describes a combination of indicators – high blood pressure, high blood sugar, unhealthy cholesterol, abdominal fat, high body mass index - that together act as a wake up call to patients. People don't need all these factors to get labelled with MS, but the closer the fit, the louder the warning.

MS sufferers are about 4x more likely to develop diabetes than the population in general, 3x more likely to have a heart attack and 50% more likely to develop kidney disease.[108] It also increases people's risk of developing coronary heart disease, having heart failure, having more complications from infections like Covid and suffering organ damage, especially pancreas, liver, gall bladder and kidney.[109]

We can use the American Heart Association guidelines to define Metabolic Syndrome by indicator. Again, remember, that these simply suggest that one's health is moving in the wrong direction; these indicators do not define someone as sick…just at increased risk. Many commentators suggest that the Metabolic Syndrome label applies to people with 3 or more of these characteristics:

- Body Mass Index > 30
- Blood Pressure < 140/90 or 150/90 for people over 60 years old * [110]
- Total Cholesterol < 200
- Triglycerides < 200
- HDL (good cholesterol) > 45
- LDL (bad cholesterol) < 130
- Total Cholesterol / HDL should be < 4.9

---

[106] Quoted in Boston Globe, November 8, 2010, page G6

[107] WebMD, good summary article https://www.webmd.com/heart/metabolic-syndrome/metabolic-syndrome-what-is-it

[108] Ibid.

[109] National Heart, Lung and Blood Institute https://www.nhlbi.nih.gov/health/metabolic-syndrome/living-with

[110] Several organizations suggest and alter their blood pressure guidelines. These are estimates. Consult your own physician to discuss your own situation.

- A1C < 5.7
- Heart Rate between 60 – 100

Again, there's no hard and firm definition at work here; more a set of indicators that together paint a picture.

Metabolic Syndrome prevalence increases with age afflicting almost 50% of 60+ year olds in this country and 60% of elderly Hispanics. The standard treatment is diet and exercise, together designed to return you to good health.

In round numbers, therefore, Americans increasingly suffer from at least 2 obesity related syndromes: Metabolic Syndrome and diabetes. We know this and have known the health and treatment costs for years.

Why, despite all this knowledge, are we so obese? Why does it affect low income people disproportionally? What happened since the 1970s to cause all this?

The Corn Story

Our domestic corn productivity grew dramatically, from about 72 bushels per acre in 1970 to 177 bushels in 2020 with the acreage up slightly over time. [111] This expansion is stimulated, many suggest, by our federal food production subsidies that averaged $30 billion annually from 2018 – 2020.[112] By some estimates, corn subsidies totaled more than $116 billion from 1995 – 2020.

Our total corn production generated 15 billion bushels in 2020. [113]

About 55% of this corn becomes animal feed and 5% sweetener, sometimes called high fructose corn sweetener, sometimes corn sweetener, sometimes corn sugar and even sometimes just 'sugar'.

Corn, as Michael Pollan has eloquently written, is

> what feeds the steer that becomes the steak. Corn feeds the chicken and the pig, the turkey and the lamb, the catfish and the tilapia and, increasingly, even the salmon, a carnivore by nature that the fish farmers are reengineering to tolerate corn. The eggs are made of corn. The milk and cheese and yogurt, which once

[111] Corn and soybean production up in 2021, USDA Reports, https://www.nass.usda.gov/Newsroom/2022/01-12-2022.php#:~:text=U.S.%20corn%20growers%20produced%2015.1,is%20up%204%25%20from%202020

[112] EWG Analysis https://www.ewg.org/news-insights/news-release/2022/06/ewg-analysis-2018-2020-farmers-reaped-916b-taxpayer-funded-usda

[113] Corn and soybean production up in 2021, USDA Reports, https://www.nass.usda.gov/Newsroom/2022/01-12-2022.php#:~:text=U.S.%20corn%20growers%20produced%2015.1,is%20up%204%25%20from%202020.

came from dairy cows that grazed on grass, now typically come from Holsteins that spend their working lives indoors tethered to machines, eating corn.

To wash down your chicken nuggets with any soft drink in the supermarket is to have some corn with your corn…after water, corn syrup is the principle ingredient. Grab a beer for your beverage and you'd still be drinking corn in the form of alcohol-fermented glucose refined from corn.

Corn is in the coffee whitener and Cheez Whiz, the frozen yogurt and TV dinner, the canned fruit and ketchup and candies, the soups and snacks and cake mixes, the frosting and gravy and frozen waffles, the syrups and hot sauces, the mayonnaise and mustard, the hot dogs and bologna, the margarine and shortening, the salad dressing and relishes and even the vitamins. [114]

Each American, on average, consumes over **half a ton** of food that uses corn as an ingredient. Here's the breakdown: [115]

- Total average annual food consumption average: 1994 lbs / person consisting of
    - **630** lbs of milk, yogurt, cheese, ice cream **(corn based as cow feed)**
    - **415** lbs of vegetables, mainly potatoes and **corn**
    - **264** lbs of meat and poultry [116] **(corn based as animal feed)**
    - 197 lbs of grains
    - 273 lbs of fruit, mainly water weight
    - 141 lbs of sweetener, including **42** lbs of **corn syrup**
    - **85** lbs of fat, butter & oil **(fat & butter from corn + corn oil)**

"When you look at the isotope ratios," in American's hair and skin according to Todd Dawson, a Berkeley biologist who's done this sort of research, "we North Americans look like corn chips with legs." [117]

One result of the corn subsidies / cheap and easy availability of corn for livestock feed, is that we eat about 40% more meat, on average per person per year, than western

[114] Michael Pollan, The Omnivores Dilemma, page 18

[115] From National Public Radio's report on food consumption by correspondent Allison Aubrey, December 31, 2011

[116] Estimate from Chartbins.com

[117] Paraphrased from Pollan, Ominvores Dilemma, page 18

Europeans [118] - about ¾ pound of meat per person per day. That's about 2.5 times the government recommendation of 1/3 pound of meat *and beans*. [119]

The US government actually recommends against eating that much meat. Here are recommendations from the US Department of Agriculture's Dietary Guidelines for Americans: [120]

Food Groups to Encourage

- Fruit
- Vegetables
- Whole Grains

Food Groups Discouraged in Large Quantities

- Meat
- Sugar

Note the advice / subsidy discrepancy. We encourage but don't subsidize fruit and vegetables. We subsidize but don't encourage meat and sugar. Money in the form of subsidies, seems to speak louder than words in the form of recommendations.

How subsidized corn affects food prices in supermarkets

I did some detective work in 2010 and 2012 at my local Shaw's grocery store in Easton, Massachusetts. Shaw's is a typical mid-market American supermarket with some 135 stores throughout New England. It's not upscale like Whole Foods nor a budget operation like PriceRite. Shaw's prices are roughly comparable to other large chain grocery stores I've visited in my travels.

In both 2010 and 2012, I determined prices per calorie of various foods by dividing the package cost by number of servings, then by calories per serving. For fruits and vegetables, I found average calories per piece or per pound online then determined the price per piece or pound at Shaw's. (I'm not sure the local branch manager was pleased with my detective work but, as I recall, I forgot to ask permission.)

The graphs I plotted for food costs/calorie were very similar both years. I'll reproduce the October 21, 2012 results below.

---

[118] The raw data comes from Chartbins.com. France, Italy, Germany, Britain and Switzerland average about 187 pounds of meat per person per year. We consume about 264.

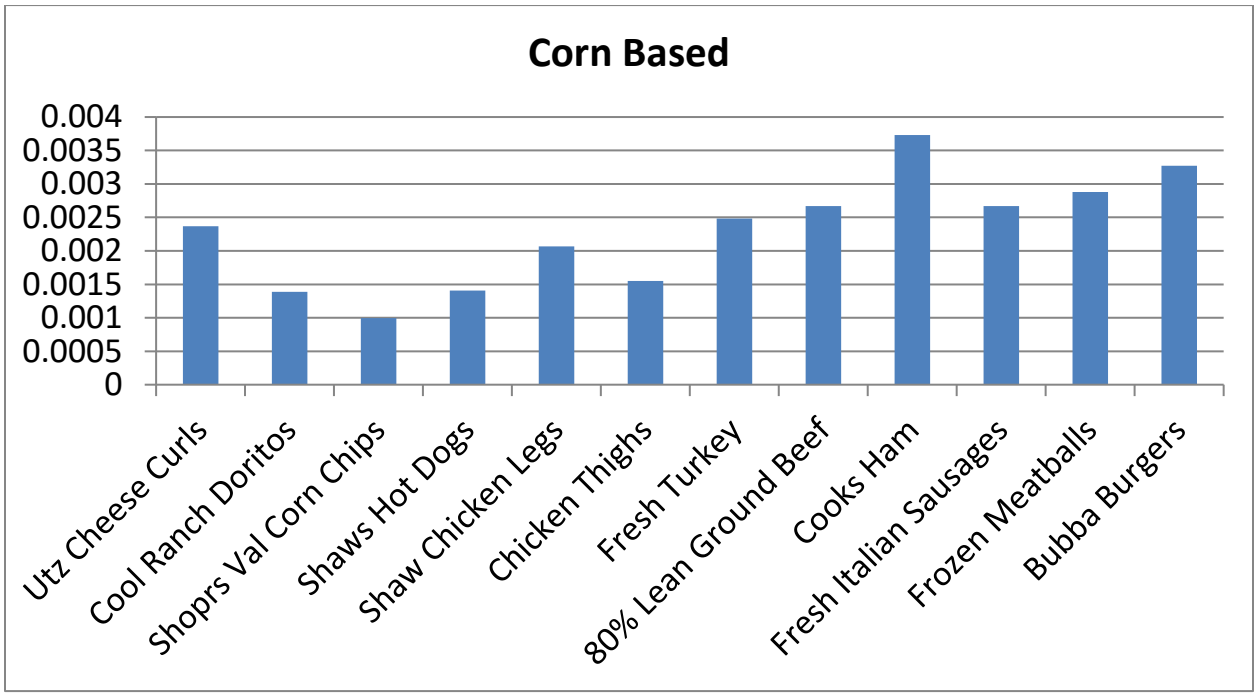
[119] See the USDA Dietary Guidelines for Americans, 2005 edition. They Guidelines are basically the same every iteration, and are the same as other country's guidelines.

[120] I refer specifically to the 2005 recommendations because they're so clearly stated. Recommendations from other years say pretty much the same things.

My goal in all this: determine how much it costs to purchase 2700 calories of corn-based products and compare that to 2700 calories of non-corn based. I wanted to see the impact of the corn subsidy on actual daily, monthly and annual food costs for an average American.

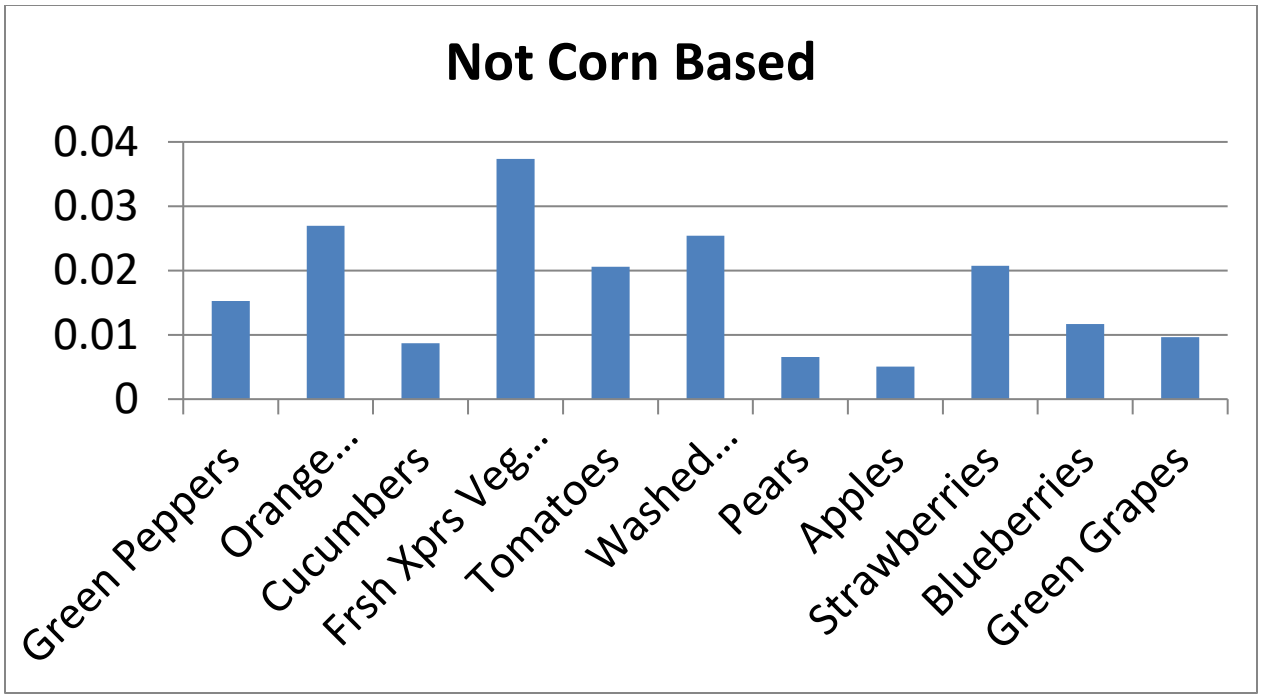
I used the relatively conservative 2700 calories / person / day, not the higher 3600 calorie estimate. My calculations below would be 33% higher using the 3600 calorie / day figure.

The first chart shows the cost/calorie of corn based foods like cheese doodles, Shoppers Value Corn Chips, Shaw's brand hot dogs and chicken legs, 80% lean ground beef, fresh Italian sausages and frozen meatballs.



As you can see, these foods cost about 2 tenths of 1 cent per calorie.

The second chart shows costs of some non-corn based foods like green and orange peppers, Fresh Express salad bags, washed green beans, tomatoes and apples – the foods encouraged by the US Department of Agriculture.



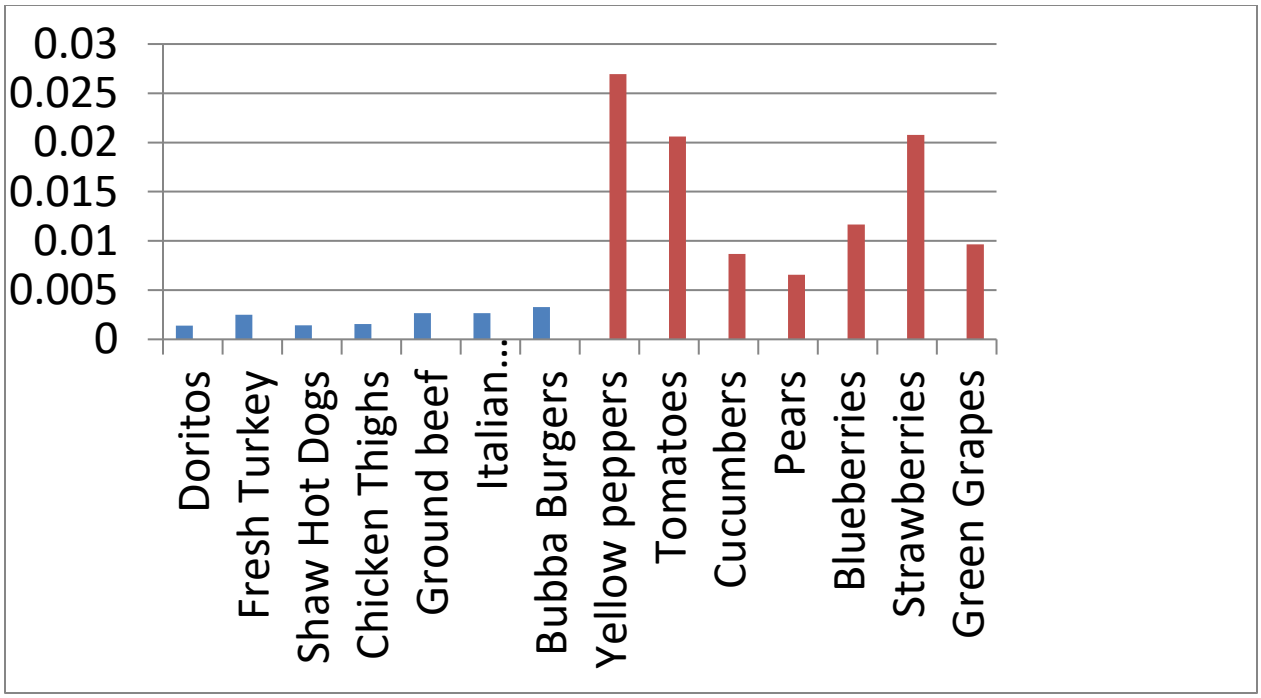
These foods average about 1 cent per calorie.

Let's assume you're a cash-strapped, low income person, trying to feed your family. You need to purchase 2700 calories of food per day to satisfy them, so when you buy the non-corn based 'healthier' foods, you choose the cheapest like apples and pears, costing about half a cent per calorie. Orange peppers, Fresh Express salad bags and strawberries become luxuries.

The difference between the *average* cost of corn-based foods and the *lowest* cost non-corn based is about 1/3 of a cent. (I'm intentionally underpricing the healthier foods to minimize the food cost differences people face; I want to understate the case here, not overstate it.)

Multiply that 1/3 of a cent times 2700 calories and you'll see that the cost of eating better runs about $9/person/day. That's not the cost of *eating*, but of eating *better*. People who eat orange peppers, bags of salad, tomatoes and strawberries see a bigger cost difference.

Here's a comparison chart showing corn based (subsidized through the corn subsidy) foods on the left in blue, and non-corn based / non-subsidized on the right in red.



At the $9 per day premium for eating better, our average American needs to spend $3000 annually to eat better.

The average household of 2.5 people spends about $7500 annually and a family of 4 about $12,000.

Remember, again, that's not the cost of *eating* but of *eating better* due to the corn subsidy, the centrality of corn in our food production system and lack of subsidies for many fruits and vegetables.

Let's correlate this to saturated fat and cholesterol, both discouraged by the US Department of Agriculture's Dietary Guidelines:

- All animal based foods – low cost these days, thanks in part to the corn subsidy - contain fat and cholesterol
- Cheese consumption – high in fat and cholesterol – has tripled since the 1970s.

  Perhaps as a result, Americans combine cheese and meat far more frequently than do people in other countries. See the popularity of Philly Cheese Steak sandwiches, cheese burgers, ham and cheese sandwiches and Egg McMuffins (a delicious combination of corn based eggs, ham and cheese).

  One BBC TV show, Top Gear, aired an amusing Q & A (sorry, I don't remember which episode. I normally watch it late at night) asking How to be an American: 'wear cowboy boots and put cheese on everything'. I guess that's how we're perceived internationally. Perhaps with good reason.

- No plants contain animal fat or cholesterol. This led Deepek Chopra and 3 other academic physicians to write in the Wall Street Journal [121]

  The disease that accounts for more premature deaths and costs Americans more than any other illness is almost completely preventable simply by changing diet and lifestyle.

But changing diet and lifestyle may be cost prohibitive for a large section of our population. Indeed, the Economist analyzed American food prices and concluded

> Americans, increasingly, cannot afford to eat a balanced diet [because] … Over the last four years, the price of the healthiest foods has increased at around twice the rate of energy-dense junk food. [122]

Let's switch now from discussing the 55% of corn that becomes animal feed to the 5% that becomes sweetener.

High Fructose Corn Sweetener and other corn byproducts

As our corn productivity increased in the 1980s and 90s, corn byproducts replaced sugar in breads, cereals, yogurts, soups, lunch meats and other products since corn was so cheap.

- HFCS consumption 1970s was about 26 pounds per person per year
- HFCS consumption 2000: 85 pounds per person [123]

Corn subsidies leading to less expensive corn sweeteners saved Coke and Pepsi about $100 million annually over the past 20 years according to studies from Tufts University researchers. [124] Soda consumption has doubled since the 1970s to about 50 gallons per person per year. [125]

Michael Pollan summarized this nicely in the New York Times: [126]

---

[121] Chopra et al, Alternative Medicine is Mainstream, Wall Street Journal, January 9, 2009

[122] *Economist* 7/9/11, If you build it, they may not come

[123] USDA agricultural fact book

[124] Harvie and Wise, Sweetening the Pot: Implicit subsidies to corn sweeteners and the US obesity epidemic, http://www.ase.tufts.edu/gdae/Pubs/rp/PB09-01SweeteningPotFeb09.pdf

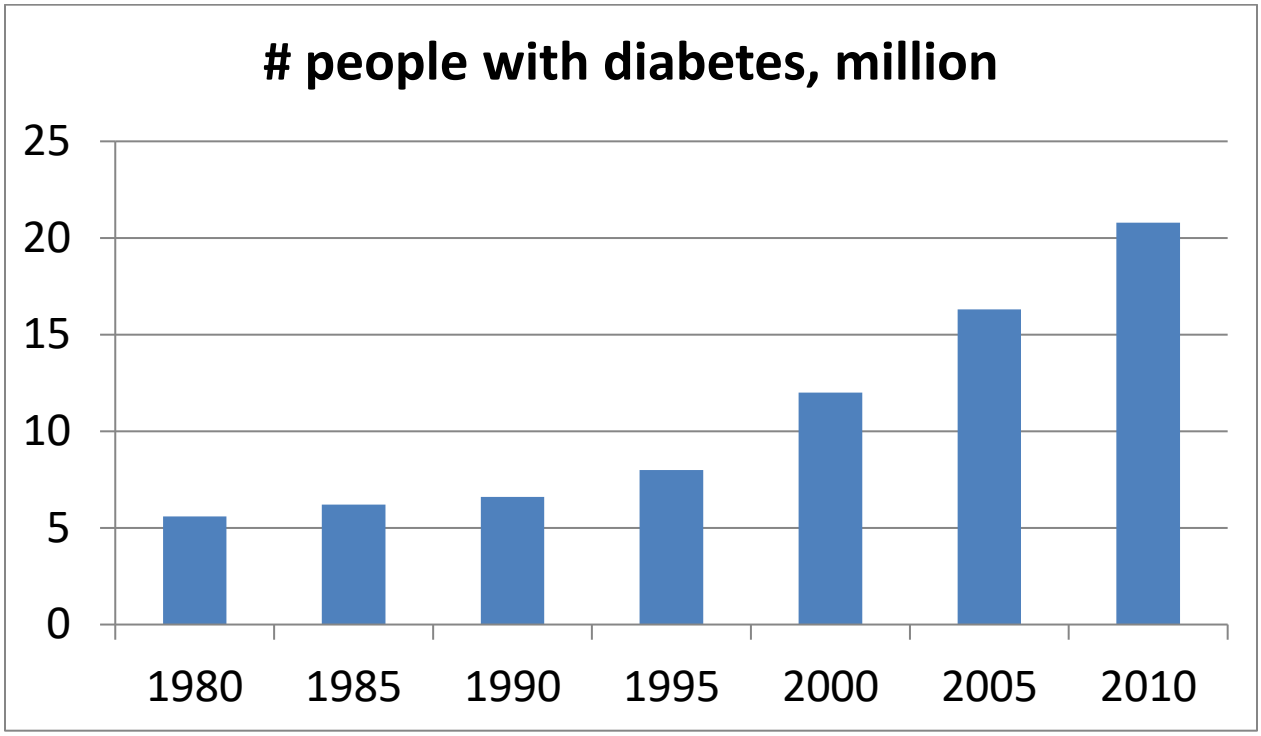
[125] Duffrey, Food Price and Diet, Archives of Internal Medicine, March 2010

[126] Pollan, When a crop becomes king, NY Times, July 19, 2002

Nearly 10% of all the calories Americans consume now come from corn sweeteners; the figure is 20% for many children [because sweeteners are in *everything*]…

Sweetness became so cheap that soft drink makers, rather than lower their prices, super-sized their serving portions and marketing budgets.

It's probably no coincidence that the wholesale switch to corn sweeteners in the 1980s marked the beginning of the epidemic of obesity and Type 2 diabetes in this country.



The rational response?
Eat fast food!

Economically, if you had just $5 to maximize your calories, that's certainly a way to do it, according to Dr. Lauren Smith, Medical Director of the Massachusetts Department of Public Health. [127]

Consider these data points about Massachusetts as one sample state:

- Average Massachusetts household income: about $67,000
- Average Massachusetts household size: about 2.5 people

[127] Boston Globe on September 9, 2010.

At 20% of income for food (my estimate) the average person in Massachusetts has about $15 to spend on food daily. What meal can you buy for $5?

The KFC $5 Fill Up, 3 Piece Tenders! You get a whopping 1120 calories, 95 grams of sugar and 18 grams of saturated fat. Here's the nutritional information, downloaded from the KFS website in December of 2014 with notes about the corn bases:

	Sugars (grams)	Calories	Saturated Fat (grams)	Sodium (mg)
3 Chicken Tenders (corn fed)	0	380	2.5	940
Mashed potatoes & gravy (corn sugar)	3	120	6	530
Flaky biscuit (corn butter)	2	180	6	530
20 oz Mountain Dew (corn sugar)	75	280	0	130
Choc Chip Cookie (corn sugar, butter)	15	160	3.5	90
Totals:	**95**	**1120**	**18**	**2220**
US Daily Recommendation	**25**	**2000**	**11 – 13**	**2300**

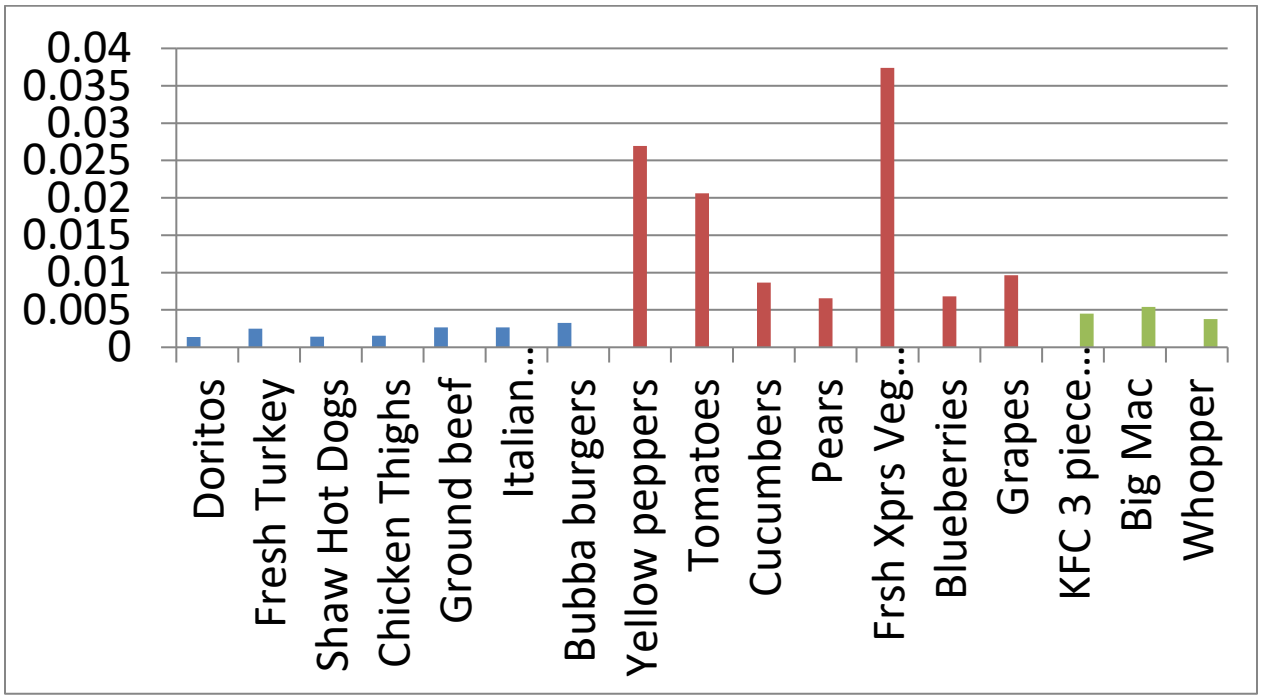
Or perhaps you prefer Taco Bell. Their $2 Beefy 5-Layer Burrito Value Meal with Mountain Dew and Nacho Cheese Doritos consists of

- chips (corn, subsidized)
- beef (corn based, subsidized)
- cheese (corn based, subsidized)
- tortilla (corn, subsidized)
- soda (HFCS, subsidized)

For $2, you get 1020 calories, 35 grams of fat, 66 grams of sugar and 2000 grams of sodium.[128]

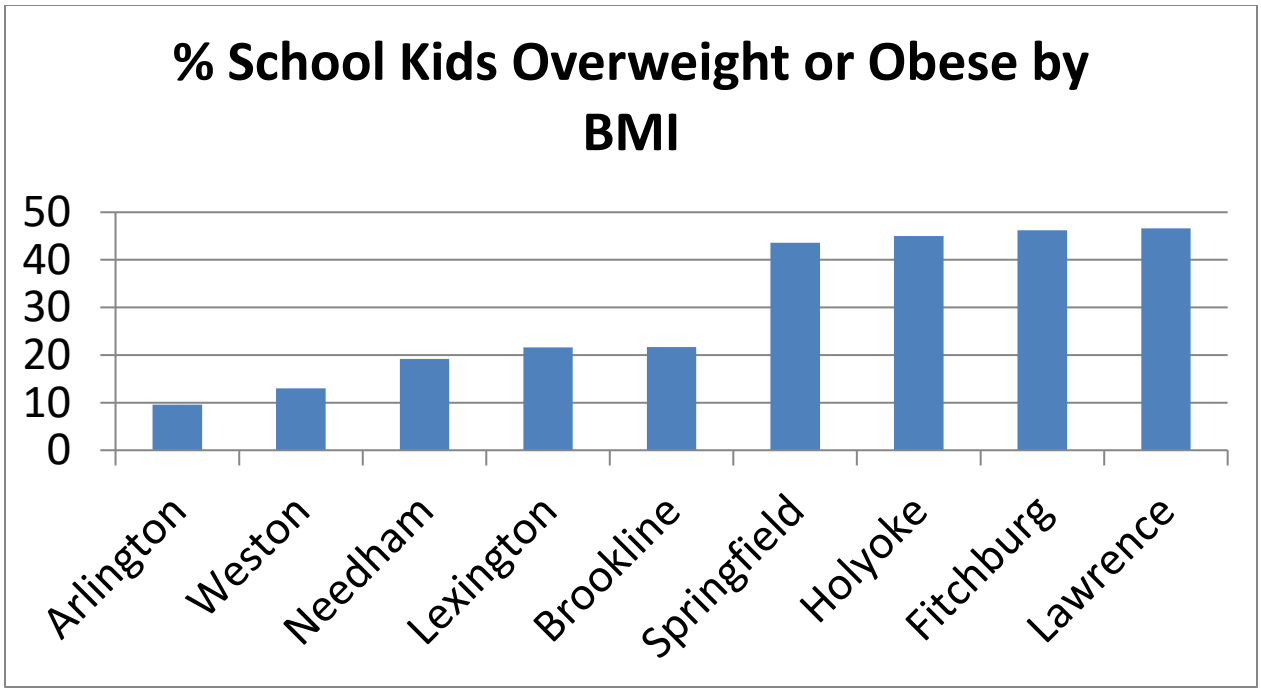
[128] Information downloaded from Taco Bell's website in 2010 or 2011 according to my notes. It was apparently not offered in 2015 when I wrote this chapter.

Let's see how fast food compares on a cost/calorie basis to food at Shaw's supermarket.



I think we're beginning to see where the obesity epidemic comes from and why it affects lower income people the most. But the proof, as they say, is in the pudding.

The Boston Globe reported, in September of 2010, rates of overweight or obese school children by town. This dramatically demonstrates the problem: Springfield, Holyoke, Fitchburg and Lawrence are among the poorest towns in Massachusetts while Needham, Lexington and Weston are among the richest.



Dietary Guidelines for Americans, 2015
Scientific Report published February 19, 2015

The US Dietary Guidelines Advisory Committee, established jointly by the US Departments of Agriculture and Health and Human Services, publishes nutritional guidelines every 5 years. Their 2015 Scientific Report summarizes our national nutritional, obesity and related medical problems. (The 2020 – 2025 guidelines say pretty much the same thing but I found the 2015 presentation more impactful and compelling. The data haven't changed much except to get worse.)

- About half of American adults have one or more chronic diseases and
- About 2/3 of American adults are overweight or obese.

Both of these situations are preventable with 'poor dietary patterns, overconsumption of calories, and physical inactivity directly contributing to these disorders'.

I'll summarize some key points below, generally as direct quotes with minor grammatical modifications: [129]

- the majority of the U.S. population has low intakes of key food groups that are important sources of nutrients, including vegetables, fruits, whole grains, and

[129] From the Executive Summary of http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf

dairy. Furthermore, population intake is too high for refined grains and added sugars.

- no matter where food is obtained, the diet quality of the U.S. population does not meet recommendations for vegetables, fruit, dairy, or whole grains, and exceeds recommendations, leading to overconsumption, for the nutrients sodium and saturated fat and the food components refined grains, solid fats, and added sugars.
- a healthy dietary pattern is higher in vegetables, fruits, whole grains, low- or non-fat dairy, seafood, legumes, and nuts; moderate in alcohol (among adults); lower in red and processed meat; and low in sugar- sweetened foods and drinks and refined grains.
- individual nutrition and physical activity behaviors and other health-related lifestyle behaviors are strongly influenced by personal, social, organizational, and environmental contexts and systems [like socio-economic status, geographic proximity to fresh food and access to safe exercise areas. See below, the discussion of the Whitehall studies, for more on this.]

The Committee wrote in their cover letter to the Secretaries of Health and Human Services and of Agriculture:

> The dietary patterns of the American public are suboptimal and are causally related to poor individual and population health and higher chronic disease rates. Unfortunately, few improvements in consumer food choices have occurred in recent decades. On average, the US diet is low in vegetables, fruit and whole grains and too high in calories, saturated fat, sodium, refined grains and added sugars….
>
> More than two-thirds of adults and nearly one-third of children and youth are overweight or obese. These devastating health problems have persisted for decades, strained US healthcare costs, and focused the attention of our healthcare system on disease treatments rather than prevention. They call for bold action and sound, innovative solutions.

The 2020 – 2025 Dietary Guidelines for Americans ‘Make Every Bite Count’ note that Americans have fallen far short of meeting the dietary gudieline recommendations, and diet-related chronic disease rates have risen to pervasive levels and continue to be a major public health concern. Today about 74% of Americans are overweight or obese with slightly over 40% of adults over age 40 being obese. Among other problems, this normalizes obesity; people say ‘I’m not that fat, look at her’ in some sort of psychological attempt to make themselves feel better. Normalizing obesity is unhealthy!

Obesity, Diabetes and Metabolic Syndrome

Obesity can – 'tends to' in academic parlance – lead to diabetes. The Cleveland Clinic estimates that obese people are about 6x more likely to develop type 2 diabetes than normal weight people.[130] The process, as explained by the Cleveland Clinic in its November, 2021 article 'Diabesity: How Obesity is Related to Diabetes, slightly edited here':

- The pancreas creates insulin, which is a hormone that moves glucose out of your blood. Normally, insulin transports glucose to your muscles to use right away for energy or to the liver, where it's stored for later.
- But when you have diabesity, your cells resist letting insulin move glucose into them. To make matters worse, the area of your liver where excess glucose is usually stored is filled with fat. It's like trying to put furniture in a room that's already packed; there's no more room.
- With nowhere to be stored, the glucose remains in the bloodstream, making your pancreas create even more insulin to accomplish that job of moving glucose out of the blood. The pancreas then becomes overworked and starts to produce less insulin. Diabetes results and gets worse if the fat resistance remains.

Diabetes comes in 3 forms: Type 1, probably genetic, is an autoimmune disorder typically identified in kids, represents about 5% of America's diabetic population. This condition has no cure but can be treated with insulin for life.

Gestational diabetes develops in pregnant women, increases risk the baby will develop diabetes, usually goes away after birth but may lead to Type 2 later in life.

Type 2 diabetes, representing about 95% of American diabetics, occurs when the body doesn't use insulin well, can't regulate sugar in the bloodstream. From here on, we'll use 'diabetic' or 'diabetes' to refer to type 2 diabetes. That has, by far, the greatest impact on our healthcare and health insurance systems. Most researchers argue that type 2 diabetes is entirely or largely behaviorally based, closely tied to obesity

In fact, the Cleveland Clinic has invented a new word to describe that link: diabesity, meaning someone is both obese and diabetic. Diabesity 'greatly' – their word – increases your risk of heart disease, the leading cause of death in this country, and make diabetes worsen faster.

Today some 37 million Americans have diabetes and about 88 million have 'prediabetes'. More on that later. Diabetes is the 7th leading cause of death in this country and the #1 cause of kidney failure, lower limb amputation and blindness. The number of US diabetics has doubled in the past 20 years.

No one knows exactly how much we spend annually to treat diabetes. The low estimate from my own research for direct costs plus lost productivity runs around $500 billion or

[130] Diabesity: How Obesity is Related to Diabetes, November 8, 2021, Cleveland Clinic Health Essentials

roughly 14% of healthcare spending. That's based on a 2017 CDC estimate of $327 billion, updated to 2022 dollars.[131] The high estimate is about 25% of all US healthcare spending, going to diabetes treatment and related expenses. That's from an American Diabetes Association 2018 report.[132] I don't know the exact answer and doubt that anyone else does but the exact number doesn't matter greatly as the message is clear: diabetes treatment is expensive!

Many medical research and treatment organizations list the key risk factors for developing diabetes. We'll use here the Mayo Clinic's version as an example. [133] You can find similar information presented by, literally, dozens of other researchers.

The main risk factors for developing Type 2 Diabetes according to MayoClinic.com:

- Weight. Being overweight or obese is a main risk.
- Fat distribution. Storing fat mainly in your abdomen — rather than your hips and thighs — indicates a greater risk. Your risk of type 2 diabetes rises if you're a man with a waist circumference above 40 inches (101.6 centimeters) or a woman with a measurement above 35 inches (88.9 centimeters).
- Inactivity. The less active you are, the greater your risk. Physical activity helps control your weight, uses up glucose as energy and makes your cells more sensitive to insulin.
- Family history. The risk of type 2 diabetes increases if your parent or sibling has type 2 diabetes.
- Race and ethnicity. Although it's unclear why, people of certain races and ethnicities — including Black, Hispanic, Native American and Asian people, and Pacific Islanders — are more likely to develop type 2 diabetes than white people are.
- Blood lipid levels. An increased risk is associated with low levels of high-density lipoprotein (HDL) cholesterol — the "good" cholesterol — and high levels of triglycerides.
- Age. The risk of type 2 diabetes increases as you get older, especially after age 45.
- Prediabetes. Prediabetes is a condition in which your blood sugar level is higher than normal, but not high enough to be classified as diabetes. Left untreated, prediabetes often progresses to type 2 diabetes.
- Pregnancy-related risks. Your risk of developing type 2 diabetes increases if you developed gestational diabetes when you were pregnant or if you gave birth to a baby weighing more than 9 pounds (4 kilograms).

---

[131] Cost Effectiveness of Diabetes Interventions, National Center for Chronic Disease Prevention and Health Promotion, undated web page

[132] American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018;41:917–928.)

[133] https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193

- Polycystic ovary syndrome. Having polycystic ovary syndrome — a common condition characterized by irregular menstrual periods, excess hair growth and obesity — increases the risk of diabetes

All these risk factors combined lead to these potential comorbidities and complications, again from MayoClinic.com:

- Heart and blood vessel disease. Diabetes is associated with an increased risk of heart disease, stroke, high blood pressure and narrowing of blood vessels (atherosclerosis).
- Nerve damage (neuropathy) in limbs. High blood sugar over time can damage or destroy nerves, resulting in tingling, numbness, burning, pain or eventual loss of feeling that usually begins at the tips of the toes or fingers and gradually spreads upward.
- Other nerve damage. Damage to nerves of the heart can contribute to irregular heart rhythms. Nerve damage in the digestive system can cause problems with nausea, vomiting, diarrhea or constipation. For men, nerve damage may cause erectile dysfunction.
- Kidney disease. Diabetes may lead to chronic kidney disease or irreversible end-stage kidney disease, which may require dialysis or a kidney transplant.
- Eye damage. Diabetes increases the risk of serious eye diseases, such as cataracts and glaucoma, and may damage the blood vessels of the retina, potentially leading to blindness.
- Skin conditions. Diabetes may leave you more susceptible to skin problems, including bacterial and fungal infections.
- Slow healing. Left untreated, cuts and blisters can become serious infections, which may heal poorly. Severe damage might require toe, foot or leg amputation.
- Hearing impairment. Hearing problems are more common in people with diabetes.
- Sleep apnea. Obstructive sleep apnea is common in people living with type 2 diabetes. Obesity may be the main contributing factor to both conditions. It's not clear whether treating sleep apnea improves blood sugar control.
- Dementia. Type 2 diabetes seems to increase the risk of Alzheimer's disease and other disorders that cause dementia. Poor control of blood sugar levels is linked to more-rapid decline in memory and other thinking skills.

I hope that very brief overview of diabetes has made its fundamental point: diabetes is a bad and expensive but potentially preventable disease. People don’t develop it either quickly or randomly; it predictably follows a series of steps and conditions. I want to discuss that progression now and introduce a relatively new term for prediabetes: metabolic syndrome. That occupies the space between normal, good health and diabetes. It doesn’t always lead to diabetes but, as careful researchers like to put it, ‘tends to’, or increases your likelihood of developing diabetes.

The term ‘metabolic syndrome’ was coined in the late 1990s to describe a cluster of medical conditions occurring together. There is not, yet, a definitive or conclusive

definition of metabolic syndrome but many physicians and researchers agree on the broad outlines. The definition here comes primarily from 4 sources; Shmerling, Metabolic Syndrome is On the Rise, Oct 2, 2020 in Harvard Health, Levine, Metabolic Syndrome, from the AARP website, Hironde, Trends in the prevalence of metabolic syndrome, *JAMA.* 2020;323(24):2526-2528, and WebMD, Metabolic Syndrome. Researchers and clinicians seem to agree that someone with only 1 of these conditions doesn't have the syndrome but people with 3 or more probably do.

- Obesity or having a Body Mass Index (BMI) greater than 30. As an alternate metric, males having a waist size greater than 40 inches or females greater than 35 inches.
- Elevated blood triglycerides, above 150 mg/dL
- Low HDL (good) cholesterol. In men, below 40 mg/dL; in women below 50 mg/dL
- High blood pressure: For people under 60 years old, having a blood pressure 130 / 85 or higher, or on blood pressure medications. The American Heart Association raises this estimate for people over 60 to blood pressure over 150/90. Note that lots of organizations publish blood pressure guidelines, by some estimates well over 100. There is some disagreement among guideline promulgators and medical practitioners about the exact levels that define good, fair and poor health. Take the blood pressure guidelines suggested here with a grain of salt, pun intended.
- Elevated blood sugar: A fasting blood glucose level above 100 mg/dL, having an A1C > 5.7 or taking diabetes medications.

People with metabolic syndrome are about 4x more likely to develop diabetes, 3x more likely to have a heart attack or stroke and 55% more likely to develop kidney disease. According to the National Heart, Lung and Blood Institute, having metabolic syndrome increases your risk of developing erectile dysfunction, heart disease, inflammation, immune system problems, and organ damage, especially pancreas, liver, gall bladder and kidney. It also increases risks of having pregnancy complications, problems with thinking and memory, sleep apnea, and some cancers. [134]

Note that simply having metabolic syndrome doesn't mean you will *definitely* develop any of these problems; many people probably live for years with the syndrome but without major complications. Having the syndrome, though, tends to increase the risks.

Some 37% of Americans – that's about 100 million people – currently have metabolic syndrome with the prevalence increasing with age: some 50% of people over 60 years

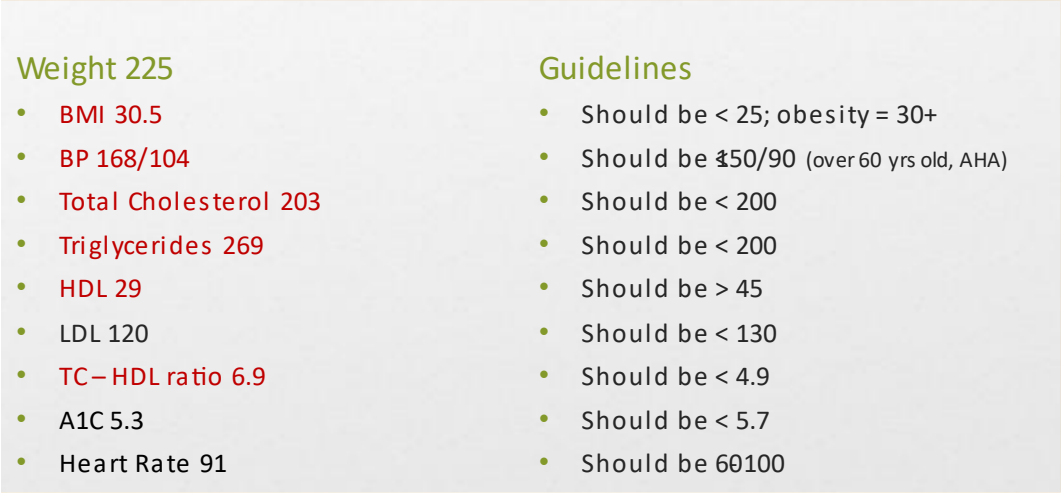
[134] https://www.nhlbi.nih.gov/health/metabolic-syndrome/living-with

old have it. It is largely preventable by maintaining a healthy weight and making healthy lifestyle choices – eating a healthy diet, exercising regularly and avoiding smoking.

How can we help people with metabolic syndrome regain good health? What steps should someone with this condition take?

A metabolic syndrome treatment case study

In August, 2020, I had a physical. It didn't go well. Here are my numbers compared to standard guidelines:



My numbers in red, for Body Mass Index, Blood Pressure, Total Cholesterol, Tryglycerides, HDL and the ratio of Total Cholesterol to HDL all indicate metabolic syndrome.

The guidelines above come from the various sources that defined metabolic syndrome listed above along with the American Heart Association's various blood pressure guidelines.

In general, I think of guidelines only as squishy suggestions that act as vague indicators of health. They correlate very loosely with sickness. Take blood pressure guidelines, for example. A large meta-analysis of blood pressure studies published in JAMA in 2018 [135] showed an all-cause mortality rate for people with systolic blood pressure below 140 of about 7 per thousand. Meanwhile, the all-cause mortality rate for people with systolic blood pressure over 160 was only about 5.5%. Confusing? Yes. Meaningful? Unclear. That small difference could be due to statistical error, some confounding factors or incompatible study methodologies.

I find the bigger picture about guidelines' correlation with medical risks more troubling. Consider the Know Your Chances Risk Charts developed by the National Cancer

[135] Brunstrom, Association of Blood Pressure Lowering with Mortality and Cardiovascular Disease Across Blood Pressure Levels, JAMA Internal Medicine, January 2018

Institute. (You can find them by googling ‘know your chances risk charts’.) These show that a 67-year-old white male for example, has a 76% chance of living for 10 more years, meaning a quarter of guys this age will die by age 77.

How will that 24% die? According to the Know Your Chances charts, 6 per thousand will die from high blood pressure. That’s .6% of white 67-year-old guys over 10 years, a very small risk in my opinion. It probably – a guess on my part – applies to people with very high blood pressure that medications fail to control. Sure, lowering your blood pressure will probably make you healthier but – again my non-medically trained opinion – probably won’t save your life. The mortality rate from high blood pressure is simply too small.

That’s why I take guidelines with a grain of salt. They simply suggest that your health is going in a positive or negative direction and act, for me at least, as a potential wake-up call. ‘You’re managing your health well or not-so-well compared to a very large sample of people. You could do better and perhaps feel better but you probably won’t die in the near term either way.’ That’s about it.

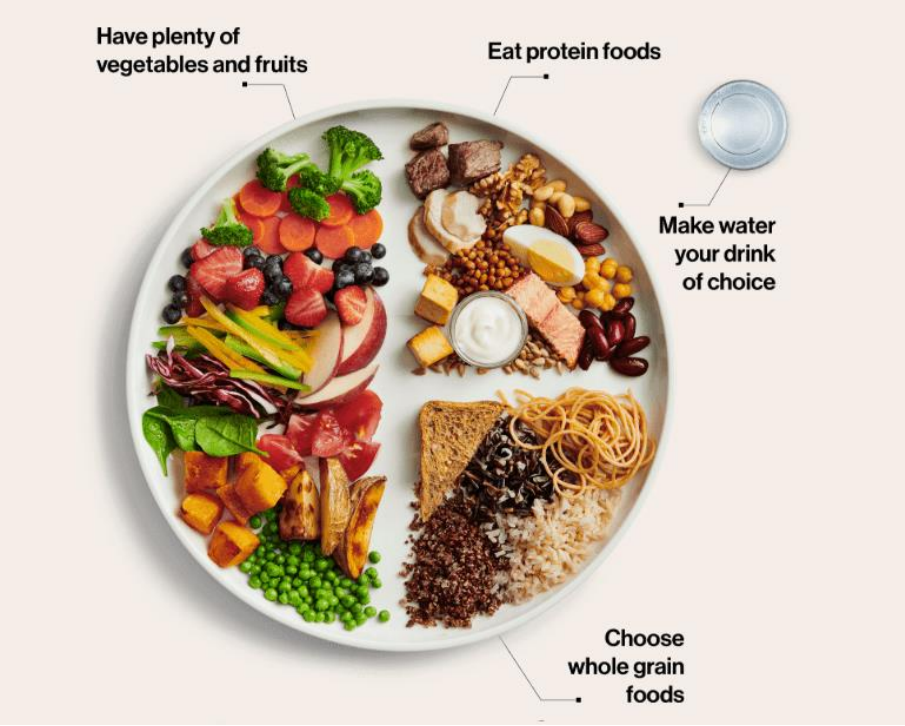
That said, my physical results / numbers acted as a wake up call to me. I was clearly in the medical syndrome arena and was unhappy about it, more-or-less the same feeling I remember from high school when I got a B on a paper that I thought was worth an A. ‘I could do better.’

I considered my options and opted against nutritional consultants – too much medical care – or commercial diets, too expense. Plus studies indicate that 80%+ of people who lose weight on commercial diets regain it within 2 years…maybe a higher percentage of people and maybe even more weight. I figured I could do that well (poorly) at least, so I researched government recommendations. I’m a researcher, after all, and the government produces tons of high quality studies. Whether or not anyone reads them is a different question.

It turns out that the government provides excellent behavioral health advice, diet and exercise.

We should eat, on average for the 340 million of us Americans, about 2000 calories per day according to the government. Since I’m a big bigger than average, I figured I should eat a bit more, about 2200. I checked that against various online calorie estimators by googling ‘how many calories per day to lose weight’. After entering my age, gender, height (72 inches), weight (225 pounds) and daily exercise amount, all suggested that I eat around 2200 calories per day to lose a pound a week. Good starting point.

What to eat? Interestingly here, both the US and Canadian government provide similar recommendations. I’ll show the Canadian food plate below, not because the recommendations are better but simply because I find their graphic presentation more compelling.



Pretty straightforward and easy to understand. I figured I'd follow it. Lots of fresh fruits and vegetables, not so much meat, bread or rice.

Next exercise. Again, clear US government suggestions: 2 ½ to 5 hours of moderately vigorous exercise per week. I choose walking as my main exercise form because of the pandemic, plus I enjoy walking outdoors. I interpreted 'moderately vigorous' to mean 'raise your heartrate and break a sweat but without exhausting yourself'.

That was my diet plan: 2200 calories and an hour brisk walk every day.

I lost 40 pounds my first year.

Fast forward to my August, 2022 physical, 2 year later. I skipped 2021 for no apparent reason. No more metabolic syndrome. I had gained 4 pounds during the second year. Here are the 2022 results compared to the guidelines:

Weight 189	Guidelines
BMI 24.9	Should be < 25; obesity = 30+
BP 142/80	Should be ≤ 150/90
Total Cholesterol 172	Should be < 200
Triglycerides 83	Should be < 200
HDL 44	Should be > 45
LDL 112	Should be < 130
TC – HDL ratio 3.9	Should be < 4.9
A1C 5.3	Should be < 5.7
Heart rate 61	Should be 60100

All my numbers were within the guidelines except HDL which was very close and up quite a bit. Below, the 2 year comparison to see the impact that diet and exercise can have on your health metrics:

Before (8/2020) Weight 225	After (8/2022) Weight 189
BMI 30.5	BMI 24.9
BP 168/104	BP 142/80
Total Cholesterol 203	Total Cholesterol 172
Triglycerides 269	Triglycerides 83
HDL 29	HDL 44
LDL 120	LDL 112
TC – HDL ratio 6.9	TC – HDL ratio 3.9
A1C 5.3	A1C 5.3
Heart rate 91	Heart rate 61

Pretty impactful. I hope this case study and the previous discussion about food costs and subsidies makes 2 fundamental points. First, you can get into and out of metabolic syndrome through diet and exercise. That's the point of the case study. But second, it's economically extremely difficult. That's the point of the food subsidy discussion above. We'll expand on that issue below.

Implications for broker services i
Wellness programs as an attempt to add value

Many corporations and agencies have introduced wellness programs, attempting to educate people to eat better with inducements for lowering their cholesterol, blood pressure, blood sugar and the like. The apparent theory: people make bad food

consumption decisions because they don't know better. Wellness programs typically provide both nutritional education and a financial incentive to change behavior.

We have some academic evidence about the impact of education on food consumption. A study published in the Archives of Internal Medicine in 2010 compared soda consumption among groups that received advice about the nutritional impacts of drinking soda *without* any financial inducement to change behavior, to a group that received similar advice *with* a financial incentive to change. The result:

- Those receiving advice *without* an economic incentive had no decrease in soda consumption
- Those receiving advice *with* an economic incentive did have a soda consumption decrease. [136]

How much of an incentive?

We can estimate the required incentive size by comparing costs for unhealthy / high calorie / high fat / high cholesterol food to costs of healthier choices. As we've already seen, the difference is about $3000 per person per year. I suggest that wellness programs need to incent people at least this much to generate the desired behavioral change….but probably more.

- Healthier foods aren't as convenient as KFC or a Big Mac. Consider convenience – ease of access and preparation - when you calculate the appropriate wellness incentive. (I, for example, hate cutting fruits and vegetables. I sometimes go without simply because I find cutting so unpleasant.)
- Healthier foods don't taste as good, especially to someone habituated to high sugar, high salt, high fat foods. You'll probably need an additional incentive to get people to change their taste preferences.

  New York Times reporter Michael Moss explored this idea in some detail in his 2014 book 'Salt, Sugar, Fat'. He writes that the giant food companies aim for the taste 'bliss point' – a combination of sugar, salt and fat – that satisfies people's taste buds and gets them to want more, to keep eating as in the famous potato chip ad 'Bet you can't eat one'. The critical factor, Moss explains, is that you generally need *all three* tastes – salt, sugar and fat - to reach bliss: having only 1 of the 3 doesn't work.

  Foods outside that bliss point - fruits and vegetables for example – are less tasty and satisfying for most people. Moss presents tons of research to back his analysis, including detailed discussions with food scientists working for the largest food production companies.

[136] Duffrey, op cit

> That's why I suggest you need additional financial incentives to get people to eat foods outside the bliss point.

My guess, somewhat educated but really only a guess: corporations would need to budget around $4000 per person per year (i.e. $16,000 for a family of 4) to effectuate real dietary change. Compare this to a 2019 wellness average of about $783 per employee, not per member of the employee's family. [137] About $3,000 short for a family of 4 just on the dietary front.

That's the wellness bind. The amount *necessary* to generate behavioral change far exceeds the amount *available* for the task.

These are, of course, averages. High income employees would probably need less of a financial incentive; low income folks probably more. (I'll address the issue of income disparity and effects on disease rates later in this chapter.)

We're starting in a $3,000+ hole per person. Those private sector wellness programs may not offer much help despite their noble attempts to create systemic value.

Let's continue but change gears. Diet is only part of the 'diet and exercise' behavior change program. Let's discuss the exercise bit next to see why.

Exercise

Americans don't exercise enough. We know that from many studies, including compliance with the 2008 Physical Activity Guidelines quoted at the beginning of this chapter.

Why don't Americans exercise enough? We all know that exercise is good for us. We all want to exercise more. I've never heard anyone say they want to exercise less (well, maybe a few landscapers). But too few of us do.

I'd like to focus on 3 reasons we exercise too little: the home interest deduction, our relatively low federal gas taxes and single acre zoning, and suggest that they explain much about our lack of daily exercise. People, I would argue, respond rationally to economic incentives.

American population densities are much lower than European or Canadian. This allows Europeans and Canadians to develop more sophisticated and efficient urban public transportation systems. An exercise impact of this, according to Alain Desroches of the Public Health Agency of Canada in a personal email:

> The denser, mixed use development in Canada makes average trip distances only half as long as in America, so more walkable than the longer trips

[137] Trends in Workplace Wellness Programs, KFF.org, Pollitz and Rae, June 9, 2020

Americans make. Canada also has higher transit user rates per capita accounting for more walking between trips.

This was at least partly due to these country's reactions to oil price hikes in the 1970s. Most Western European countries dramatically shifted their urban transportation policies in the 1970s to curb car travel and promote public transportation and walking according to John Pucher, writing in Transportation Policy magazine. [138] They walk to work, shopping and social events; we drive.

Our suburban physical environment, dominated by single family houses, exacerbates this problem. Over time, Americans have purchased bigger and bigger houses, generally on larger and larger lot sizes.

- In 1970 the average new house contained about 1400 square feet of living space
- In 2012 new houses averaged almost 2600 square feet

'The home mortgage interest deduction subsidizes Americans to buy bigger homes…Americans, even poor Americans, have *almost twice as much living space* as the average resident of France or Germany' claims Harvard economics professor Edward Glaser. [139] Our government tax policy incents us to place these homes on larger lots by making local property taxes deductible on our annual Federal income tax. Local property tax deductibility acts as a subsidy to buy larger lots: the bigger the lot, the higher the property tax deduction.

Commuting from these larger homes on larger lots requires a car. Consider the person who passes 100 dwelling units while going from home to work:

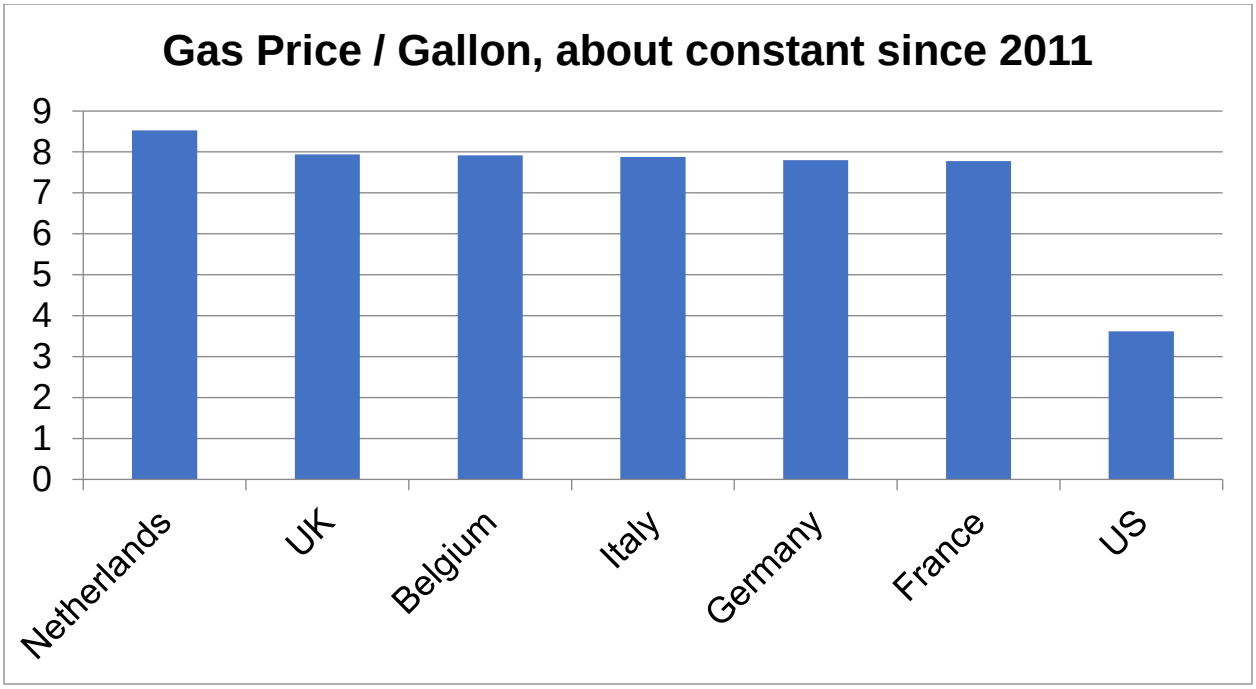
- Pass 100 homes on single acre lots = go 100 linear acres (about **4 miles** if square acres). Too far to walk. And too difficult to locate a public transportation hub nearby.
- Pass 100 homes in cluster = perhaps 5 linear acres (about **1/5 of a mile**). Easily walkable and, with high population density, much easier to locate a public transportation hub nearby.

As gas prices rose over time, our government responded by keeping gas prices low through below-world-market gas taxes. Consider this chart comparing prices per gallon of gas in various countries in February 2011:

---

[138] Pucher, Why Canadians cycle more than Americans, Transportation Policy, 2006 http://vtpi.org/pucher_canbike.pdf

[139] Boston, Globe 5/7/10, page A19



Americans paid about $3.75 per gallon compared to western Europeans who paid about $8. (Though prices have fluctuated since, the relative ratios remain roughly constant.)

Exercise summary

The three government subsidies – behavior incentives, if you will - significantly impact American's daily exercise:

- Home mortgages are income tax deductible, incenting people to buy bigger houses
- Property taxes are income tax deductible, incenting people to buy bigger lots
- Gas taxes are below the world market, incenting people to drive, not walk or take public transportation

Let's do a quick calculation to assess the impact:

- Assume someone walks 5 minutes from their home to and from the local public transportation stop to get to work, total 10 minutes daily, at the *home end* of each journey
- Then assume he/she also walks 5 minutes from public transportation to work each day, total 10 minutes daily at the *work end* of each journey
- The 5 day commute to and from work on public transportation accounts for **100 minutes** per week of walking

- Now assume 5 more journeys per week, to shopping (because of the local availability of stores) and socializing (restaurants, cafes, bars and walks to and from public transportation) = 100 more minutes of walking per week for a **grand total of 200 minutes** or about 166 hours of walking exercise per year that typical suburban Americans don't get.

At 3 miles per hour – a comfortable walking pace – our typical European or Canadian walks about 500 miles more annually than a typical American, burning perhaps an extra 50,000 calories per year.

Compare this exercise pattern --- about 200 minutes of public transportation related walking per week – with the government's recommended 2 ½ to 5 hours per week. Right in the sweet spot.

The physical environment in western Europe and Canada helps residents meet this standard; the physical environment in the US mitigates against it. That, in and of itself, can explain some of the obesity rate differences between us and them.

Implications for broker services and wellness programs ii

We've already discussed the cost difference between eating healthier and less healthy food and implications for wellness program incentives. I suggested that incentives in the $4000 range, per person per year, would probably be necessary to generate the desired food consumption behavior change, though that's a guess on my part: the actual number may be lower *or higher*.

Now let's add an exercise incentive. Consider these factors:

- People generally value their leisure time at about 1/3 of their hourly income, or at least that's the rule of thumb I learned at Harvard so many years ago.
- The 2019 average hourly wage was $22.98. Estimate 1/3 of that at $7.50 / hour for budgeting purposes. Four hours of exercise / week, about the mid point of the government' recommendations, would thus cost an employer about $15, or $1500 per year.

The conclusion: Wellness programs would need to pay about $1500 per person per year to incent people to spend 4 hours / week of their leisure time in corporation-sponsored exercise endeavors.

Of course, some exercise programs burn calories more quickly than walking so an appropriately incented program would offer a range of options, time commitments and payments.

Our wellness program, therefore, would need to budget $5500/person/year or more to generate the desired nutritional and exercise changes. That's per employee and family member; a family of 4 would cost $22,000. Remember that this may be a low estimate: I only calculated the cost difference between eating poorly and well, and not exercising at

all and getting 4 hours/week. I left out any behavior change premium: some people may enjoy their current lifestyles and need some additional payment to get out of that comfort zone. I have no idea how much that might be.

Targeting behavior change

Now for the wrench in the works.

All the analysis above describes ‘average’ people and ‘average’ disease rates. But studies indicate a very wide population divergence from ‘average’ with some groups exhibiting far higher disease rates and others lower. Targeting programs at those with highest risk is more expensive than the ‘averages’ above, perhaps much more so.

One outstanding group of studies called the Whitehall studies aimed to identify groups at highest risk. Unlike most medical studies, the Whitehall folks didn’t focus on *what causes* disease but rather *who gets sick*. Incorporating their information into wellness programs will help managers target interventions.

Some background: ‘Whitehall’ in Britain is the same as ‘Capitol Hill’ in the US, the seat of national government power and offices of many national civil servants. The Whitehall studies have tracked disease rates among British bureaucrats since the late-1960s.

Whitehall researchers choose the British civil service as their Petri dish for several reasons:

- British public administrators tended to remain on their jobs for many years, often their entire career. This gave researchers longitudinal information.
- British privacy laws, at least during the initial period of these studies, allowed researchers to identify specific individuals rather than just groups of people. This gave researchers the ability to follow up on specific disease and behavior details at an individual level.
- The British civil service was very hierarchical and status oriented, consisting of several different grades. Oxford and Cambridge graduates entered the service at the highest grades, made the most money and enjoyed the highest status; high school dropouts exactly the opposite.

  Given the status-based nature of hiring and promotions, it was highly unlikely that someone entering the civil service at grade 4 would be promoted to grade 2 or even grade 3: the grade at which you entered was generally the grade from which you retired.

  This gave researchers the ability to track disease rates by income and status.

I'll let Professor Michael Marmot, Director of the Whitehall studies, summarize what they found: [140]

- *Firstly, just looking at heart disease, it was not the case that people in high stress jobs had a higher risk of heart attack, rather it went exactly the other way: people at the bottom of the hierarchy had a higher risk of heart attacks.*
- *Secondly, it was a social gradient. The lower you were in the hierarchy, the higher the risk. So it wasn't top versus bottom, but it was graded.*
- *And, thirdly, the social gradient applied to all the major causes of death.*

Those at the bottom of the hierarchy were 3x more likely to die of heart disease than those at the top.

Today's corporate benefits advisors and wellness program managers – at least, those who have read this far in this chapter - could have predicted this, largely based on the food cost analysis above. People at the bottom of the hierarchy earned less money so ate a less healthy diet. They had, consequently, higher cholesterol rates, higher blood pressure, were more frequently overweight and consequently less healthy.

Unfortunately that conclusion is wrong! Here's Professor Marmot again

- *we looked at the usual risk factors that one believes that are related to lifestyle -- smoking prime among them, but plasma cholesterol, related in part to fatty diet and an overweight, sedentary lifestyle.*
- *We asked how much of the social gradient in coronary disease could be accounted for by smoking, blood pressure, cholesterol, overweight, and being sedentary.*
- *The answer was somewhere between a quarter and a third, no more.*

After controlling for risk factors like cholesterol and smoking, people in the lowest grades were twice as likely to die of coronary disease as those in the highest grades.

- *The social gradient applied to all the major causes of death -- to cardiovascular disease, to gastrointestinal disease, to renal disease, to stroke, to accidental and violent deaths, to cancers that were not related to smoking as well as cancers that were related to smoking -- all the major causes of death…*
- *2/3 at least of this gradient is unexplained*

[140] These quotes come from an interview at UC Berkley in March 2002, http://globetrotter.berkeley.edu/people2/Marmot/marmot-con3.html

Was Whitehall unique? Does it apply to America? Or, stated differently, is Senator Frist right (from the first page of this chapter) when he claims 'health is socio-economic status and disparity'?

The answer is yes to the second two questions above. These patterns exist not only in Britain but also here in the US. Here's the New England Journal of Medicine discussing Class: The Ignored Determinant of the Nation's Health [141]

- Differences in rates of premature death, illness and disability are closely tied to socio-economic status
- Unhealthy behavior and lifestyle ***alone*** do not explain the poor health of those in lower classes
- There is something about lower socioeconomic status *itself* that increases the risk of premature death

Sounds like Whitehall's conclusion.

The International Journal of Cancer considered the impact of socio-economic class on breast cancer survival rates. Their rather startling conclusion [142]

- breast cancer patients of low Socio-Economic Status have a significantly increased risk of dying as a result of breast cancer compared to the risk in patients of high SES.
- Low SES patients were diagnosed at a later stage, had different tumor characteristics and more often received suboptimal treatment.

However…

- Even after adjusting for all these factors, the risk of dying of breast cancer remained 70% higher among patients of low SES than among patients of high SES.

Madeline Drexler of Harvard's School of Public Health summarized the issue here succinctly

> 'an individual's health can't be torn from context and history. We are both social and biological beings…and the social is every bit as real as the biological …' [143]

[141] September 9, 2004

[142] Bouchardy et al, Social class is an important and independent prognostic factor of breast cancer mortality, International Journal of Cancer, Vol 119, Issue 5, March 2006

[143] Drexler, The People's Epidemiologists, Harvard Magazine, March 2006

The 2015 Dietary Guidelines Advisory Committee report echoes this, saying (in typical governmental bureaucratese)

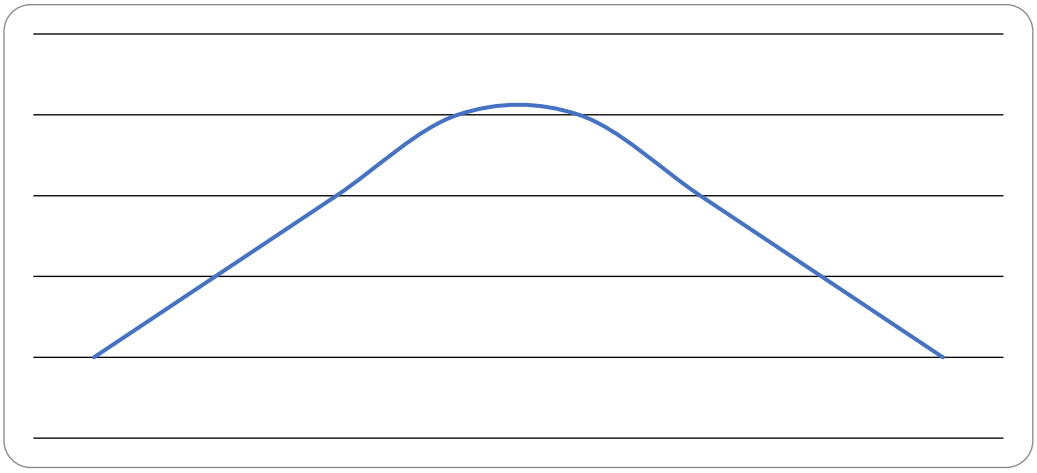
- Health and optimal nutrition and weight management cannot be achieved without a focus on the synergistic linkages and interactions between individuals and their environments [144]

That's the same conclusion Professor Stuart Wolf reached in his study of disease rates and social patterns in very poor but very egalitarian Roseto, Pennsylvania [145]

> the characteristics of a tight-knit community are better predictors of healthy hearts than are low levels of serum cholesterol or tobacco use.

Whitehall and wellness programs

Let's apply this information to a typical corporate wellness program. Screening for cholesterol, blood pressure and other disease indicators assumes a bell curve model.

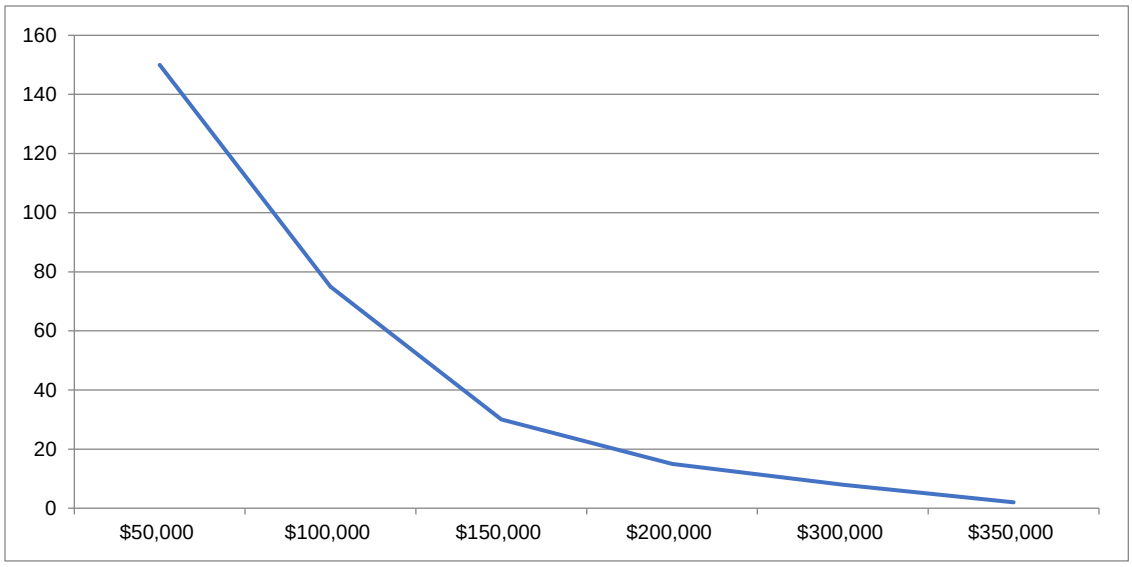


A few people at the far left have low cholesterol, blood pressure or blood sugar and are unlikely to get sick, while people at the far right have high levels and are therefore at risk. Most people fall in the middle. The appropriate wellness program focus using this model is the group at the far right.

But Whitehall, the New England Journal of Medicine, Madeline Drexler and Stuart Wolf suggest a different disease risk model:

[144] 2015 Dietary Guidelines Advisory Committee report issued February 19, 2015, Part D, Chapter 4

[145] Wolf and Bruhn, The Power of the Clan: Influence of Human Relationships on Heart Disease



Here, a lot of people earn $50,000 or less per year while a few earn $250,000 or more. Whitehall suggests that disease rates among the $50,000 earners will run about 3x the rate of the $250,000 folks, making the low income folks and equally appropriate wellness program target.

Let's assign some numbers to a hypothetical risk scenario. The company above has 10 employees earning $250,000 or more annually (high income, high status) and 150 employees earning $50,000 or less (low income, low status). For every heart attack in the high income, high status group, how many heart attacks can we expect among the low income people?

Take a second to think this through.

The correct answer is 45. Three times the risk and 15 times the number of people. While it's unlikely that these numbers would play out in a company as small as this, the ratios would likely hold over very large numbers of companies and employees.

Whitehall and the 2015 Dietary Guidelines Advisory Committee report

The 2015 DGAC report specifically acknowledged that low income groups face greater impediments to healthy lifestyle behavior than do others in our society, saying, for example 'household food insecurity hinders the access to healthy diets for millions of Americans'. [146] More than 49 million people in the United States, including nearly 9 million children, live in food insecure households. [147] For these people, the issue is not

[146] From the Executive Summary of http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf

[147] Part B of the 2015 DGAC report

'what should I eat' but rather 'will I eat anything at all'. Food access, rather than nutritional quality, becomes a primary concern. As does food price.

Related to this, the Committee found that closer proximity and greater access to convenience stores (as in lower income, inner city food deserts) is associated with significantly greater Body Mass Index scores in the community and/or increased odds of being overweight or obese. [148] Access, not quality, often rules nutrition decision making.

The Committee bluntly stated that

> nutrition services *that take into account the social determinants of health are largely unavailable in the U.S. health system* to systematically address nutrition-related health problems, including overweight and obesity, cardiovascular disease, type 2 diabetes, and other health outcomes. [149]

Can employer-based wellness programs address this disparity?

Implications for broker services and wellness programs iii

We've previously discussed how corporate wellness programs need to budget some $5500 per person per year if they hope to accomplish their goals.

Now we see that targeting these programs to the most at risk – and medically most expensive - can raise those amounts. The lowest income, lowest status employees are probably the least interested in the program. They worry about doing their jobs, losing their jobs and may even need to rush to a second job just to pay their rent.

- They're probably suspicious of people telling them to eat or behave differently.
- They may face food insecurity issues.
- They probably lack any financial cushion or discretionary income, so the wellness incentive may go to other basic needs like rent, car payments, clothes or children's education rather than their own behavior change.

These people - the corporate medical cost drivers - are the most expensive to reach and impact.

Interestingly, I once described all this socio-economic risk stuff to a health insurance company medical director. His response: that fits our experience. Almost all the largest claims come from lower income employees.

Your highly compensated, well educated, higher status employees will probably gladly participate in wellness programs. They'll take your wellness bonus money and possibly

[148] DGAC report, Part D, Chapter 4, Question 2

[149] From the Executive Summary of the 2015 DGAC report, emphasis added

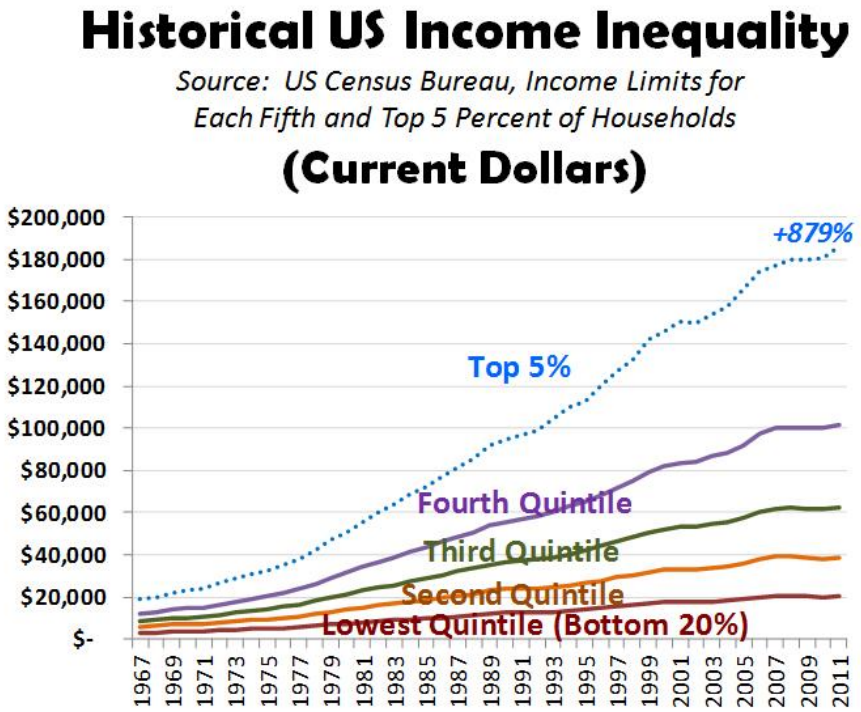
even spend it appropriately. But that won't impact your claims experience much because they're typically not the cost drivers.

Corporate wellness programs seem particularly ill suited to address the socio-economic lifestyle disparity problems in this country.

The gap between high and low income groups in the US
income trends over time

Whitehall and related studies indicate that lower socio-economic groups have higher disease rate than higher socio-economic groups. Whitehall and the others also found a gradient: the greater the socio-economic and status differences, the greater the disease rate differences too, even after controlling for risk factors like cholesterol and smoking.

Over time, US income differences between high and low socio-economic groups have expanded. Consider this chart based on US Census data showing an increasing gap between higher status / socio-economic groups and lower.



Here are some questions that follow from this analysis, with their unsettling answers:

- Do the highest American income groups enjoy 'really great' health while the lowest still enjoy 'pretty good'? In other words, do the wealthiest 'drag up' the poorest so we all enjoy better health over time? or

- Do the poorest groups have ‘really lousy’ health while the wealthiest enjoy ‘pretty good’? In other words, do the poorest ‘drag down’ the healthiest so our overall health improves, but very slowly (especially given our medical spending levels)?

While some evidence exists that we all, on average, enjoy better health over time (e.g. longer life expectancies than previously) the stronger evidence appears to indicate that increased income discrepancies over time ‘drag down’ the wealthiest rather than ‘drag up’ the poorest.

Consider Harvard Magazine’s analysis, ‘Unequal America’ by Elizabeth Gudrais published in its July-August 2008 issue. Here are some of the observations and data points as direct quotes.

- Between 1983 and 1999, men’s life expectancy decreased in more than 50 U.S. counties
- For women … life expectancy decreased in more than 900 counties—more than a quarter of the total.
- 4 percent of American men and 19 percent of American women can expect their lives to be shorter than or, at best, the same length as those of people in their home counties two decades ago.
- People at the top of the U.S. income spectrum “live a very long time,” says Cabot professor of public policy and epidemiology Lisa Berkman, “but people at the top in some other countries live a lot longer.”

Harvard Magazine’s observation:

> *There is … evidence that living in a society with wide disparities—in health, in wealth, in education—is worse for all the society’s members, even the well off….*

echoing Stuart Wolf’s decades old research into disease patterns in Roseto Pennsylvania. *More* income inequality seems to ‘drag down’ the wealthiest rather than ‘drag up’ the poorest. Relative deprivation seems more impactful than absolute.

Some conclusions

The three quotes with which I started this chapter – Senator Frist, the Massachusetts Health Policy Commission and Harvard’s Richmond and Fein – are all probably spot on. Here they are again as a reminder:

From Frist

> Health is not health services. Health is behavior, it’s genetics, it’s socio-economic status, it’s disparity, it’s environment.
>
> Health services has about a 15 – 20% impact.

From the Mass Health Policy Commission

> Research shows that [medical] outcomes are driven largely by social and behavioral factors, along with public health policies, while health care services delivered account for only 10 percent of general variation in health status.

From Richmond and Fein. Our health gains since World War II

> were largely the consequence of applying our knowledge of health promotion and disease prevention rather than improved clinical care**…**the revolution in biology subsequent to World War II, a revolution that had brought many advances to clinical care, as yet had only marginal effects on improving our vital statistics.

Lots of others echo these sentiments too.

We've seen how government subsidies and tax policy make some foods very inexpensive and others relatively more expensive. Admonitions to eat healthy food in the face of these cost differences generate little behavioral change. Our national health, as measured by obesity or average cholesterol rates for example, has declined over time.

Similarly, we've seen how zoning and tax policies affect our physical environment, impacting exercise rates among Americans. Again, admonitions to exercise more tend to generate little behavioral change.

And we've estimated the financial incentive necessary to change employee behavior. My guess – between $5000 and $6000 per person annually – falls way outside any corporate wellness budget.

We've seen how the lowest paid employees tend to be the highest risk, most expensive medically. I suggested some problems attracting this group to wellness programs. Perhaps most significantly, I think wellness programs that fail to attract this higher-risk group can't possibly succeed.

Wellness programs are, I suspect, necessary given the incentives that make healthy living so expensive. But they're also probably ineffective for exactly the same reasons.

No company has the financial power to overcome all the government incentives, subsidies and tax breaks that make wellness programs necessary.

The real tragedy in all this

We face a 'triple whammy' in healthcare costs today.

- Our population is aging and older people always cost more medically.
- Our government programs make healthy eating and exercising increasingly unaffordable to more and more Americans. Obese people cost the same as people 20 years older, which compounds our aging problem.

- Our increasing socio-economic inequality drags down the overall health of our society on average, including the wealthiest, leading us all to demand more medical care, not less than we might otherwise need.

In the face of these trends, our healthcare system wastes $700 billion or more annually on unnecessary care: our inefficiently organized *supply* of medical services exacerbates the problems of our unnecessarily high *demand* for those services.

Corporate wellness programs won't ameliorate these trends and, even if they do, probably won't reduce the number of unnecessary cardiac stress tests or the false positive rate from those tests.

- Probably won't reduce the number of back MRIs and unnecessary spinal fusion surgeries that result [150]
- Probably won't reduce the number of head CT scans related to sinusitis, advised against by the American College of Emergency Physicians and the American Academy of Pediatricians [151]
- Probably won't reduce the number of pediatric antibiotic prescriptions for ear aches, unnecessary 95% of the time and harmful about 15% [152]
- Probably won't reduce the amount of ineffective medical care like postnatal dexamethasone therapy for lung disease of prematurity, use of laparoscopic mesh for inguinal hernia repair or any of the 144 other ineffective interventions listed in Vinay Prasad's seminal article in the Mayo Clinic Proceedings [153]
- Probably won't reduce geographic treatment variation rates for cancer treatments, orthopedic treatments, cardiovascular treatments and others that alone represent about 1/3 of medical spending, at least according to tons of research published by scholars at the Dartmouth Institute, among other places.

In all these senses, government subsidies and tax policies fail to create healthcare system value and seem, at least according to my analysis, to destroy it. This public

[150] See ChoosingWisely, position statements by the American Academy of Family Physicians and others http://www.choosingwisely.org/doctor-patient-lists/imaging-tests-for-lower-back-pain/ . Some research suggests that people who have back MRIs shortly after they feel back pain are 8x more likely to have back surgery but don't recover faster.

[151] See ChoosingWisely, http://www.choosingwisely.org/?s=ct+scans+sinusitis&submit=

[152] See Antibiotics for Otitis Media on the NNT website, http://www.thennt.com/nnt/antibiotics-for-otitis-media/

[153] See Prasad et al, A Decade of Reversal, Mayo Clinic Proceedings, August, 2013 http://www.mayoclinicproceedings.org/cms/attachment/2007391767/2029532464/mmc2.pdf

sector failure has led to the private sector development of wellness programs, aimed mainly at undoing the harms caused by these various subsidies and tax programs.

I worry that these programs are ill targeted. I fear that even if wellness programs worked well, we would still waste the same $700 + billion annually. Being thinner doesn't lead to making wiser medical treatment choices.

Instead, consumer education about treatment options and outcomes does. But that's a different topic, unrelated to the corn subsidy and corporate wellness programs and perhaps more complicated and subtle than the market wants right now.

That said, it's probably still a good idea to eat more fruits and vegetables…If you can afford them.

Review Questions

Answers on next page

1. About how much more does it cost, per calorie, to eat healthier foods?

    a. About 1/3 of a cent
    b. About $1
    c. About $10
    d. About $100

2. Americans each eat about 2700 calories of food daily. About how much more does a typical family of 4 need to spend annually in order to eat healthier - rather than less healthy - food per year?

    a. About $1.96
    b. About $100
    c. About $125
    d. About $12,000

3. The US government encourages us to eat certain foods and discourages us from eating large quantities of other foods. Which food groups does the government subsidize?

    a. Both
    b. Neither
    c. The food groups we are encouraged to eat
    d. The food groups we are discouraged from eating in large quantities

4. This text suggested a ball park annual amount of money necessary to incentivize people to change their diets and choose healthier foods rather than less healthy. What is that annual amount of money?

    a. $150
    b. $200

c. $4000
d. $100,000

5. What impact do our zoning laws have on the amount of daily exercise most Americans get?

a. Single acre zoning generally puts more distance between someone's house and work, requiring driving to work, rather than walking to a public transportation stop. This lowers the daily amount of walking most Americans do, as compared to Europeans or Canadians.
b. Single acre zoning makes our neighborhoods more beautiful and less crowded, thus making evening / after dinner walks more attractive
c. Single acre zoning makes the distance to the nearest gym too long to drive, especially in the winter when it's typically cold and snowy outside
d. There is no relationship between zoning laws and daily exercise

6. This course suggested that the 'average' European or Canadian walks about 166 hours per year more than a similar American. Studies show that people value their free time at about 1/3 of their average hourly wages. The average American wages in 2014 were about $24. Roughly how much would an employer have to pay an employee to incent that employee to walk 166 hours in his or her spare time?

a. $1600
b. $200
c. $150
d. $200,000

7. Former Senator William Frist, a cardiologist, suggested roughly the impact that 'health services' have on 'health'. What is Frist's estimate?

a. 98%
b. 96%
c. 15%
d. Less than 1%

8. About what impact will wellness programs have on our rate of ineffective or harmful medical services, like using head CT scans to diagnose sinusitis, or using laparoscopic mesh for inguinal hernia repair?

a. No impact at all
b. A major impact. Wellness programs will reduce the rate of these and similar ineffective medical services by well over half
c. Wellness programs are expected to eliminate the amount of ineffective and unnecessary medical care within 8 – 10 years
d. Recent studies suggest a decrease of 5 – 10% of all ineffective services by 2025.

Review Questions

Correct answers in bold

1. About how much more does it cost, per calorie, to eat healthier foods?

a. About 1/3 of a cent
b. About $1
c. About $10
d. About $100

2. Americans each eat about 2700 calories of food daily. About how much more about a typical family of 4 need to spend annually in order to eat healthier - rather than less healthy - food per year?

a. About $1.96
b. About $100
c. About $125
d. About $12,000

3. The US government encourages us to eat certain foods and discourages us from eating large quantities of other foods. Which food groups does the government subsidize?

a. Both
b. Neither
c. The food groups we are encouraged to eat
d. The food groups we are discouraged from eating in large quantities

4. This text suggested a ball park annual amount of money necessary to incentivize people to change their diets and choose healthier foods rather than less healthy. What is that annual amount of money?

a. $150
b. $200
c. $4000
d. $100,000

5. What impact do our zoning laws have on the amount of daily exercise most Americans get?

a. Single acre zoning generally puts more distance between someone's house and work, requiring driving to work, rather than walking to a public transportation stop. This lowers the daily amount of walking most Americans do, as compared to Europeans or Canadians.
b. Single acre zoning makes our neighborhoods more beautiful and less crowded, thus making evening / after dinner walks more attractive
c. Single acre zoning makes the distance to the nearest gym too long to drive,

especially in the winter when it's typically cold and snowy outside
d. There is no relationship between zoning laws and daily exercise

6. This course suggested that the 'average' European or Canadian walks about 166 hours per year more than a similar American. Studies show that people value their free time at about 1/3 of their average hourly wages. The average American wages in 2014 were about $24. Roughly how much would an employer have to pay an employee to incent that employee to walk 166 hours in his or her spare time?

a. $1600
b. $200
c. $150
d. $200,000

7. Former Senator William Frist, a cardiologist, suggested roughly the impact that 'health services' have on 'health'. What is Frist's estimate?

a. 98%
b. 96%
c. 15%
d. Less than 1%

8. About what impact will wellness programs have on our rate of ineffective or harmful medical services, like using head CT scans to diagnose sinusitis, or using laparoscopic mesh for inguinal hernia repair?

a. **No impact at all**
b. A major impact. Wellness programs will reduce the rate of these and similar ineffective medical services by well over half
c. Wellness programs are expected to eliminate the amount of ineffective and unnecessary medical care within 8 – 10 years
d. Recent studies suggest a decrease of 5 – 10% of all ineffective services by 2025.

Issue 3: Plan Design Formats

Let's start with an analogy.

Clayton Christensen, a professor at Harvard Business School best known for studying business innovation - and particularly disruptive innovation - wrote an insightful article about the US educational system in the May 11, 2014 Boston Globe.[154] As you read some highlights from that article, consider the analogy to our healthcare system.

- *Tuition costs have been ballooning faster than general inflation…and what do we get in return?*
- *Nearly half of all bachelor's degree holders do not find employment or are underemployed upon graduation. At the same time, employers have not been satisfied with degree candidates.*
- *Two recent Gallup polls showed that although 96% of chief academic officers believe they're doing a good job of preparing students for employment, only 11 percent of business leaders agree that graduates have the requisite skills for success in the workforce.*
- *And this is all occurring while higher education leaders were convinced that they were innovating all along.*

Now let's substitute 'healthcare' for 'education' and rewrite:

- *Premiums have been ballooning faster than general inflation…and what do we get in return?*
- *Lower life expectancies, higher infant mortality and poorer access than other countries.*
- *At the same time, employers have not been satisfied with broker services.*
- *A recent poll showed that although most brokers believe they're doing a good job of developing benefit strategies and communications, only about half of business leaders agree that brokers do a good job implementing and executing desired programs.*
- *And this is all occurring while brokers are convinced that they were innovating all along.*

[154] Clayton Christensen et al, Thank You MOOCS, Boston Glove, May 11, 2014

The poll in question was Zywave's 2013 study of customer satisfaction with broker services that received 5500 responses. Some highlights: [155]

- Creates strategic plan that aligns with company goals: **43% unsatisfied**
- Offers employee benefits and consumerism communication / education: **41% unsatisfied**
- Assists with creating or maintaining a workplace wellness program: **66% unsatisfied**

Part of the problem comes from our employer based health insurance distribution system. We are the only major advanced, industrialized country that uses employer based health insurance as the primary mechanism of financing healthcare. Other countries use employer based coverage – if they allow it at all – to supplement the national health insurance system.

We, in the US, use public programs like Medicaid and Medicare to supplement employer based coverage, exactly the reverse of everyone else. If you can get health coverage through your employer, you (generally) cannot get public coverage. How does employer based primacy impact our overall healthcare system?

Princeton economic professor Uwe Reinhardt answered that question in his New York Times piece 'The Culprit Behind High US Health Costs' in 2013. [156] Here are some direct quotes:

- *Most health-policy analysts I know regret that employers appointed themselves their employees' agents in the markets for health insurance and health care*
- [Employers are] *the sloppiest purchasers of health care anywhere in the world. For more than half a century, employers have passively paid just about every health care bill that has been put before them, with few questions asked.*
- *One reason for the employers' passivity in paying health care bills may be that they know, or should know, that the fringe benefits they purchase for their employees ultimately come out of the employees' total pay package.*
- *In a sense, employers behave like pickpockets who take from their employees' wallets and with the money lifted purchase goodies for their employees*
- *[Carriers] are merely the conduits for the employers' wishes.*

[155] This study was summarized at the Massachusetts Association of Health Underwriters annual 'Benefest' in a presentation by Sarah Lucas of Marshberry entitled 'Trends and Best Practices in Employee Benefits Agencies'.

[156] Uwe Reinhardt, The Culprit Behind High US Health Costs, NY Times, June 7, 2013

- *When agents perform poorly, one should look first for the root cause at the principals' instructions.*
- *a decade of health care cost growth under employment-based health insurance has wiped out the real income gains for an average family with employment-based health insurance.*

Reinhardt then provided his data. In 2013, for an average family of 4, employer based health insurance cost $22,000, up $10,000 since 2003, compared to median family income of $55,000. He then suggests

- *One must wonder how any employer as agent for employees can take pride in that outcome*

I would extend that query to brokers, echoing the Christensen and Zywave points above.

Over time we developed more and more 'fill in' programs to cover people excluded from the employer based system – old people, unemployed people, veterans, children and others. Combining and coordinating these various programs leads to confusion, inefficiencies and costs.

One confusing consequence of employer based primacy and myriad fill in / supplementary programs, for example, is that our system treats people differently based on non-health factors, like who they are or where they work. Unlike other advanced countries, we have different systems and rules for

- Full time employed people
- Part time or low income people
- Very poor people, provided they are also either **i** children, **ii** blind or disabled, **iii** elderly, **iv** mentally ill, **v** pregnant women or **vi** mothers (if they don't fit into one of these six categories, they are treated like 'part time or low income people'. Understand?)
- People over 65 years old
- Young people who don't otherwise qualify for health insurance
- Military veterans provided their medical problems are 'combat related' and
- People with kidney disease, among others.

As you move from group to group – in other words, as your economic conditions change (generally) - you face different medical access rules, different financing rules and tons of paperwork. This does nothing to improve health and adds no efficiencies to our system.

We, in other words, base our healthcare financing and access systems on non-health related categories of people. Since the groupings are arbitrary, much more a function of interest group lobbying than healthcare distribution efficiency, compliance becomes extraordinarily difficult: compliance experts can't apply logic or reason to regulations. Instead, they must memorize or continuously consult the regs. This makes absolutely no medical or economic sense except, perhaps, to the favored business interest groups.

It only adds overhead, inefficiencies and costs to the system.

Complexity and confusion add costs more in the US than in other countries

Consider the relative inflation rates in the US and some other advanced countries. Inflation, of course, is driven by many factors, only one of which is systemic complexity. But it's difficult to design rational, cost-cutting, efficiency-promoting reform on top of an inefficient, irrational structure.

I use 2003 as my comparison basis because that was the year we introduced tax advantaged deductibles, designed to reduce unnecessary utilization and costs. Policy makers in the W. Bush administration figured that if patients pay with their own money they'll be more frugal and less wasteful. That was a big change from the traditional first-dollar-coverage in managed care that many saw as promoting unnecessary care.

	2003 healthcare spending	
US	$3788 per capita	
Canada	$2054 per capita	US spends 1.84x as much
United Kingdom	$1344 per capita	US spends 2.82x as much
France	$2093 per capita	US spends 1.81x as much
Germany	$2943 per capita	US spends 1.29x as much

	2011 healthcare spending	
US	$8508 per capita	
Canada	$4522 per capita	US spends 1.88x as much
United Kingdom	$3405 per capita	US spends 2.50x as much
France	$4118 per capita	US spends 2.07x as much
Germany	$4495 per capita	US spends 1.89x as much

From passage of the Medicare Modernization Act in 2003 at least under passage of the Affordable Care Act in 2010, our relative healthcare spending position has worsened vis-à-vis other countries. We not only spend *more* than these countries but, on average over time, we spend *more* more.

An underlying problem, at least from the broker or 'benefits advisor' perspective is that the enormous complexity of our healthcare system leads brokers to become expert at compliance, not at healthcare or healthcare systemic efficiency. In fact, 'health' insurance brokers today need understand nothing about 'health', only about compliance, to have successful, financially lucrative careers.

But compliance, as I suggested above in the discussion of Christensen and Reinhardt, does nothing to control costs or improve systemic value. Benefits advisors who *only* advise about compliance provide far less value to their clients than they could.

This was made poignantly clear to me one day in a lecture. I asked an experienced broker why she attended, as her agency normally didn't contract with me. Her response:

> *I sell CDH plans, understand HSAs, HRAs, deductibles, FSAs, networks and all the rest.*
>
> *But I recently switched employer, and I now have a high deductible plan…*
>
> *And **I** don't know how to use it!*

Consumer engagement to the rescue … or not

My somewhat depressing response to her comment: if the pros don't know how to navigate our healthcare system for themselves – don't know which services to use, which are wasteful and harmful – how much can they help their clients? Too often, their compliance advice only helps their clients access unnecessary, inappropriate or wasteful services, with up to some 40 or 50% of all healthcare spending going to services that do nothing to promote health.[157] The compliance focus only promotes easier access to care, much of which is unnecessary.

Brokers, and far too often also their clients, lack the tools to differentiate necessary from unnecessary interventions. That's the real impact of the broker comments quoted above.

Indeed, today's 'consumer engagement' emphasis falls into the same quagmire as the rest of our system. 'Consumer engagement' to health insurance brokers means knowing deductibles, plan design details, tax implications and the like. Knowing these things does not decrease costs, waste, unnecessary care or improve patient outcomes.

---

[157] Several scholars at Dartmouth Medical School, notably Elliott Fisher and John Wennberg, have written extensively about this. Shannon Brownlee's excellent Overtreated provides plenty of detail. I'll belabor this point myself later in this book. The 'up to 50%' estimate is mine, not theirs.

But better outcomes are (almost) always cheaper than poorer outcomes!

Healthier people cost our healthcare system less, and the more efficiently our system turns people from *un*healthy to healthy, the less we spend on them. Poorer outcomes – infections, returns to operating tables, ineffective medications, high false positive test rates etc – always cost more. (Yes, I know that MRI costs vary significantly. But no one wants the cheapest unnecessary MRI.)

That's why the medical community, as opposed to the brokerage community, defines consumer engagement as knowing ***how well*** medical care works, not how to access it financially or where to get the cheapest. The well informed consumer, to the medical community, knows about the 'health' part of health insurance.

Note the discrepancy between the insurance and medical definitions. The insurance definition does nothing to improve outcomes or reduce waste and thus can't have much cost control impact.

But the medical definition directly attacks waste and improves outcomes so ***can*** significantly reduce costs. In fact scholars like Dr. Michael Barry of the Informed Medical Decisions Foundation and Dr. Albert Mulley of Dartmouth Medical School, suggest that well informed (medical definition) patients cost roughly 20% less than poorly informed patients. Much more on this coming up.

Unfortunately, our medical consumer engagement process falls trap to yet *another* definitional problem. Here's Dr. Suzanne Koven, summarizing it in the Boston Globe: [158]

- I appreciate patients informing and advocating for themselves
- I don't appreciate patients arguing with me about anatomy and physiology

In the 10 or so minutes patients typically spend with doctors, they can either question their doctor's competence ('arguing about anatomy and physiology') or discuss treatment options. They probably don't have time to do both.

And they'll probably lose the anatomy and physiology argument. Doctors know much more about medical care and technology than the typical patient ever will. Four years of medical school really do provide a solid technical foundation. Your doctor can out-fact you many times over. (Yes, your doctor may have misdiagnosed your problem. But that's best remedied by a second opinion, not an argument about physiology.)

You, however, know much more about your own treatment preferences than your doctor does. That's the real goal of consumer engagement: aligning treatment processes with patient preferences. That process – having doctors and patients explore treatment

[158] Suzanne Koven MD, Is physician burnout really a problem? Boston Globe, May 26, 2014

options to choose the best for each patient – can have a huge impact on utilization and costs. [159]

We have not, in this country, developed a standard definition of 'consumer engagement' or 'well informed patient' because, I suggest, of the 'mess' [160] that our system has become, largely due to the irrational employer based financing model upon which it rests. Compliance issues have become so overwhelming that brokers, and often their clients, simply don't have the time or energy to discuss more impactful issues.

As brokers struggle with compliance and plan designs, physicians with appropriate consumer information and advocacy, and the internet explodes with medical factoids and information, consumers get overwhelmed. Who gives them direction for their own research? What do they need to know? Which information is correct? Which is valid and appropriate?

Six faulty assumptions

Too often patients make assumptions and medical decisions that are, simply, wrong. I'll give some examples. How many of these resonate with you?

Faulty assumption #1: Good medical care leads to good health

Many people believe that good medical care leads to good health. As one thoughtful and articulate broker once said to me over an informal lunch, describing his young family, 'I have great healthcare for my kids. They're doing really well.'

Nonsense, I responded. 'Your kids are doing well because they're intellectually and emotionally within the normal range, have a mother and father who love them, live in a safe neighborhood, get plenty of good food and fresh air, have friends, and are warm in the winter and cool in the summer. The quality of their physicians and hospitals has virtually nothing to do with their health.'

Indeed, overwhelming evidence shows that good health comes from, in no particular order, good nutrition, exercise, emotional security, environment, public safety, socio-economic status *and* medical care, but that medical care is a relatively small component of good health.

How small a component? About 10%, according to the Massachusetts Health Policy Commission's 2013 cost trends report. Here are direct quotes from page 22:

[159] We'll discuss preference sensitive decision making in detail later in this book

[160] "Mess' comes from the title of Dr. Julius Richmond and Rashi Fein's 2005 book 'The Healthcare Mess'. Both authors were professors at Harvard Medical School.

- Massachusetts residents have better overall health than the United States average, with an additional 1.6 years of life expectancy and 0.9 fewer physically or mentally unhealthy days per month.

but

- Research shows that such outcomes are driven largely by social and behavioral factors, along with public health policies, while health care services delivered account for only 10 percent of general variation in health status.

Richmond and Fein, the two highly respected Harvard Medical School professors, echoed this in their 2005 book The Healthcare Mess: [161]

> Health gains since World War II were largely the consequence of progress in applying our knowledge of health promotion and disease prevention rather than improved clinical care.

Dr. William Frist, cardiologist and former US Senate Majority Leader, estimates medical care's impact slightly higher than the Massachusetts Health Policy folks, at 15 – 20%, saying

> Health is not health services. Health is behavior, it's genetics, it's socio-economic status, it's disparity, it's environment. Health services has about a 15 – 20% impact. [162]

We all know this but we forget it when we, ourselves, get sick or frightened. One reason, I submit, is that we have not been taught how best to use our medical care system. (Now *that's* an interesting value added role for brokers. Don't worry – I'll go into it in detail later.)

Here are some numbers to bolster my argument that 'more medical care isn't better for you'. Compare average medical spending per capita in various states with average longevity in those states. The assumption, of course: if more medical spending had a big impact, people who live in high spending states would live longer than people in low spending. That is not nearly the case.[163]

State	**$/capita 2009**	**Longevity at birth** 2013
Massachusetts	$9,278	80.5
Minnesota	$7,409	80.9

[161] Richmond and Fein, The Health Care Mess, pages 92 and 94

[162] CNBC Meeting of the Minds: The Future of Healthcare, broadcast in July 2009.

[163] Spending data from Kaiser Family Foundation. Longevity data from Measure of Americans. I used longevity data 4 years in the future to account for any potential health benefits of high 2009 spending.

Washington state	$6,782	79.9
Utah	$5,031	80.2
Mississippi	$6,571	75.0
Oklahoma	$6,532	75.9
West Virginia	$7,667	75.4

Good medical care doesn't necessarily lead to good health. Lots of other things are far more important.

By the way, based on the state data presented above, should a broker provide the same benefits advice in Minnesota and West Virginia? Or Massachusetts and Utah?

Faulty assumption #2: Lower deductibles and wider networks = better health insurance

Brokers and consumers too often equate better health insurance policies with lower deductibles and wider provider networks. Poorer policies have the opposite.

Unfortunately, there's no evidence - none that I've seen, at least, and I've looked - that lower deductibles or wider networks lead to better patient outcomes.

One reason for the faulty equation of wider networks with better policies: we have very poor outcome data by provider in this country. Lacking such data, consumers apparently prefer easier access to lots of (potentially mediocre) physicians and hospitals, figuring that one of them should be good in a crisis I guess.

Though we lack evidence that lower deductibles and wider networks lead to better patient outcomes, we have some evidence that lower deductibles and generous benefits can lead to patient harm. Here's Bernard Rosof, Chairman of Huntington Hospital in New York:

> Often people with generous insurance plans can run up large bills and face life threatening complications from unnecessary care. [164]

We also have extensive evidence that *better decision making* leads to better outcomes.

Faulty assumption #3: Newer technologies and medications are better

This is almost a mantra in this country: newer technologies / newer meds / robotic surgeons etc are better, so, when in doubt, get the newest.

This overlooks the fact that 'newer' is a very poor proxy for 'better'. Extensive evidence shows that *outcome based decision making*, not the newest shinny object, leads to better outcomes.

[164] More care is not necessarily better care, Connolly, Washington Post, 9/29/09

Consider Pradaxa, a newer blood thinner than warfarin, heavily advertised on TV and designed to overcome warfarin patient's need for excessive testing. Pradaxa's annual sales hover around $800 million. Its TV ads claim

> *In a clinical trial, Pradaxa was proven superior to warfarin at reducing the risk of stroke in patients with Afib not caused by a heart valve problem*

suggesting to the poorly informed, who don't know the right questions to ask or how to make outcome based decisions, that the newer drug was better. However…

In their legal settlement announced in May of 2014, Pradaxa paid **$650 million** to settle **4,000 claims** that company didn't adequately warn of risks including severe or fatal bleeding. (If death is a side effect, what's the main effect?) Unlike warfarin, there is no known reversal agent or antidote for Pradaxa.

Or consider robotic surgeries for hysterectomy patients. The da Vinci robot, approved by the FDA in 2005, is designed to generate better results and an easier recovery that traditional laparoscopic surgery, meaning less pain and fewer complications [165] all of which sounds great to the uninformed.

But a massive study of 264,000 women who had either laparoscopic or robotically assisted hysterectomies at 441 hospitals between 2007 and 2010 showed no benefits from robotic surgery when benefits are measured as complication rates or blood transfusion rates. The robotic procedures, however, cost about $2000 more. That's roughly 1/3 more.

Again an interest group, the robot manufacturers, benefited by making more money, while patients did not, at least in terms of enjoying better outcomes. Just higher costs.

The morale of these stories, and there are many more: *newer* isn't necessarily better in medicine. *More heavily advertised* isn't necessarily better. Instead *better* is better, based on outcomes from comparative studies. Well informed patients learn the right questions to ask and types of information to consider when evaluating their treatment options.

Faulty assumption #4: Publishing price lists will save money

Today, almost as an article of faith, brokers, carriers and healthcare consumers claim that knowing prices will save money. This is commonly called 'transparency' and the theory runs rampant among health insurance thinkers.

While I agree that a wise consumer should compare prices of similar quality products, then choose the least expensive to get the best value, I *don't agree* that simply publishing price lists will lead to any benefit, either systemic or individual. Remember:

[165] Rabin, Questions about Robotic Hysterectomy, New York Times, Feb 25, 2013

- You don't want the cheapest *unnecessary* care
- You also don't want the cheapest *poor quality* care
- You don't want cheap *inappropriate* care when slightly more expensive care might be preferable.

Let's consider tonsillectomies in northern New England. Here are tonsillectomy rates per 1000 children in various pediatric service areas during the period 2007 – 2010.[166]

Middlebury, Vt	5.6	Burlington, Vt	2.9
Berlin, NH	10.4	Lewiston, Maine	5.2
York, Maine	7.3	Portland, Maine	4.0
Presque Isle, Maine	5.8	Bangor, Maine	2.7
Dover, NH	8.1	Waterville, Maine	3.6
Manchester, NH	8.1	Ellsworth, Maine	3.8
Exeter, NH	8.4		

We know from these data that having about 3 tonsillectomies per 1000 children is appropriate, since there are no reports of kids in Burlington Vermont, Bangor Maine, Waterville Maine or Ellsworth Maine suffering poor health due to an insufficient number of tonsillectomies.

We also know that about 2/3 of tonsillectomies in Berlin New Hampshire, and half the tonsillectomies in York Maine are unnecessary since their tonsillectomy rates are so high.

Shopping for the least expensive tonsillectomy in Berlin or York leads to a bad medical care decision over half the time: people doing that get the cheapest unnecessary care. Imagine that your child has a bad reaction or needs a surgical re-do from an unnecessary tonsillectomy!

A far better approach is to learn the service quality and necessity first, and then, for two equally necessary services of similar quality, choose the least expensive. Don't put the cart before the proverbial horse.

Perhaps a better way to understand transparency is to consider the many types necessary to enhance good medical decisions. A wise patient would want access to transparency data addressing:

[166] These data come from the Dartmouth Atlas of Healthcare, Tonsillectomies per 1000 Children by Pediatric Surgery Area, 2007 – 2010. 'Pediatric service areas' are the geographical regions served by a specific pediatrician office. Kids in Burlington Vermont, for example, typically use Burlington pediatricians, not Berlin New Hampshire docs.

- Prices
- Treatment intensity as, for example, our tonsillectomy example above, or C-section rates by hospital, mastectomy rates by region or similar
- Clinical quality/ infection rates by provider and by treatment
- Treatment benefits
- Provider conflicts of interest

Providing only 1 may distort the message and lead patients away from making wise decisions rather than toward systemic efficiencies.

Another way to express this: homeowners who hire the cheapest plumber, framer, roofer, electrician and painter end up with the most expensive house that leaks. We tend to forget this when we consider healthcare prices.

Faulty assumption #5: Getting the least expensive care saves money

This variation on 'publishing price lists will save money' ignores a key factor in physician compensation: that doctors want to maintain their incomes and that time is their main inventory. When they receive less money per patient, they respond by seeing more patients.

This has negative, foreseeable but generally unforeseen consequences.

Dr. Sandeep Jauhar MD, PhD, and director of the heart failure program at Long Island Jewish Hospital, claims that 'there is no more wasteful entity in medicine than a rushed doctor'. [167] Because we're so rushed, he says, 'we order tests, prescribe drugs, hospitalize patients and — one of the costliest decisions a doctor can make today — call specialists for help' rather than explain to patients why some tests are unnecessary and specialist referrals inappropriate. 'Specialists in turn,' he says, 'order more tests, scans and the like.'

Cutting payments to physicians becomes a self defeating strategy.

Faulty assumption #6: Raising deductibles saves money

Deductibles, generally running about $1000 per year, are designed to act as a speed bump when patients consider medical care. Patients will spend their own money more wisely and frugally than they would spend the insurance carrier's money, according to the theory, thus avoiding unnecessary care and saving money.

Deductibles, unfortunately, act as a blunt instrument, perhaps doing more harm than good by failing to differentiate necessary from unnecessary medical care. Reducing

[167] Sandeep Jauhar, Busy Doctors, Wasteful Spending, New York Times, July 20, 2014

unnecessary care can, indeed, save money. But reducing *necessary* care can lead to poorer outcomes and higher costs.

Consider, by contrast, the French approach to deductibles. The French modify or exempt from cost sharing by **person** (disabled, elderly or sick), **treatment** (expensive, effective or necessary) and **medical condition**. The deductible is waived for people suffering from one of 30 'long and costly diseases' like cancer, severe chronic disease or long term psychiatric illness *for medical care is related to that condition*. But these people are still responsible for unrelated medical deductibles, say a broken leg or sprained ankle.

Our 'one size fits all' deductibles, by not differentiating among people, treatments or medical conditions sometimes actually add to costs rather than reducing them. One Medicare study showed that adding a modest copayment reduced the number of outpatient visits by about 20% per year.

But that came at the cost of 2 additional hospitalizations per 100 patients per year. The study conclusion, published in the New England Journal of Medicine:

> uniform increases in cost sharing for prescription drugs can have deleterious effects on health [168]

without reducing costs at all.

These faulty assumptions – and the system developed from them – lead to these types of conclusions by eminent scholars:

- American health outcomes among insured populations lag substantially behind those of other countries.[169]
- Americans at top income levels live longer than people at bottom income levels, *but less long than people at top income levels of other countries* [170] and
- Even the people most likely to be healthy, like college-educated Americans and those with high incomes, fare worse on many health indicators …[171]

Despite us paying more for medical care than any other country in the world!

---

[168] Trivedi 'Increased Ambulatory Care Copayments and Hospitalizations Among the Elderly, NEJM Jan 28, 2010

[169] Bradley and Taylor, The American Healthcare Paradox, page 9

[170] Gudrais 'Unequal America' Harvard Magazine July 2008 referring to research by Harvard Prof Majid Ezzati

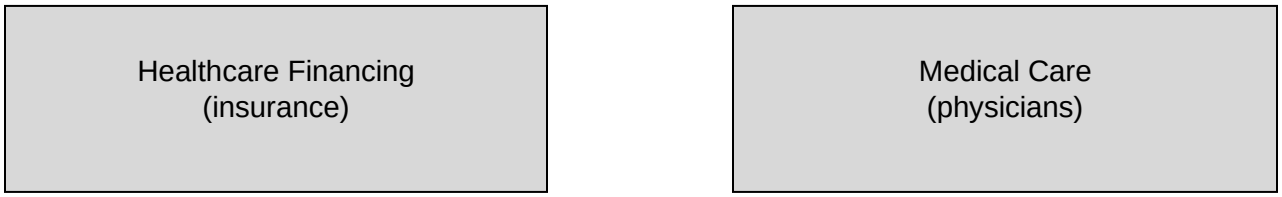
[171] For Americans Under 50, Stark Findings on Health, Tavernise, NY Times, Jan 9, 2013

The Fundamental Problem: Old School Thinking

Our systemic confusion and complexity has led to remarkable levels of specialization, not only in medical care but even in the brokerage community. Some brokers focus on Medicare, others on large group benefits, others on small group, some operate only in 1 state, others in many. Some agencies have wellness specialists, tax specialists and CDH specialists, others contract these functions out.

But few advise their clients about medical care issues, leaving that arena to physicians, often harried, often leading time compressed lives.

Our healthcare distribution system looks like is:



Two equally important but completely unrelated boxes. In the Old School, brokers provide financing programs while physicians provide medical care, but never the twain shall meet.

Brokers typically explain that they can't give medical advice because they're not trained or licensed to do this, which is, of course, true. **But I think they've conceptualized the problem incorrectly, relying more on superficial thinking than serious analysis.** Read on…

In the Old School 'nonintegrated' model, we expect physicians to address the following issues during an average 15 minute meeting with each patient:

- Patient's personal health status
- Disease diagnosis
- Treatment recommendations and alternatives
- Lifestyle issues and impacts on health
- Medication options, benefits and risks of each
- Individual risk factors and likelihood of future medical events
- Specific tests including benefits and risks of each
- Trends in medical care and new information since the patient's last visit
- Risks of having / not having specific tests or treatments
- Referral options *and more*

It's obviously very difficult to address all these issues satisfactorily in 2 hours, let along 15 minutes.

Five concerns about leaving all medical education to doctors

First, doctors respond to uninformed patient demand.

Studies show that about 1/3 of physicians would order a clinically unwarranted MRI if the patient demanded it, which raises patient risks without benefits since the MRIs in question are 'clinically unwarranted'. [172]

Many patients assume, as discussed above, that more medical care is better medical care, so a physician who doesn't prescribe a medication, test or treatment is a poorer physician.

Increasingly, physicians are compensated based on patient satisfaction survey results. Patients who believe 'more care is better care' penalize doctors who withhold painkillers, fail to prescribe a requested drug or test or skimp on referrals. This decreases the physicians' ability to counter the 'more is better' argument, even if they want to.

Studies show that, perhaps as a result of these factors, when faced with a potential screening test option, 95% of physicians recommended the screening test to their patients, and when faced with the option to prescribe medications, over 90% of physicians prescribed. [173]

Second, doctors respond to our legal / tort system, in which fear of malpractice lawsuits leads to excessive testing, Rx prescribing, excessive diagnoses and treatments. In one Gallup survey, physicians attributed 34 percent of overall healthcare costs to defensive medicine and 21 percent of their practice to be defensive in nature. Specifically, they estimated that 35 percent of diagnostic tests, 29 percent of lab tests, 19 percent of hospitalizations, 14 percent of prescriptions, and 8 percent of surgeries were performed to avoid lawsuits. [174]

Third, doctors get burned out so sometimes order tests, medications or treatments because it's easier than not ordering. One doctor described his interaction with a patient this way:

> *I could tell she wasn't happy. I decided that discussing the evidence would have been futile and I was too tired anyway*

Fourth, doctors pathologize or medicalize normal human behavior. Consider the patient who tells his doc 'I sometimes forget people's names in social settings.' Early stage dementia? (There's a drug for that). Social anxiety (There's a drug for that too.)

---

[172] O'Reilly, Patient satisfaction: when a doctor's judgment risks a poor rating, AMED News, November 26, 2012

[173] Data from presentation by Benjamin Moulton at Dartmouth's 2014 Summer Institute for Informed Patient Choice

[174] Hettrich, The Costs of Defensive Medicine, AAOS Now, December, 2010. AAOS Now is the Journal of the American Association of Orthopedic Surgeons

Or a normal human reaction to noise and social stimulation? (There may even be a drug for that but it's probably not necessary.)

Or the patient who went to the beach last weekend and tells his doc 'I love watching the women parade around in their bikinis.' Diagnosis: hyper-sexual disorder.

But the next patient, who went to the same beach, reports that 'I completely ignored all the women parading around in their bikinis.' (Low-T and, of course, there's a pill for that)

Pathologizing, of course, ties closely to malpractice issues described above as well as the problem of uninformed demand.

Fifth, physicians favor interventions. This is sometimes called 'supply sensitive care' which simply means that if medical technologies or interventions are available, physicians will use them.

This is also sometimes called Roemer's Law after Professor Milton Roemer who first discovered the relationship between medical supply and utilization in the 1950s. Roemer found that as more hospital beds are built in a community, more hospital beds are used. His law: a hospital room built is a hospital room occupied because physicians, whether consciously or not, tend to use all the medical resources at hand.

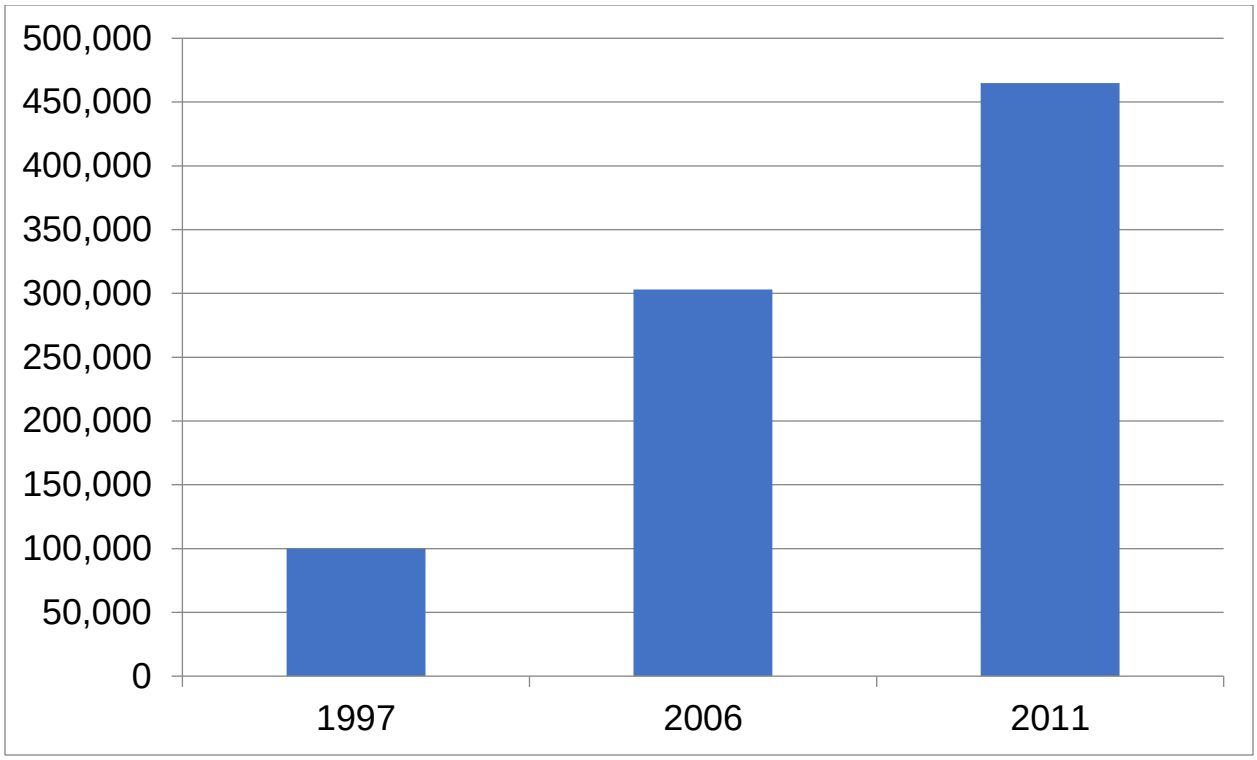
Let's apply Roemer's Law to radiologic scanners. Consider the growth of scans since the mid 1990s as more and more machines became available.

In 1966, Americans had about 52 MRI scans / 1000 people / year. But in 2010, we had about 149. Ditto CT scans: 17 per 1000 people in 1996 vs. 65 in 2010.

Note in passing the (non) impact of the internet on reducing medical care intensity. Google doesn't have much impact on reducing excessive or unnecessary care, despite most patients today claiming that they're 'well informed' since they do online research before engaging in medical care. Sorry, I don't buy it.

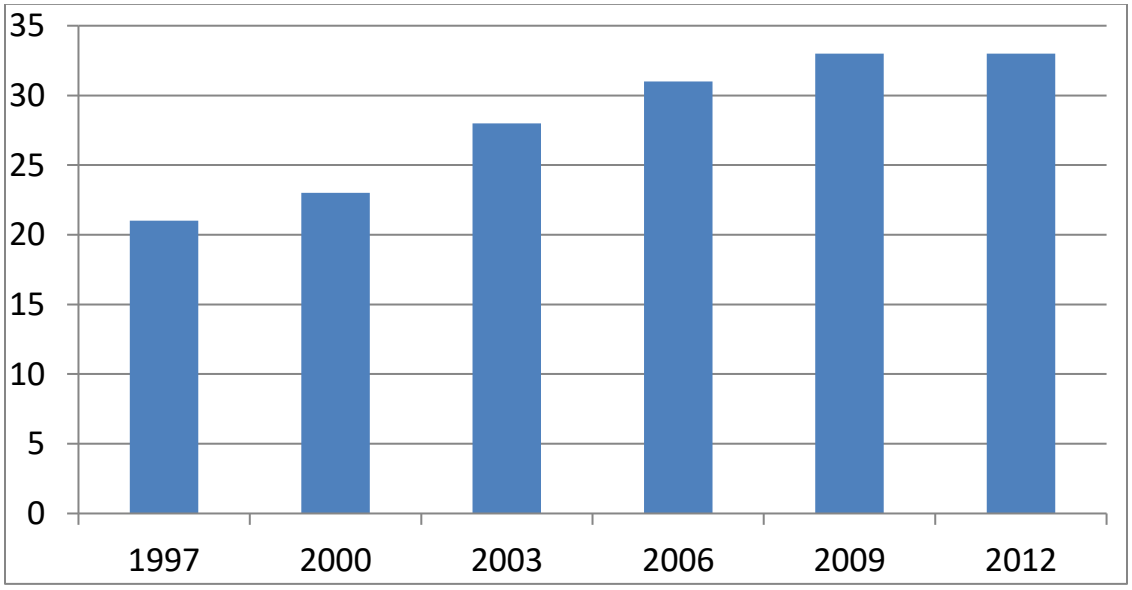
Now look at the impact of graduating more orthopedic specialists from medical schools:

Number of Spinal Fusion Surgeries
performed annually in the US



Since the mid-late 1990s, fetal oxygen sensors have become almost universally adopted in delivery rooms, despite the US Preventive Services Task Force not endorsing this technology in birthing. Fetal oxygen sensors identify stress on the fetus' heart and can lead to emergency C-sections. That's one of potentially many reasons for our increased rate of C-section deliveries since the mid-1990s.

Rate of C-sections
as percentage of all US births



Many more examples exist. But to summarize: Doctors face different financial, corporate and emotional pressures and incentives from the patients they advise. Here are some of those differences:

Physician Issues and Concerns	Patient Issues and Concerns
Success	Success
Fear of lawsuit	Pain
Fear of feeling guilty	Recovery process
Local / regional / hospital norms	Infection / readmission risk
Income and time constraints	Impact on family
Personal preferences (religion, experience, etc)	Personal preferences (religion, personal image, etc)

Asking ‘Doc, what would you do if you were me?’ tends to get answers from the Physician List, while patients worry about issues on the Patient List.

Doctors may also have different goals and risk tolerances from patients. Research suggests, for example, that 72% of oncologists advising early stage breast cancer patients rate ‘keeping your breast‘ a top goal while only 7% of patients do.

Meanwhile, 0% of oncologists rate ‘avoid using prostheses’ highly while 33% of patients do. [175]

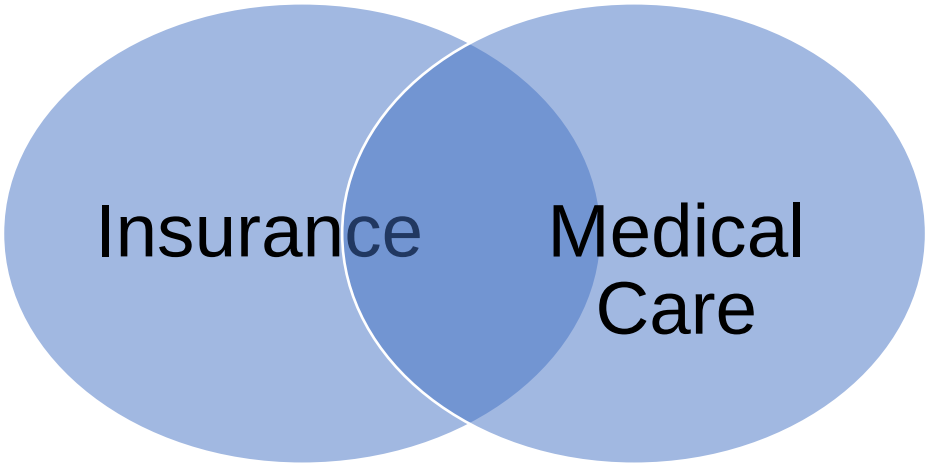
We have learned, over the past few decades, that leaving medical education entirely to physicians - even with a bit of online research - has led to healthcare inflation at approximately gdp + 3 to 5% with, unfortunately, poorer national statistics than other countries that spend less on medical care.

Splitting healthcare financing from healthcare delivery has been proven inefficient. It’s time to reconsider the Old School model.

New School: Integrating Finance and Care Delivery

Rather than continue with the ineffective Old School model, let’s introduce a New School approach.

[175] Data from presentation by Benjamin Moulton at Dartmouth’s 2014 Summer Institute for Informed Patient Choice



In the New School, financing and medical care overlap.

- Doctors understand networks, deductibles, plan designs and prices and *include them in treatment prescriptions.*
- Brokers understand medical terms, preference-sensitive decision making, outcome metrics, treatment intensity issues and *include them in plan designs*.

To do this, brokers need to understand and communicate 3 fundamental concepts to their subscribers:

- **Outcomes**, meaning how well does a medical intervention work. Brokers who help their clients focus on medical outcomes will help them avoid unnecessary medical care and choose higher quality care over lower.

  The best way to determine outcomes is from studies comparing patients who had a specific medical intervention with patients who did not. Other attempts to quantify outcomes are less robust, provide less good information and can lead to suboptimal medical decisions.

  We too often in this country, use proxies for outcomes. Proxies include ‘famous hospital’, ‘well known surgeon’, ‘well advertised medication’, or ‘game changing therapy’. Proxies may or may not correlate closely to actual patient outcomes.

  The important point for brokers to communicate to their clients: shop for medical care based on outcomes. They’ll enjoy better outcomes that way.

- **Process**, meaning *how* providers implement a particular treatment.

  Extensive evidence shows that some hospitals favor C-sections in situations that other hospitals do not, and that doctors in some regions routinely treat early stage breast cancer with mastectomies while doctors in others routinely prescribe other treatments. The Dartmouth Atlas of Healthcare has tracked these differences at hospital, regional and state levels for years.

One simple tool for brokers here: advise patients to ask their physician 'am I in a high or low intensity region / hospital for this procedure?' They can use that information when they obtain a second opinion.

- **Preference-sensitive**, meaning that two patients with similar diagnoses and prognoses may choose different treatments *and both be right*.

  This is, perhaps, the single most important issue in American medicine. Scholars ranging from Harvard Business School's Regina Herzlinger to Dartmouth's John Wennberg suggest that patients enjoy the best outcomes, often at the lowest costs, when they make well informed decisions. 'Well informed' means knowing the likely treatment outcomes (both benefits and risks), their process options (mastectomy or lumpectomy for example) and the prices.

  Laura Landro, writing in the Wall Street Journal, summarized the impact: [176]

  Studies show that when patients understand their choices and share in the decision making process with their doctors, they tend to choose less-invasive and less expensive treatments than they would otherwise have received.

The broker's educational role in this New School paradigm is to inform patients that they have choices and help them access key information to make wise choices; it is **not** to give specific medical advice.

My Proposed Decision Making Tree
that integrates clinical and insurance information

Brokers and benefits advisors can teach people to use this Decision Tree. It can organize your thinking and ensure that you address the key issues in making your medical decisions.

First identify the most likely benefits and risks of a particular medical intervention and the chance of each. Ask 'do the likely benefits of this medical intervention outweigh both the treatment risks and doing nothing?'

I you answer 'no, the likely benefits do not exceed the risks and are not better than doing nothing' then stop.

But if you decide that the likely benefits exceed the risks, continue.

Second identify your intervention options. You almost always have them. You can have surgery or physical therapy for example, take a brand name medication or generic, have an injection or take a medication, change your diet or take a pill.

[176] Laura Landro, Weighty Choices in Patient's Hands, Wall Street Journal, August 4, 2009

Decide which process you prefer. Research shows that different processes often generate similar outcomes. There's often no objectively right or wrong process decision. Rather these are personal choices or preference-sensitive decisions.

Third decide which provider generates the best outcomes using the treatment process you prefer. Some orthopedic surgeons may generate better spinal fusion surgical outcomes than others; some physical therapists better knee pain reductions.

Provider outcomes often – though not always – correlate with experience. The more shoulder surgeries a surgeon performs, the better his/her shoulder surgery patients tend to do.

If you can't determine actual outcomes by physician, use volume or experience with patients like you as a responsible proxy. Though not perfect, it can lead you in a positive direction.

Fourth, if two providers generate the same outcomes using the process you prefer, consider price.

Be sure to consider price 4th, only after you've determined that an intervention is likely beneficial, that you're getting the process you prefer and that you've chosen the best provider available.

Follow this 4-step process and you'll likely end up with better outcomes, be more satisfied with your care and perhaps even save some money along the way.

America's research community is developing tools to help patients with these tasks.

The Affordable Care Act on Decision Aids and Shared Decision Making

Section 3506 of the Affordable Care Act or Obamacare addresses Decision Aids and the Shared Decision Making process. The goal is to engage patients in *informed* decision making with healthcare providers.

Decision Aids are **tools** that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes. Decision Aids are not simply articles describing how a medical treatment works but without quantifying likely benefits and harms; that's an encyclopedia, not an Aid.

Shared Decision Making, on the other hand, is a **process** in which patients and their physicians decide together how to proceed. Unlike the old school paternalist model in which physicians *tell* patients which treatment to have, in the Shared Decision Making model physicians *help patients decide* which treatment option best suits their goals.

Shared Decision Making acknowledges that about 85% of medical decisions are 'preference sensitive', meaning the patient has more than 1 reasonable option and that two different patients suffering from the same medical condition can make different treatment decisions but both be right.

This may seem intuitively obvious to many. Unfortunately, research shows that physicians only discuss alternatives with patients about 14% of the time, and only about 9% of physicians inform patients that they have choices. [177] As a result, the impetus to inform patients that options exist most of the time may fall on the insurance community.

Decision Aids and Shared Decision Making also implicitly acknowledge a new vision of the physician's role. The ideal modern physician, suggests Dr. Atul Gawande of Harvard Medical School insightfully

> should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them. [178]

This means patients need to learn basic outcome and intensity information outside the doctor-patient framework and opens a new, and potentially role redefining opportunity for brokers and carriers.

A Decision Aid Example

Decision Aids, currently under development at several medical schools and institutions, provide outcome data quantifying risks and benefits of medical interventions.

Consider the Number Needed to Treat. This tells how many people need to take a medication, have a test or have a treatment for 1 person to benefit from it.

The NNT acknowledges that medicine doesn't work perfectly, equally well on all people, all the time. But various interventions work - to paraphrase Abraham Lincoln - on some of the people, some of the time. The NNT tells how often, so how likely you are to benefit from a particular intervention.

The most comprehensive source of NNT information is a website entitled, not surprisingly, TheNNT.com.

Here's an example: 18 adults suffering from acute sinusitis need to take a course of antibiotics for 1 to benefit by having a faster resolution of symptoms. [179] The Number Needed to Treat for adults with sinusitis to benefit from antibiotics is 18.

Another example: 5 kids suffering from the croup need to take steroids for 1 to enjoy respiratory improvement. The NNT here is 5.

Some more NNT examples [180]

---

[177] Benjamin Moulton, op. cit.

[178] Sheri Fink's review of Atul Gawande's Being Mortal, New York Times Book Review, November 6, 2014

[179] http://www.thennt.com/nnt/antibiotics-for-clinically-diagnosed-acute-sinusitis/

[180] This chart appeared in BusinessWeek, January 2008.

Knowing the NNT can help patients in two different ways:

- First, patients can decide if a medical intervention works well enough to have. An NNT of 300, for example, make work so poorly – in your opinion – that it's not worth having.

  But an NNT of 2 works so well that you may decide to have this treatment.

- Second, the NNT helps patients decide which intervention works better. The lower the Number Needed to Treat, the better the medication intervention works.

How to determine the Number Needed to Treat

Researchers compare two similar groups of people, as alike as possible, except that one group gets the medication while the other does not. This comparison study identifies the medication as the independent variable. Researchers then note the outcomes from both groups and quantify the medication's impact.

That helps explain why the NNT numbers above seem so high: most adults recover from sinusitis and most kids recover from croup even without medication.

TheNNT.com lists dozens of medical interventions.

A second type of Decision Aid

ChoosingWisely, an initiative of the American Board of Internal Medicine Foundation, invited dozens of specialty medical associations to list *5 Things Patients and Doctors Should Question*. The ABIM Foundation then posted these lists on a website called ChoosingWisely.

Here are 3 examples from the hundreds listed:

- *Don't do imaging for low back pain within the first six weeks, unless red flags are present*, a recommendation of the American Academy of Family Physicians.

  The Family Physician Academy's justification: Imaging of the lower spine before six weeks does not improve outcomes

- *Don't indiscriminately prescribe antibiotics for uncomplicated rhinosinusitis*, a recommendation of the American Academy of Allergy, Asthma & Immunology.

  The Allergy, Asthma & Immunology Academy's justification: Viral infections cause the majority of acute rhinosinusitis and only 0.5 percent to 2 percent progress to bacterial infections.

  Most acute rhinosinusitis resolves without treatment in two weeks.

- *Don't perform annual stress cardiac imaging as part of routine follow-up in asymptomatic patients*, a recommendation of the American College of Cardiology.

The College's justification: Performing stress cardiac imaging or advanced non-invasive imaging in patients without symptoms on a serial or scheduled pattern (e.g., every one to two years or at a heart procedure anniversary) rarely results in any meaningful change in patient management. This practice may, in fact, lead to unnecessary invasive procedures.

As of January, 2015, some 63 medical associations participated in the ChoosingWisely campaign, posting more than 300 treatment recommendations.

Other Decision Aids exist and are being developed all the time.

Decision Aids help focus doctor-patient discussions. No longer need patients argue about anatomy and physiology. Instead, doctors and patients can interpret Decision Aids together and discuss treatment outcomes and processes – far more fruitful discussions.

Decision Aids: necessary for Shared Decision Making

The Decision Aids listed above – and others - are a necessary step toward true patient involvement in medical decisions. 'Involvement' is sometimes called 'Shared Decision Making' in which patients and doctors together decide how to proceed.

Decision Aids are tools; Shared Decision Making is a process. Both work together.

How impactful are Decision Aids and Shared Decision Making?

Research presented at the Dartmouth Summer Institute for Informed Patient Choice, Hanover New Hampshire, June 2014 shows the following:

- Patients with stable coronary angina who used Decision Aids and engaged in Shared Decision Making with their physicians, were 20% less likely to choose stent insertion than patient who did not so engage
    - Absent Decision Aids, 88% of patients thought stents would help them
- Patients suffering from hip or knee arthritis were 25% less likely to choose hip or knee replacement after viewing Decision Aids
- Back pain patients with herniated disks opted for spinal fusion surgery30% less frequently
- Men diagnosed with early stage prostate cancer were 50% more likely to choose 'watchful waiting' than more invasive treatments.

Using Deductibles and HRAs with Decision Aids

The broker can now evolve from CHD version 1, deductibles with some tax benefits, to CDH version 2, deductibles that can incorporate consumer education into a true employee engagement / benefits program.

To move successfully from CDH 1 to CDH 2, brokers need to incorporate three components into their programs:

- Content
- An employee communication program, and
- Plan design incentives

Let's brainstorm, first with a radiology education program:

Consumer Engagement Example: Radiology

Incentive: $25 per employee to complete the following educational module. Then, $50 toward the out-of-pocket costs if an employee decides to have a back MRI.

Module content: Low back pain is the fifth most common reason for physician visits. This brief tutorial can help you *benefit* from your physician visit and *avoid unnecessary costs and medical harms.*

Medical research shows that getting an X-ray, CT scan or MRI shortly after the pain begins rarely helps since most people feel better in a month or so with or without the scans.

But imaging raises costs and risks of unnecessary care:

- Lower back MRIs cost about $1000
- CT scans about $1200
- X Rays about $250

One study found that back-pain sufferers who had an MRI in the first month were *eight times more likely* to have surgery, and had a *five-fold* increase in medical expenses—but didn't recover faster.

The excess imaging problem is that people both with and without back pain can show similar imaging results, meaning an identified abnormality in the test may not be the cause of your pain.

Once identified however, abnormalities need further evaluation. This can subject patients to costs and treatments which are often unnecessary since they don't speed recovery.

Review Questions:

1. How common are visits to the doctor due to back pain?
    - Uncommon

- Very common. Back pain is the 5th most common reason for physician visits

2. If you have back pain, should you automatically, immediately get an imaging exam, like an MRI, CT scan or X-ray?
    - Yes, as soon as you feel any kind of back pain
    - Maybe not, since people who have imaging tests don't seem to get better medical results than people who wait before having the test
3. About how much does a lower back MRI cost?
    - About $20, my radiology co-payment,
    - About $1000 on average

Content continues: Some medical organizations recommend *against* imaging tests for back pain within the first month.

The American Academy of Family Physicians, representing 105,000 primary care physicians advises:

- Don't do imaging for low back pain within the first six weeks, unless red flags are present.
- Imaging of the lower spine before six weeks does not improve outcomes, but does increase costs.

The North American Spine Society, representing 7500 doctors, advises:

- Don't have advanced imaging (e.g., MRI) of the spine within the first six weeks for non-specific acute low back pain in the absence of red flags.
- In the absence of red flags, advanced imaging within the first six weeks has not been found to improve outcomes, but does increase costs.

The American College of Physicians, representing 126,000 physicians, advises:

- Don't obtain imaging studies in patients with non-specific low back pain.
- In patients with back pain that cannot be attributed to a specific disease or spinal abnormality, imaging with X-ray, CT scan or MRI does not improve patient outcomes.

The American Society of Anesthesiologists – Pain Medicine, representing 50,000 members who advocate for patients in pain, advises:

- Imaging for low back pain in the first six weeks after pain begins should be avoided in the absence of specific clinical indications

- Most low back pain does not need imaging and *doing so may reveal incidental findings that divert attention and increase the risk of having unhelpful surgery*.

Review Questions:

1. Do many medical professional organizations recommend that you wait 4 – 6 weeks before having a back imaging test, or have the test immediately upon feeling pain?
    - Wait 4 – 6 weeks unless specific red flags are present
    - Have the test immediately
2. Why do several medical professional organizations recommend waiting 4 – 6 weeks before having an imaging test?
    - To reduce patient costs and risks
    - To harm patients

Here are some Red Flags:

- a history of cancer or unexplained weight loss,
- fever or recent infection ,
- loss of bowel or bladder control,
- abnormal reflexes or loss of muscle power or feeling in the legs.

And here are some Key Questions to ask your doctor:

- Do you agree with the recommendations from the American Academy of Family Physicians and others that I wait 6 weeks before having a scan for my back pain?
    - If not, why not?
    - Do you think those recommendations apply to me?
- Do you worry that back imaging tests may incorrectly identify the cause of my back pain?
- Do I have the red flags listed above?
- And What other therapies do you recommend?

Many more Decision Aids and Educational Modules exist

Research organizations are continuously developing Decision Aids about the major healthcare cost drivers. A short research project will identify some of these for you. That’s the easy part.

The hard part is integrating the clinical information with insurance plan designs. Though difficult, it's necessary if brokers want to change the Zywave reported client satisfaction numbers:

- Creates strategic plan that aligns with company goals: **43% unsatisfied**
- Offers employee benefits and consumerism communication / education: **41% unsatisfied**
- Assists with creating or maintaining a workplace wellness program: **66% unsatisfied**

Brokers face a dilemma: whether to remain in their comfort zone which we call CDH version 1, providing spreadsheets, products and compliance services or move to CDH version 2 that integrates financial and clinical considerations into plan designs.

I encourage anyone who has read this chapter to consider: If you were a client, would you prefer a broker who engaged in traditional insurance brokerage or who integrated clinical education into plan designs?

I'd also encourage people to consider their own history: Are you satisfied with health insurance trend and utilization rates?

I suggest that if you consider these two questions, your path forward becomes clear.

Robert Frost articulated the options poetically:

> Two roads diverged in a wood and I –
>
> I took the one less traveled by,
>
> And that made all the difference

Review Questions

Answers on next page

1. One consequence of having employer based health insurance as the central mechanism of financing medical care in this country is the development of various 'fill in' programs for non-employed people. Examples include Medicare for elderly people and the Veteran's Healthcare Administration for military veterans, each with its own eligibility requirements, access criteria and payment programs. About how many such major programs exist in the US?

a. 1
b. About 6
c. About 295
d. About 13,500

2. We have two different definitions of 'well informed consumer'. The health insurance industry defines a well informed consumer as one understanding deductibles, network restrictions, referral requirements and similar. How does the medical industry define well informed consumer?

a. The same way, someone who understands deductibles, network restrictions and referral requirements
b. As someone who understands how well medical care works
c. As someone who has read lots of books about medical care
d. As someone who uses google to research their treatments

3. Can we usefully separate healthcare *financing* from healthcare *service* provision?

a. Yes. A professional broker, for example, only need describe the insurance policy to provide a complete service to his/her customers
b. No. We cannot usefully separate healthcare financing from service delivery. Every attempt to do that has resulted in higher costs and poorer outcomes
c. Sometimes. We can usefully separate financing from service deliveries for orthopedic conditions but not for cardiovascular
d. Sometimes. We can usefully separate financing from service deliveries for acute conditions but not for chronic

4. What is the best way to determine a medical care outcome?

a. From a comparative test, one that compares a group of people who had a specific medical intervention with a similar group that did not
b. By reviewing the relevant biological information
c. By reviewing the relevant anatomical information
d. By reviewing the relevant genetic information

5. What does 'preference sensitive' mean in medical care?

a. That one patient may prefer one treatment process while another, similar patient may prefer something different and that both patients can make the right decisions
b. That some people prefer one physician while others prefer someone else
c. That some physicians prefer one type of patient while other physicians prefer a different type
d. That some patients may prefer one hospital while others prefer a different hospital

6. What is the Number Needed to Treat?

a. The number of patients who need to have a treatment for one to benefit
b. The number of doctors who need to perform a surgery for 1 to get it right
c. The number of patients a doctor needs to treat in order to have one patient benefit from his/her care
d. The number of surgeries a hospital needs to host to get optimal outcomes

7. What are Decision Aids?

a. Decision Aids are tools that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes.
b. Techniques that can aid a physician who needs to make an important decision
c. Surgical tools to help hospital residents make better use of their time
d. Computer programs that determine the optimal treatment protocol for a specific patient

8. Which, below, is NOT a credible decision aid?

a. TheNNT
b. ChoosingWisely
c. The US Preventive Services Task Force
d. Brochures developed by Pfizer, the manufacturer of Lipitor, that explain the benefits of taking statins

Review Questions

Correct answers in bold

1. One consequence of having employer based health insurance as the central mechanism of financing medical care in this country is the development of various 'fill in' programs for non-employed people. Examples include Medicare for elderly people and the Veteran's Healthcare Administration for military veterans, each with its own eligibility requirements, access criteria and payment programs. About how many such major programs exist in the US?

a. 1
b. About 6
c. About 295
d. About 13,500

2. We have two different definitions of 'well informed consumer'. The health insurance industry defines a well informed consumer as one understanding deductibles, network restrictions, referral requirements and similar. How does the medical industry define well informed consumer?

a. The same way, someone who understands deductibles, network restrictions and referral requirements
b. As someone who understands how well medical care works
c. As someone who has read lots of books about medical care
d. As someone who uses google to research their treatments

3. Can we usefully separate healthcare *financing* from healthcare *service* provision?

a. Yes. A professional broker, for example, only need describe the insurance policy to provide a complete service to his/her customers
b. No. We cannot usefully separate healthcare financing from service delivery. Every attempt to do that has resulted in higher costs and poorer outcomes
c. Sometimes. We can usefully separate financing from service deliveries for orthopedic conditions but not for cardiovascular
d. Sometimes. We can usefully separate financing from service deliveries for acute conditions but not for chronic

4. What is the best way to determine a medical care outcome?

a. From a comparative test, one that compares a group of people who had a specific medical intervention with a similar group that did not
b. By reviewing the relevant biological information
c. By reviewing the relevant anatomical information
d. By reviewing the relevant genetic information

5. What does 'preference sensitive' mean in medical care?

a. That one patient may prefer one treatment process while another, similar patient may prefer something different and that both patients can make the right decisions
b. That some people prefer one physician while others prefer someone else
c. That some physicians prefer one type of patient while other physicians prefer a different type
d. That some patients may prefer one hospital while others prefer a different hospital

6. What is the Number Needed to Treat?

a. The number of patients who need to have a treatment for one to benefit
b. The number of doctors who need to perform a surgery for 1 to get it right
c. The number of patients a doctor needs to treat in order to have one patient benefit from his/her care
d. The number of surgeries a hospital needs to host to get optimal outcomes

7. What are Decision Aids?

a. Decision Aids are tools that present clinical evidence of risks and benefits of treatment options; they focus on likely outcomes.
b. Techniques that can aid a physician who needs to make an important decision
c. Surgical tools to help hospital residents make better use of their time
d. Computer programs that determine the optimal treatment protocol for a specific patient

8. Which, below, is NOT a credible decision aid?

a. TheNNT
b. ChoosingWisely
c. The US Preventive Services Task Force
d. Brochures developed by Pfizer, the manufacturer of Lipitor, that explain the benefits of taking statins

Issue 4: Risk Management Overview

This chapter was originally written as the introduction to a book on the history of medical education by Andy Lazris, a primary care physician in Maryland. My thanks to Dr. Lazris for allowing me to include it here.

It was a chilly fall day in Baltimore, 1911, and Abraham Flexner was preparing for his meeting with William Welch. He meticulously parted his thinning, dark hair that sat on a long and stern face, barely cracking a smile. He slipped into his dark suit and wide tie, and then trod over to the kitchen for a cup of black coffee. He stood tall at just over six feet. He Semitic features were somewhat obscured by a bushy mustache that was curled at its edges. He wore small wire spectacles over his beady black eyes. He was neither engaging nor distant; he seemed to exist is a space all his own, and, as his friends and enemies often said, he lived within his own perception of reality. In a mere year, this former minor educator vaulted himself to fame and prominence, taking the entire medical world by storm. He understood the significance of his accomplishments and his new-found worth, and today he hoped to transform that into something that would forever alter American health care.

His hotel sat just outside the Johns Hopkins medical campus, in a well-manicured area of East Baltimore well beyond the stench of its more industrial harbor. Here there was a mix of poverty and wealth, and the Johns Hopkins Hospital, an innovative leader in medical education, had catered to both, transforming itself into the beacon of American medical excellence. Flexner himself had graduated from Hopkins many years ago with a degree in education. He obtained his diploma in just two years before moving to Indiana to establish a school. His brother, Simon, was a prominent doctor on staff, a man who had gained fame in discovering a bacterial infection that still bears his name. Now Abraham even eclipsed Simon in fame; William Welch, Johns Hopkins Hospital's president and a pathologist on staff, sought to meet with him to discuss perhaps the most significant change that the medical school, and all of American health care, would ever incur.

To Abraham Flexner, who believed in process and order, it was going to be just another day. One year earlier he had penned a comprehensive report sponsored by the Carnegie Foundation that scrutinized all of the nation's medical schools and picked winners and losers from among them. For Flexner and his allies, the report that would ultimately bear his name was the first requisite step in professionalizing and standardizing not only medical education, but the entire field of American health care. This was the culmination of work from the American Medical Association (AMA), an organization that had been fighting for half a century to gain control over the training and practice of doctors. Now with Flexner's report, the AMA, whose prior work had spurred Flexner's findings, put itself in a position to be the final arbiter regarding what a school must prove to be worthy of graduating "credentialed" physicians. Many schools did not make the cut and quickly died a natural death. Many doctors—women, blacks,

alternative practitioners, those without certified education—lost their ability to practice medicine. In an instant, because of Flexner, the entire medical landscape changed.

Flexner believed that it was about time that American health care followed the European example and adapted a rigorous scientific approach to education. And it was at Hopkins he hoped to drive in the first stake of a grand new program of reform. As he finished his single slice of toast and coffee, Abraham Flexner prepared to meet with Welch, an ally of his, and the most powerful man at Hopkins since Sir William Osler retired. Doctors Welch and Osler had personal enmity for each other and proclaimed very different visions about what health care, and specifically Johns Hopkins' mission, should encompass. One of American's premier medical institutions, Johns Hopkins stood at the forefront of the medical world, but both Welch and Flexner knew that it could be even better. With Osler gone, and with both Flexner's report and the promise of large amounts of corporate money in his back pocket, Dr. Welch now could do as he had always hoped. He would conspire today with Abraham Flexner to transform Johns Hopkins from a clinical institution that taught students how to care for patients to the nation's most prominent research facility, replacing clinical staff with full time scientists, and instituting a rigid curriculum for students that emphasized a pursuit of pure science, a curriculum (based on Flexner's recommendations) ultimately that every credentialed school would be compelled to follow, and one that largely has remained intact even today.

To exorcize the ghost of William Osler from Hopkins, Welch needed money and a template, and on this day in Baltimore, Abraham Flexner was prepared to offer him both. Now working for the Rockefeller Foundation, Flexner promised Welch with enough money to hire full-time research faculty, increase lab facilities, and institute a rigorous 4-year scientific curriculum. With Osler gone, William Welch could have his way.

Osler had established a program of clinical instruction, in which community physicians like him and his colleagues trained Hopkins students. As Osler said, "Medicine is learned by the bedside and not in the classroom. Let not your conceptions of disease come from words heard in the lecture room or read from the book. See, and then reason and compare and control. But see first." Osler not only reformed Hopkins and transformed it into a premier medical institution through his novel bedside patient-centric approach to teaching, but he did it with part-time instructors who were actual doctors and made their living by seeing patients. While he valued research and teaching, he believed that both were subservient to an education obtained in the real world by working with real patients. "He who studies medicine without books sails an uncharted sea," he said. "But he who studies medicine without patients does not go to sea at all." Osler never did any research on his own; he published books and gave lectures around the world about how to take care of patients, and how to raise a new class of physicians who would be expert in patient care. Hopkins was his grand laboratory for change.

William Welch despised Osler and sought to move Hopkins away from the community and into the lab. As a pathologist and a disciple of the scientifically-oriented German school of thought, he believed that clinical teachers were no more than greedy hacks who would sully students and prevent them from achieving medical greatness. Osler held sway at Hopkins, at least while he remained. But once he retired, his hand-picked clinical colleagues lacked the influence to maintain Osler's vision. Welch slowly drove them out, one by one, replacing them with scientists. When Flexner approached him with money and new method of education—one that Welch himself help to formulate through his position at the helm of the AMA—Welch now had the power and authority to entirely expunge Osler's stamp from Hopkins. He hired full-time faculty and fired all the clinical staff, including many of Osler's friends. Students now received their education in the class, in labs, and on the wards, not with patients in the community. They were taught by doctors who did not practice medicine but who merely read and researched it. All of this happened rapidly once Welch and Flexner shook their hands and made a deal on that chilly fall day in 1911. Hopkins was entirely transformed, and a new epoch of medical education began.

But 3500 miles west in London, Sir William Osler was fuming mad. A man known for his biting wit, his sardonic insults, and his medical genius, Osler had laid the path of modern medicine in America through his teaching and writings. Now, with Flexner's report taking root at Hopkins and elsewhere, all that he held dear was being threatened by the very man now glibly eating a piece of toast in Osler's city of Baltimore, a man who knew nothing about patients or medical care, a man prepared to exterminate all that Osler had accomplished for his profession by allying with no other than Osler's nemesis, William Welch. So, Osler wasted no time; he found his allies and used his influence to save the very field and institution to which he had devoted his life.

The struggle between Osler and Flexner set medical education and the entire health care industry on a trajectory that continues to this day. Not much has changed since the battle ended. One of the men continues to be quoted and well known, although his ideas have evaporated from our medical horizon. That is William Osler, whose books and innovations are thought to have initiated the birth of modern medicine, but whose soul was permanently shattered by the battle that commenced. The other was Abraham Flexner, a man known to very few, neither a physician nor a person with any knowledge about health care, but one whose report on medical education stamped a template upon medical care in America that we use even today. Its message is the very antithesis of what William Osler had so passionately advocated, and the changes it sparked transformed health care from a field devoted to the patient, as Osler so desperately endorsed, to one devoted to science alone and to the corporate foundations that funded scientific pursuits. And when we look at the proliferation of low value medical care today, at the trillion dollars of health care money that is squandered every year on medical interventions that help no one, at the generic medical school curriculum that emphasizes rote memorization and irrelevant sciences instead of critical thinking and patient-centered care, we owe all of that to Flexner. Osler's vision was just the

opposite of what we have today. And upon Osler's ashes, the medical system took a jagged turn and went far off course.

Medical care in America sat on a precarious spire through the latter part of the nineteenth century. Most medical schools were diploma mills with few standards, and those who could pay were able to obtain a degree. Hundreds of such schools were scattered across the country, producing far too many doctors as was necessary. (B12) Educated people typically eschewed the medical field; a survey in 1851 showed that from top colleges 26% of students became clergymen and lawyers, and only 8% became doctors. The salaries were low and the competition for patients fierce, a situation that remained in tact at least until 1900. (G82-4) The result were poorly trained doctors who held no mastery of their skills. A popular book in the 1880's, *The Physician Himself*, by DW Catheell, encouraged doctors to be more concerned with showing an image of competence rather than actually being competent. According to Paul Starr, "Cathell's guide reflects the exceptional insecurity of the 19th center doctors, their complete dependence on their clients, and their vulnerability to competition from laymen as well as colleagues." (g86-8)

In many ways to counter the beleaguered state of health care, a group of physicians in 1846 started a small organization called the American Medical Association (AMA). Meeting in New York, these doctors orchestrated a national organization whose goals were to raise and standardized medical degrees with the aim of improving the caliber of practice, decreasing the physician pool, and increasing doctor salaries. Throughout the century, the AMA met only once a year and remained small, exerting most of its influence on state medical societies. By accommodating with other forms of medical practitioners, especially homeopaths and eclectics, and by becoming a confederation of local medical societies instead of a top-down voice of change, the AMA gained members and influence. It also consolidated medical licensing state by state, (G90-112) setting standards by which physicians would be required to practice. This went a long way toward creating a set of licensed doctors would could now distinguish themselves from the mass of untrained practitioners dotting American's medical landscape.

The AMA's rise was not beneficial for all physicians, nor necessarily for patients. African-American doctors, unwelcome in many local medical societies, became marginalized, unable to obtain credentials. Similarly, women and doctors who practiced non-orthodox medical care, such as chiropractors, were excluded from those able to be credentialed. At this juncture, the AMA never elucidated a vision of health care that encompassed science and patient-centered care as the core of a viable medical system; its concrete objectives were much more nuanced and vague. It essentially was more a trade association that imposed laws and restrictions that were favorable to its members. Only in 1900 did it begin to see the advantage of "touting itself as a promotor of scientific education" to advance its agenda. (H2-3) In fact, even as late as 1906, the AMA promoted a pharmaceutical policy that on the surface sought to remove

sham drugs from the market, but in reality promoted a regulatory system to “withhold information from consumers and re-channel drug purchasing through physicians.” (G129-32) The ultimate intent of the AMA was not necessarily to improve the drug market, but to make sure that doctors have control over it, so as to increase the power of physicians in health care delivery.

But one ingredient was essential for the AMA and its licensed physician members to improve their status: better control of medical education. And that is the crux of the Flexner – Osler conflict. As long as medical schools remained unregulated, as long as they could proliferate without any rules or standardization, as long as diploma mills and substandard schools could produce large numbers of poor physicians, then American doctors could not achieve the status, money, and exclusiveness that the AMA sought. And as long as the AMA did not directly control the apparatus of medical education, then the less its influence would be over the health care delivery system. The AMA sought to cultivate a landscape with fewer schools training fewer doctors that were directly controlled by the AMA’s regulatory system. To that end, in 1904 the AMA established a council of medical education, formulating minimal standards that should be implemented in all medical schools. In 1906 it inspected all 160 medical schools and made judgments about which ones (82 in all) met minimal standards. But it kept its findings secret, fearful that any judgment it imposed on medical schools would be viewed as being self-serving, (G11-18) which of course it was.

To appear more objective, the AMA commissioned the Carnegie Foundation essentially to repeat its survey of medical schools and render an opinion about which schools met standards, so as to get “independent and presumably disinterested support for its efforts.” (B73) By 1908, when the AMA sanctioned this second survey, medical education had already been improving on its own, primarily due to state regulations and also the high cost of providing of running a school. The 450 schools training doctors in the late 1800’s had already been whittled down to 150. Many schools were already undergoing reforms to improve themselves. Many other schools remained marginal; they did not have any lab equipment or hospital affiliations, some even had sparse curricula and were situated in one room homes. 60% of schools did not have requirements for admission, only an eighth of the schools required two years of colleges, and many remained for-profit institutions. (B70-1) The Carnegie Foundation, led by Henry Pritchett, had similar concerns about medical education as the AMA, so their collaboration made sense. (B 73)

Many in the Carnegie Foundation touted the German model of medical education as a good template upon which any recommendations should be made. German schools utilized a hard science curriculum; students were well versed in chemistry, physics, biology, and math, and this provided the crux of their education. Labs and classroom work constituted requisite ingredients of education; clinical experience was far less important. The goal was to develop a very rigid science-based curriculum that would be the same in every American medical school without variation, emphasizing lab science,

qualifiable data, and a view of disease as a scientific entity that was not patient-specific. (I598) To orchestrate and implement the survey, Pritchett chose Abraham Flexner, an unknown former educator, a man with no medical training or background, but someone who adhered to the German model. Flexner also had a famous physician brother at Johns Hopkins, and the Carnegie Foundation had very close ties to that school and its president, William Welch. Welch, a pathologist, had transferred Hopkins into a living example of the model medical school that Carnegie and the AMA espoused.

But why Flexner? Why not a medical doctor or someone privier to the controversies in medical education? Or even someone who had set foot in a medical school? According to one source, Pritchett's hiring of Flexner was "one of the strangest appointments in education history." But Pritchett was counting on the AMA to lead the actual effort, with Flexner being more of a figurehead who followed the AMA roadmap. (B68) But Flexner was not a type of man who liked to be directed. As someone who had lived in Germany, who graduated from Hopkins, and who had experience in education, he had very established ideas about what he hoped to achieve with his survey. He made very profound decisions about many schools by only spending a few hours studying them. After consulting with doctors from Hopkins and others in the AMA, his report would do more than just set standards for medical schools; it would profoundly alter the very foundation of American medical education and practice, a legacy we will live with today, over 100 years later.

Who was Abraham Flexner? Born in Louisville, Kentucky in 1866 he was a son of Jewish German immigrants. He received a Bachelor of Arts at Johns Hopkins after only two years. He moved back to Kentucky where he founded an experimental school based on the German model, a school that ultimately failed. He met his wife, Annie Crawford, a former student in his school, and she ultimately became a successful Broadway playwright, bringing the couple to New York. Buoyed by her income, he then studied psychology both at Harvard and at the University of Berlin, never receiving a degree. While in Germany he was influenced by Fredrich Paulsen, a leader of the German school system, who believed that American education was not sufficiently serious and fact driven. Like German physician Fredrich von Mullen, from whom Flexner also learned, Paulsen advocated a stringent gymnasium system of learning whereby teachers taught students through a very formulaic and scientific fact-based curriculum. (B59, 91) After returning to New York, Flexner landed a job with the Carnegie Foundation through his brother Simon, a medical researcher at Hopkins and a good friend of Henry Pritchett's. (A63, B63)

The President of Johns Hopkins medical school, William Welch, a pathologist who also adhered to the German school of education, happened to be the president of the AMA at this time. Welch and Simon Flexner were good friends, and Welch was also connected to the Carnegie Foundation and supported its proposed survey of medical schools. Welch had co-authored the AMA's report on medical education in 1907 with Simon Flexner, a report many people think that Abraham Flexner's report is based.

Welch believed in a rationalistic and scientific view of medical education: if students can master science, they can figure out a patient's diagnosis and treatment without necessarily seeing or speaking with the patient. They just need data. Welch felt that medicine was a branch of pathophysiology, the science of studying the human body's operating system. He also insisted that all doctors, and all teachers, needed to be proficient in lab science rather than clinical skills; the vector of treatment for Welch ran from the lab to the bedside. In other words, doctors need only understand science and engage in research, and they will then be able to diagnose and treat diseases. (I599) As a corollary, Welch was adamant that all medical educators should be full time lab faculty; the clinical faculty (those who actually practiced medicine) were too busy and not sufficiently qualified to teach, he said. (K1860)

Abraham Flexner attacked tasks with purpose and an unbending agenda. Although often funny, and a person who enjoyed teasing colleagues, he also could be brutal and one-sided. He was known to be verbally abusive, scornful of compromise, self-centered, and only receptive to ideas and suggestions that mirrored his pre-conceived notions. (B2,3). Said one source, "Flexner did not tempter his language to please readers—a quality that was to become typical of Flexner's style. He was as tenacious as a bulldog in holding to his positions." (D64-5). And what were his positions regarding the report he was charged to write? Clearly, Flexner derived many of opinions from the people at Hopkins and the AMA with whom he conversed, people like Welch and his own brother, who believed that research and science must be the bedrocks of all medical schools, that faculty must be research based and full time, that schools needed to have a uniform science-based curricula, and that AMA would henceforth regulate medical schools and its graduates to ensure compliance with very strict, unwavering regulations. In other words, his report would match his own personality, and reflect the German-focused vision of William Welch and the program he had constructed at Johns Hopkins. In fact, Hopkins became Flexner's model school.

Flexner felt that two-thirds of the schools were hopeless and should not be allowed to survive, and that most of the others needed significant reform. All but two African-American schools were told to shut down, and the remaining two were expected to train black "practitioners" whose main job was to care for the black community and assure that they don't spread disease to whites. Said Flexner, "The practice of the Negro doctor will be limited to his own race, which in its turn will be cared for better by good Negro physicians than by poor white ones. But the physical well-being of the Negro is not only of moment to the Negro himself. Ten million of them live in close contact with sixty million whites. Not only does the Negro himself suffer from hookworm and tuberculosis; he communicates them to his white neighbors…. The Negro must be educated not only for his sake, but for ours. He is, as far as the human eye can see, a permanent factor in the nation" (Flexner report) Similarly, all schools that trained women, and all that trained alternative doctors, were eradicated by Flexner's report. Those schools deemed salvageable all were primarily white institutions with close ties to the AMA. If they complied with the report's recommendations regarding curricular,

structural, and faculty reform, then they would be accredited by the AMA's Association of American Medical Colleges, be eligible for philanthropic funding from groups like Carnegie and Rockefeller to help defray full-time faculty and structural cost, and look to Hopkins as a model of how to succeed. (H2)

The report was front page news across the country. The New York Times headline stated that most medical schools were "Factories for the making of Ignorant Doctors," lauding the Carnegie Foundation for uncovering the basest features of medical education and practice in the United States. (B69) No organization or newspaper said much about Flexner or his motivations, linked the report to Hopkins or the AMA, or questioned the report's conclusions. The report, it was believed, represented a milestone in American medical care, a turning point whereby the health care delivery system in this country would be purged of its most corrupt and loathsome elements. The response was fairly uniform adulation.

The focus of the report, and the model of what a reconstructed American health care system would look like, could be found at Johns Hopkins. Medical schools now looked to Baltimore for guidance, to William Welch, and to the German model. All doctors henceforth trained and credentialed in America would be scientifically oriented and experts in research. They would be taught by full time researchers, not clinicians who saw patients. And they would follow a science-based pre-medical and medical curriculum uniform in structure. But in reality, a purely scientific bent to medical education did not reflect the reality of Johns Hopkins. Hopkins was much bigger and broader than how Flexner portrayed it, mostly because of the tremendous presence of William Osler, the most respected and well-known doctor in America, who now was knighted and retired in England. His legacy was the blood and soul of Hopkins Medical School.

"It is much more important to know what sort of a patient has a disease than what sort of disease a patient has," said William Osler as he and his contingent of practicing physicians taught the medical students of Johns Hopkins through the late 1800's. "Listen to your patient, he is telling you the diagnosis." To Osler and the clinicians of Hopkins, the vector of education ran from the patient to the lab; students learned from seeing and working with patients, not from research or lectures, and then brought that information back to the scientific theater. Teachers needed to be practicing physicians, and students needed to learn at the bedside. Osler believed in the very opposite ideals of his nemesis William Welch and of the German school. And until his retirement, Osler's word was law at Hopkins.

William Osler was born in Ontario, Canada in 1849. After graduating from medical school in Canada, and working at McGill, he was recruited in 1889 the be the lead physician at the new Johns Hopkins Hospital in Baltimore, and in 1893 he helped create and lead the new Johns Hopkins Medical School. He essentially created the school from scratch, designing a curriculum based on his primary dictate: that students learn

only through immersion in direct patient care. To that end he eschewed a focus on science and the lab, and he hired as instructors practicing physicians in Baltimore. From the day they entered the school, students interacted with patients, an act that became their only forum of learning in the third and fourth year. To further their clinical proficiency, Osler invented the residence, whereby after graduating from medical school, new doctors would essentially take apprenticeships for several years before going off to practice on their own.

While men like William Welch did expose students to lectures and lab work, this was not the focus of Hopkins. Said Osler, "I cannot imagine anything more subversive to the highest ideal of clinical school than to hand over young men who are to be our best practitioners to a group of teachers who are ex officio out of touch with the conditions under which these young men will live…" To Osler, researchers and scientists should not teach medical students; this, after all, was the very lifeblood of Hopkins' Zeitgeist. (C387-9) The thrust of Osler's educational focus was to emphasize problem-solving and critical thinking skills, and the evaluation of medical information through directive observation of and interaction with real people, whose problems not only were medical but were socio-economic and cultural as well. He specifically rejected the "inculcation of facts through rote memorization" and the assumption that one could apply scientific dogma to patients without knowing the patient first. (F6-8)

When Osler left Hopkins in 1905 he was not only the primary driver of Hopkins' medical educational philosophy that vaulted the new school to the very pinnacle of American medical institutions, but he was also a national celebrity, having authored the widely read *The Principles and Practice of Medicine* and given lectures all over the country. He retired to England and left the cherished institution he created to his many clinical colleagues and friends.

But to William Welch and the scientists at Hopkins, a different type of school was needed to push Hopkins into the new age of medical education, one based on science, one in which full-time researchers and scientists taught students, and one in which practicing physicians (who men like Welch felt were greedy and contemptuous for earning money by seeing patients) were absent from the faculty. Welch was a powerful man, he was President of the AMA, he helped to write the first national review of medical schools, he had connections at the Carnegie Foundation. And he helped Flexner turn Hopkins away from a clinical institution to one that was inexorably married to hard science, research, and an inflexible curriculum based on the German school of thought.

By painting Hopkins as his model school, Flexner was in fact looking at a Hopkins that existed not in the realm of reality, not in the blueprint of its founder and primary architect, but rather through the stilted lens of non-clinical researchers like Welch, who sought to increase their power and influence now that Osler had slipped away. That Hopkins was the type of school that Flexner revered is a great absurdity; in many ways

it was the very anthesis of the rigid science-based bastion of learning that Flexner sought to promote in his report. But by painting the school using brushes and canvas supplied by Welch, Flexner in essence altered the very heart of Hopkins by making it comply with what he believed it already was.

From his perch in England, Osler did not stay subdued for long. Known for his fiery personality and pointed wit, he immediately conferred with his clinically-minded friends still at Hopkins, many of whom were being threatened by Welch with dismissal and demotion. Osler rejected Flexner's conclusions, believing that researchers should be in research institutions and not medical schools because they were poor teachers and they lacked the ability to enable students to learn how to practice medicine and interact with patients. (I600) He read the report "as a brutal and ignorant attack on his staff, his principles, and his sense of professionalism." Osler did not understand how faculty could be composed of anyone other than physicians actively practicing the art of medicine. "We chance the sacrifice of something that is really vital, the existence of a great clinical school organically united with the profession and the public," he said. He believed that the report will "likely spell ruin to the type of school I have always said should be and which we have tried to make it…," a place of refuge for the poor, a place where the best that is known is taught to the best students, where "men are encouraged to base their art upon the science of medicine…." Stating that Flexner had a "very feeble grasp of the clinical situation at Johns Hopkins Hospital" and that the institution was "more brilliant from the clinical side than the laboratory side," he felt that the report would diminish the educational experience of its students drastically. "The danger would be of the evolution throughout the country of a set of clinical prigs, the boundary of whose horizon would be the laboratory, and whose only human interest was research, forgetful of the wider claims of a clinical professor as a trainer of the young…." (C385-88)

Osler and others fought back as best they could. He wrote to Welch and to his clinical colleagues, asking them to repudiate the report, and not move Hopkins and the entire medical educational establishment in a direction he knew to be deleterious to the field. At Harvard, Francis Peabody, another clinician who was trying to inculcate medical education with real-life experiences, similarly assailed the Flexner report. Peabody who famously stated that "The secret of the care of the patient is in caring for the patient," (F20) felt that Flexner's approach "weakened the soul of the clinic." He, like Osler, sought a less rigid and lab-based means of teaching students how to practice medical science that focused on actual patient care rather than theoretical scientific theories that may not apply to the individual patient for whom they were caring. (B15) They both believed that Flexner's report "fossilized medical education into following a standardized format" that moved so far away from patients as to be useless in training competent physicians. (H3). Said one author: "Osler and Peabody recognized the danger of reducing the patient to simply a pathophysiology characterized by laboratory tests" while fearing that such a parochial focus blinds doctors from "the broader contextual issues that so often play a crucial function in disease." (I600-1)

But there were larger forces afloat than merely a few men who fought over medicine's direction. Despite the experience, status, and wisdom of men like Osler and Peabody, their words evaporated in the report's wave of acclamation. In fact, although Flexner's report did reflect what he and others believed to be the most logical path upon which the American medical system needed to tread, replacing corruption and incompetence with the scientific rigor of the German school of thought, the report was also a tool used by others to achieve a very specific agenda. Not only did the AMA gain power and notoriety by now grabbing the reigns of American medical education and licensing, but other corporate philanthropic groups like the Carnegie Foundation, who sponsored Flexner's study, and the Rockefeller Foundation, where Flexner worked for much of his subsequent life, had carefully crafted the report to create an American medial system that met their needs and expectations.

For the next 15years of his life, Flexner worked in the Rockefeller Foundation general education board, dictating which schools would receive foundation money and which would not. During that time, he approved the donation of half a billion dollars to schools that met all the rigid criteria of his report and in the process "profoundly altered the medical education landscape;" the schools that did not follow Flexner's script received no money and could not afford to stay afloat, (B1) failing too to be granted requisite accreditation by the AMA. As one author states, "Money was power, and contributors to medical education knew that." (F12)

What was the agenda of groups like the Rockefeller foundation, and why did they buy into Flexner's model? Essentially, their hope was to create great bastions of medical research, whereby American medical institutions could engage in scientific study that matched that of Europe and created breakthroughs that would advance the medical industry and, undoubtedly, generate financial gain for the foundations and their parent corporations. These foundations had very specific agendas for the many schools they sponsored, and their donations were tied to the realization of those agendas, which typically required moving the schools from a clinical direction to one that was purely scientific and lab-based. (F12) Schools had to eliminate clinical faculty, hire full-time science based faculty, emphasize basic science research in their teaching, and adhere to the very rigid science-based curriculum that Flexner laid out in his report. This instigated bitter struggles between old line clinical teachers like Osler who used to have clout, and the newer research scientists who were now taking over. Full time faculty could only exist if the schools were subsidized, and these large foundations were happy to pay the schools so long as the schools adhered to their rules. (B21-3)

As the tide of funding and accreditation became clear in the years after Flexner, most schools accommodated to the new reality. As clinical professors disappeared from these schools, full-time researchers took their place. The foundation leaders—who were in fact agents of the large corporations who funneled money to them—then dictated to these schools the forms of research they desired. Hence began a cycle in American medicine in which clinical skills fell prey to basic science, and in which

corporate entities dictated the direction of medical education and medical practice. "Whether their motives were shrewd business instincts or noblesse oblique, the influence of these industrialists and financers was profound, some would say pernicious." (B19) Within years, the clinical institution that Osler always envisioned, ones in which patients and clinicians taught students, and in which students would leave the school with both a scientific and humanistic knowledge of disease and treatment, completely vanished from the medical landscape. Osler's name remained well-known and respected, but Flexner's ideas won the day. All this occurred because the corporate boards gained enough power to impact the direction American medicine would flow. "Though the board represented itself as a purely neutral force responding to the dictates of science and the wishes of the medical schools, its staff actively sought to impose a model of medical education more closely wedded to research than to medical practice. These policies determined not so much which institutions would survive as which would dominate, how they would be run, and what ideals would prevail." (B121)

On that chilly day in 1911, when a well groomed and stern-faced Abraham Flexner walked through Baltimore to meet with William Welch, he planned to describe to Welch a plan that both men had already conspired to create. Flexner had been working with Frederick Gates of the Rockefeller Trust, who wanted to provide Hopkins with a $1 million grant if the school transformed to the model school described by Flexner's findings. Essentially, Hopkins would be the nation's premier research institute, with salaried researchers paid in part by the grant spearheading all teaching responsibilities, with all students following a rigid curriculum focused on science (A74), and with strict guidelines for admission and graduation. The clinical realm championed by Osler and his colleagues would be relegated to a footnote. Clinicians "have long ceased to be scientifically significant…. Whether the extremely prosperous physician or surgeon should have a place in such an institute as the Johns Hopkins Hospital seems to me most doubtful," said Flexner to Gates. (C-381)

In the realm of large foundations like Rockefeller and Carnegie, medical schools served as the best repositories of research and the production of scientists, upon which these companies were focused. Often, they sought to promote research pertinent to their own corporate interests. In fact, under Flexner's new guidelines requiring full-time faculty and ample research facilities, schools needed foundation money if they were to survive. As a result, within a decade all medical schools became dominated by researchers and not clinical physicians and teachers. "Many have argued that this was a mistake. They would have preferred to see only a few schools like Johns Hopkins training scientists and specialists, while the rest, with more modest programs, turned out general practitioners to take care of the everyday ills that make up the greater part of medical work. But this was not the course that American medical education followed…." (G123)

Despite emphatic and frequent protests from Osler in England, the world that he created at Hopkins and beyond quickly dissolved. His colleagues were fired and replaced by a

purely research-based staff. No longer did clinicians teach students, and no longer did students learn from their patients, as Osler so vehemently insisted. Welch readily accepted the million dollar grant from Rockefeller, and spearheaded a dramatic transformation in medical education and practice that relied on Flexner's template, the AMA's leadership, and Corporate dollars. Flexner went on to spend most of his career working for the Rockefeller Foundation.

The other winner in the battle for medicine's soul was the AMA, which stood as the only organization capable of assuring that Flexner's vision was properly implemented and executed. After Flexner, "the AMA would largely control medical school accreditation which would become bureaucratized and sclerotic. It also became the officially recognized entity authorized to speak on behalf of all physicians." (H3) Because doctors had to be licensed, and because licensing was controlled by the AMA, and because only AMA sponsored medical schools could graduate certified physicians, the AMA in fact controlled the global American medical system, and in many ways it was beholden to corporate foundations that help fund them and the schools. Flexner himself believed that medical education and practice would change and grow as times changed. "The flexibility and freedom to change—indeed the mandate to do so—was part of the system's mission from the very beginning. Contrary to popular myth, the system was always intended to evolve." (F25). Unfortunately, groups like Rockefeller and the AMA were not interested these changes.

Today, medical schools, and the entire health care network in this country, reflect the legacy of Flexner. As one author stated, "The practice of medicine was seen as a rigorist science with clear answers to defined questions, the foibles of patients being the province not of the laboratory-trained physicians but of clergymen and social workers." (K1860-1) The medical system would now focus on "disease organically defined, not on the system of health care or on society's health more generally." Patient-centered care, prevention, and the nuances of disease all were extirpated from training as a very parochial view of science as fact reduced medical education to a technical pursuit. (F25). Using a narrow set of courses in chemistry, physics, and biology to determine which students best qualified to be physicians, and then teaching students the science of the human health through a set curriculum that today is nearly identical to the one recommended by Flexner, medical schools have moved far away from the vision of Osler. Humanistic qualities, critical thinking, and a patient-focused approach to care have lost all significance both in the selection of students and in their training. "Isn't it astonishing that the medical school curriculum structure has remained unchanged for more than 100 years? And if we omit the 'dynamic sociological encounter between patient and physician' [as Osler advocated], is it any wonder a health care crisis would emerge?" (H3)

The legacy of Flexner's report and the rise of the AMA has left many scars with which we are living today. On the positive side for physicians, many charlatan practices have disappeared, and physician competency and income increased considerably. In 1900

the average doctor earned $750-$1500. By 1928 they were already earning on average $6354, with salary escalating continually due to a deliberately low physician supply and strong advocacy by the AMA. (G142)

But the physician class changed dramatically. Now only one, scientifically-based model of medical care predominated; the field became quite homogeneous and dependent on a scripted formula of practice to achieve success. The increased cost of medical education, required to help defray costs for full-time faculty and research facilities, eliminated all but the wealthy from the ranks of medical students. And Flexner's report and its ramifications triggered deliberate policies of discrimination against women, African-Americans, and Jews. (G124) Only two African-American medical schools remained, and the black doctor only survived through the efforts of the newly created National Medical Association (NMA) which sponsored a parallel black medical system given the pervasive bigotry sewed into the AMA and the American medical system it helped to create.

The other casualty of Flexner was the slaying of Osler. Today many people know Osler, or at least have heard the name. Virtually no one has heard of Flexner, the Rockefeller and Carnegie Foundation, or men like William Welch. Yet Flexner's report and its subsequent embrace by the AMA, charitable foundations, and established medical schools like Hopkins have secured Osler's irrelevance to the practice of medicine and the training of physicians. Researchers and specialists have trumped clinical generalists, the very physicians Osler's bold reforms were promoting as the cure to health care's ills at the turn of the century. After Flexner, researchers were "regarded as of greater intellectual worth than clinical practitioners which, not lending itself to grants, publications, or academic glory, was deemed a lesser calling." Even when schools trained non-research physicians, the emphasis on clinical education revolved around specialization and a scientific view of disease. (K1861) According to historian Howard Berliner, Flexner's "language leaves little doubt that he held the mass produced 'family doctor' in low esteem and he considered the new standard among physicians to be the highly scientific and sophisticated clinicians molded in the Hopkins environment of its equivalent." (B15)

In 1984 an AAMC report recommended changes in medical education that would move clinical medicine beyond the narrow confines of Flexner's report, changes they predicted would take root within just a few years. These were to:

- Develop analytic skills and instill patient-centric values into the curriculum.
- Encourage a broad liberal arts pre-med education
- Emphasize critical thinking over memorization
- Ensure that clinical clerkships encourage respect and concern for patient values
- Reward doctors who are educators. (I598)

Needless to say, none of those reforms transpired. Pre-meds are required to focus on science, and the Medical College Admission Test (MCAT) requires memorization and regurgitation of a large quantity of purely scientific data. Even through medical school, memorization, not critical thinking, is the skill that is necessary for testing success. Virtually no generalists teach students, and students are exposed almost entirely to specialized highly-scientific medical practices and ideas. Most significantly, patient-centered care as advocated by Osler has become a token gesture rather than the crux of all medical education.

We are indeed in a health care crisis. In our country we spend a trillion dollars of health care dollars for interventions that have been shown to be ineffective or even dangerous. Almost 50% of all we do as doctors is considered low value. Despite all we spend on health care, we rank among the worst in outcomes among all industrial countries. We are a nation of specialists, of high-tech medical practice, and of excessive drug use. Virtually all research is financed and controlled by industry and is conducted within medical schools whose research faculty are dependent on industry to survive and thrive, thus leading to conclusions that are sullied by self-interest. Patients feel frustrated, and their needs often fall prey to generic protocols and an emphasis on rigid scientific dogma. Students continue to be trained as scientists and not as physicians. Said one historian, “The Flexner Report… has taught us the danger of establishing a confining (and ultimately damaging) standard” in medical education and practice. (I601)

Can our health care delivery system ever change? To do so, we first must understand why it has moved so far off the rails of common sense and medical sanity. Today, over 100 years after Flexner, we should ask why we have not changed yet. Are there too many people and organizations benefitting from the current system? Do medical thought leaders believe that Flexner’s formula is still the best one for our health care delivery system? Or is it perhaps inertia and a lack of understanding of what needs to be fixed? In the end, we should peak back to a time before Flexner and grasp what William Osler had already gifted to the medical world. When read today, Osler’s words and ideas make sense. Certainly, if we are ever to transcend the health care mess in which we are embroiled, me must understand and embrace Osler and finally acknowledge the flaw of Flexner’s errant course.

References:

A. Bonner, Thomas. Inconoclast: Abraham Flexner and a life of learning. Johns Hopkins Universtiy Press, Baltimore, 2002.
B. Nevins, Michael. Abraham Flexner: a flawed American Icon. Universe Press, New York, 2010.
C. Bliss, Michael. William Osler: A life in Medicine. Oxford University Press, 1999.
D. Flexner, Abraham. “Medical education in the United States and Canada: A report to the Carnegie Foundation for the advancement of teaching,” 1910.
E.
F. Ludmann, Kenneth. Time to heal: American medical education from the turn of the century to the era of managed care. Oxford University Press, 1999.
G. Starr, Paul. The Social Transformation of American Medicine. Basic Books, 1982.
H. “Flexner vs Osler: Medical education suffers to this day,” alertandoriented.com/Flexner-versus-osler

I. Tauber, AI. “the two faces of medical education: Flexner vs. Osler revisited.” Journal of the Royal Society of Medicine, V85, 10/92.
J. Letter from Flexner to Osler from Carnegie Foundation, 10/6/1911
K. Rae, A. “Osler vindicated: The ghost of Flexner laid to rest.” JAMA, 164 (13), 6/26/01.
L. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1293684/pdf/jrsocmed00106-0012.pdf

Review Questions

Answers on next page

1. Which statement below best summarizes the European or Flexner approach to medicine?

a. Medicine is entirely scientific. As long as doctors gather enough data on the patient and are well enough trained, they will make the correct diagnosis and prescribe the correct treatment
b. Medicine is entirely an art. Tests and data are irrelevant since each patient is unique
c. Medicine is a combination of science and art. Doctors need to combine patient hard data from tests with wisdom and experience
d. Medicine is a religion. As long as patients believe strongly enough, they will recover from their medical ailments

2. Who said “It is much more important to know what sort of a patient has a disease than what sort of disease a patient has…Listen to your patient, he is telling you the diagnosis.”?

a. William Osler
b. Abraham Flexner
c. Alfred E. Neuman
d. Albert Einstein

3. Which type of physician would you prefer to diagnose and treat you: one trained in the Flexner style or one trained in the Osler style?

a. Flexner
b. Osler

4. How can a patient determine which type of physician – a Flexner or an Osler follower – treats them?

a. By interviewing the physician before receiving care. Note that this requires that the patient be well informed (medical definition) about care and treatments
b. There is no good mechanism available today to help patients make that choice
c. By staying ‘in-network’ based on your health insurance plan
d. By getting all your medical care overseas

Review Questions

Correct answers in bold

1. Which statement below best summarizes the European or Flexner approach to medicine?

a. **Medicine is entirely scientific. As long as doctors gather enough data on the patient and are well enough trained, they will make the correct diagnosis and prescribe the correct treatment**
b. Medicine is entirely an art. Tests and data are irrelevant since each patient is unique
c. Medicine is a combination of science and art. Doctors need to combine patient hard data from tests with wisdom and experience
d. Medicine is a religion. As long as patients believe strongly enough, they will recover from their medical ailments

2. Who said “It is much more important to know what sort of a patient has a disease than what sort of disease a patient has…Listen to your patient, he is telling you the diagnosis.”?

a. **William Osler**
b. Abraham Flexner
c. Alfred E. Neuman
d. Albert Einstein

3. Which type of physician would you prefer to diagnose and treat you: one trained in the Flexner style or one trained in the Osler style?

a. Flexner
b. Osler
c. **The correct answer is up to each individual patient**

4. How can a patient determine which type of physician – a Flexner or an Osler follower – treats them?

a**. By interviewing the physician before receiving care. Note that this requires that the patient be well informed (medical definition) about care and treatments**
b. There is no good mechanism available (either a or b can be correct)
c. By staying ‘in-network’ based on your health insurance plan
d. By getting all your medical care overseas

Issue 5: Risk Management Problems in today's health insurance environment

As Andy Lazris so eloquently discussed in the previous chapter, Abraham Flexner believed in science and facts. He idealized the then-cutting-edge German approach to medical education that focused on 3 laboratory based disciplines - physiology, pathology and bacteriology – at the expense of the humanities and experience. Science gives answers, 'facts', and the medical student's role to Flexnerians, is to collect them.[181]

The more facts the student accumulates, the better the student.

The better the student, the better the doctor.

The ideal physician accumulates as many scientific facts about medicine in general, and then the patient in particular, as possible in order to make the best diagnosis and treatment recommendation. Facts drive the process.

It's not even necessary to see the actual patient in Flexner's world. To quote Andy's comments on the German approach:

> if students can master science, they can figure out a patient's diagnosis and treatment without necessarily seeing or speaking with the patient. They just need data.

Or, stated differently, Flexnerians believe that the human body is a mechanical object to be understood and fixed when it malfunctions, a huge wall of knobs and dials that doctors optimize with medications, therapies and surgeries. Treating a patient essentially becomes the same as baking a cake or building a car. Cake too sweet? Dial down on the sugar. Cholesterol too high? Dial up on the statins. Knee pain? Arthroscopic debridement.

An extension of the Flexnerian mechanical world view is that there's always some way that medicine can improve the patient's condition, leading to the proposition that more medical care is better than less. Why settle for a *pretty* healthy patient when we can create, through science, a *very* healthy one?

This scientific-mechanical approach to medicine minimizes the problem of complexity, sidesteps the problem of overreach and ignores the issue of patient preference. Each independently poses a significant objection to this mechanical view of medicine. Altogether, they pose a mortal one. We'll explore below.

The Problem of Complexity

[181] *Flexner's exact quote was 'The student is to collect and evaluate facts.' Abraham Flexner (1910). "Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching"*

The human body, as any practitioner or recipient of medical care knows, is north of unbelievably complex. Each medical intervention creates primary effects, side effects and rebound effects which may serve to mitigate the intended impacts. Statins, for example, have a primary effect of preventing heart attacks, which they do, on average according to Pfizer's estimates of patients without known heart disease but with risk factors, about 1% of the time. [182]

But statins cause diabetes about half as often. [183] Diabetes, in turn, can cause heart attacks. So the statin rebound effect ultimately negates some of the primary impact.

Michael Porter and Elizabeth Teisberg, in their massive Redefining Health Care treatise, summarized the medicine complexity problem. 'There are too simply too many dimensions of process to track and too much heterogeneity among patients,' they write.[184] Clinicians may tend to focus not on the most important medical variables but on those most easy to identify, quantify and affect.

Often these become 'guidelines', 'checklists' or 'established protocols.'

We humans, it appears, like guidelines and protocols. It's one of our foibles. Checklists help us reduce the number of potentially important variables to a manageable handful, help us target our investigations and streamline the medical diagnostic and treatment process. Guidelines help us avoid starting every patient analysis from the underlying biological and physiological principles, then reasoning toward a specific diagnosis and treatment. Protocols tell us which interventions commonly succeed with a particular type of patient.

Those efficiency gains are the good bits.

The bad bit comes from a second human foible: intellectual and bureaucratic inertia. Once we accept a standard approach, we tend to ignore contrary evidence, put blinders on in other words. Some research suggests that this is the reason it takes up to 10 years for a new medical process to become widely accepted even if it's clearly scientifically based and clearly better than the old process, or even longer for an outdated one to disappear. [185]

---

[182] See the Lipitor ad, Dec 4, 2007 Wall Street Journal. The small print, bottom left of that ad states 'in a large clinical study, 3% of patients taking a sugar pill or placebo had a heart attack compared to 2% of patients taking Lipitor.' This study was of patients without known heart disease. The number differ for patients with heart disease.

[183] See Statin Drugs Given for 5 Years for Heart Disease Prevention (Without Known Heart Disease), 2017 version by John Abramson on TheNNT.com.

[184] Porter and Teisberg, Redefining Health Care, page 87

[185] See Vinary Prasad, Ending Medical Reversal and Richard Pearl, Mistreated for more on these estimates.

In Flexner's model, physicians would, theoretically, constantly review and revisit guidelines and protocols to ensure their accuracy in the face of new research and information. But that's simply not what happens in real life. Our foibles – fatigue, complacency, greed, intellectual laziness perhaps - don't permit it.

As Atul Gawande summarized in his 2015 Overkill New Yorker article:

> We can recommend care of little or no value because it enhances our incomes, because it's our habit, or because we genuinely but incorrectly believe in it.

Flexner apparently thought well trained physicians wouldn't take this approach; Gawande, the product of our Flexner based medical education system, admitted to it.

How often does this actually happen? Vinay Prasad answered that in a brilliant analysis of medical reversal. [186]

Prasad and his team reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that tested an established medical practice, one commonly used on patients like intensively lowering blood sugar in Type 2 diabetics to reduce cardiovascular events … interventions, in other words, that were scientifically fact based and that the medical community embraced.

363 studies qualified.

Prasad then asked 'Of those 363 studies, how many *affirmed* the practice?' i.e. found that it benefited patients.

38% affirmed the practice, 40% negated the practice, (found it ineffective or harmful) and 22% were ambiguous.

The Prasad team's research shows that if you base your medical decisions on biology, physiology, anatomy and logic – *exactly as Flexner prescribed* – you are wrong about as often as you are right.

That strikes me as a pretty dismal report card on the Flexner / Germanic approach to medical education.

Porter and Teisberg attack Flexner's medicine-as-mechanics approach from a second point of view also. Mediocrity, errors and the important human / personal interaction factor in doctor-patient relationships go unaddressed. Even if two physicians have managed to master Flexner's scientific facts equally well, one may be a better medical practitioner. Fact based knowledge and process compliance don't always lead to similar outcomes.

Consider cystic fibrosis treatment and outcomes. [187]

All CF patients receive care from one of 117 ultraspecialized centers that follow the same extremely detailed treatment guidelines. CF specialists attend the same

[186] Prasad, A Decade of Reversal, Mayo Clinic Proceedings, August 2013

[187] This discussion comes from Atul Gawande's article The Bell Curve in his book Better, 2007.

conferences, shared the same knowledge base, focus on the same variables and facts, and treat patients the same way. But they generate different patient outcomes.

The two primary CF outcome metrics are lung function and longevity. The Flexner / German expectation would be that all centers would generate approximately similar outcomes on these two measures, within a fairly narrow margin. After all, they all use the same science and facts in their diagnostic and treatment protocols and treat similar patients.

But research shows that the 117 cystic fibrosis facilities generate quite discrepant outcomes. The average clinic, according to a 1997 study, generated patient life expectancies of just over 30 years. But the best managed 46.

Ditto for lung capacity.

That's only part of the issue. Perhaps the more astonishing thing is that one CF center routinely outperformed the others. It was at Fairview-University Children's Hospital in Minneapolis. (This is based on an early 2000's study, is likely out of date and I don't give cystic fibrosis treatment advice.) Patients at Fairview apparently routinely had lung capacities equal to the average non-CF population, higher than at most CF clinics.

How could a facility far outperform the average, and how could the same one outperform the average year after year? The answer appears to be some amorphous combination of physician-patient connections, a corporate culture that wouldn't accept sub-par outcomes and the personality of the director.

Flexner's mechanical model doesn't describe or account for these results.

But William Osler's does. 'The good physician', he claims, 'treats the disease. The great physician treats the patient who has the disease.' Medical excellence is only partially grounded in science and facts – those are necessary but not sufficient conditions. Excellence also requires empathy, interpersonal connections, clinician perceptiveness and a human connection that somehow, almost indescribably, adds therapeutic value. That's the art of medical care, present to Osler but missing from Flexner.

The difference between good and great to Flexner is some measure of scientific understanding and fact accumulation. The difference between good and great to Osler appears in other arenas like human connections, the non-scientific ones that medical education too often leaves out.

But we've so far only discussed the 'complication' critique of Flexner's approach. Let's now turn to the treatment overreach objection.

Low Quality and Unnecessary Care

The US medical care system, and perhaps others with which I'm unfamiliar, offers an astonishing amount of poor quality care. I'll define poor quality in a couple of ways:

- Unnecessary care or waste: Care that generates no patient benefit according to comparative studies. In other words, outcomes from the control and treatment groups are the same or practically so.
- Low quality care: Care that generates some benefit to a clearly specified group of patients according to studies but that is offered to a wider group so likely generates no benefit to the wider population.

Consider statins to prevent heart attacks as a simple example.

TheNNT.com estimates the Number Needed to Treat (NNT) is 39 for people with known heart disease, meaning that for every 39 people with known heart disease who take statins for 5 years, 1 will avoid a heart attack.

The Flexnerian, caring physician might look at a patient *without* heart disease though and say 'This patient shares certain important biochemical and physiological factors with the studied group. I think patients without heart disease will also benefit though probably not quite as much' and prescribe statins to the wider group, expecting somewhat similar results.

But that's not the case, at least not by an order of magnitude. TheNNT.com estimates that only 1 in 217 patients without known heart disease will benefit by avoiding a heart attack over 5 years. [188]

Are 1 in 39 and 1 in 217 similar care quality? I think not. There seems to me at least, a qualitative difference here. I'll postulate as a thought experiment that if 1 in 39 is 'good quality care', then 1 in 217 is 'low quality care'.

And if 1 in 39 is 'low quality care', then 1 in 217 is 'unnecessary care or waste'. (Yes there's some benefit but differentiating value from waste at these levels strikes me like splitting hairs with an axe.)

And we haven't even considered the treatment risks.

Where would a caring physician, draw the line between high and low quality care, or between low quality and unnecessary? I certainly don't know.

And neither, I'll postulate, does a Flexnerian, fact based scientist.

Extending this argument – that care generating reasonable quality care to a narrowly defined group might generate low quality care to a larger group – uncovers tremendous waste throughout our medical system.

[188] http://www.thennt.com/nnt/statins-persons-low-risk-cardiovascular-disease/

David Cordani, Cigna's CEO estimates somewhat conservatively, that 'slippage' or care that should benefit patients but doesn't, accounts for at least 25% of all US healthcare spending but probably much more. [189]

Aetna, another huge national health insurer, says less conservatively on its website that

> Wasteful spending likely accounts for between one-third and one-half of all US healthcare spending. [190]

And the Dartmouth Atlas, generally considered the bible of healthcare utilization analytics, uses a widely quoted estimate of 'up to about 1/3' of all US healthcare spending but added 'we view this as an underestimate given the potential savings even in low cost regions'.[191]

I think they're right, especially about the 'underestimate' bit.

This shouldn't happen according to Flexner's German school view. Physicians should accumulate all the facts and develop the right interventions. That's what science is all about – being right.

They shouldn't miss 30 – 50% of the time!

Let's put some meat on this low quality and unnecessary care bone by reviewing a 2018 Washington State study.[192] The Washington Health Alliance analyzed utilization and billing data from 2.4 million commercially insured patients and found that 45% of services delivered were wasteful. 45%!

Why does our system engage is so much low quality care? I think our human foibles are largely to blame. These fall into 3 general categories:

- Physician role definition, basically 'this treatment *might* benefit my patient and I don't want to withhold any potential benefit'. We might call this the medical plausibility foible – 'it might happen';
- Tort issues, basically 'I might get sued it I don't do it'; and
- The Upton Sinclair insight that 'it's difficult to get a man to believe something when his salary depends on him not believing it.' That's why surgeons tend to recommend surgery, therapists therapy and urologists interpret PSA study results differently from the US Preventive Services Task Force.

None of these foibles fit Flexner's world view. They're not science and fact based.

---

[189] Cordani's Keynote Address at the 2015 Yale Healthcare Conference

[190] http://www.aetna.com/health-reform-connection/aetnas-vision/facts-about-costs.html

[191] http://www.dartmouthatlas.org/keyissues/issue.aspx?con=1338

[192] First, Do No Harm: Calculating Health Care Waste in Washington State, February 2018, www.wacommunitycheckup.org

But they're all human characteristics and all impact the actual practice of medicine.

And they all, in various ways, touch on the third major flaw in Flexner's approach, the problem of patient preferences.

Preference sensitive decisions

Unnecessary care to one person might be reasonable care to another just like in our statin example above. John Wennberg, founder of the Dartmouth Institute calls this a 'preference sensitive' decision, meaning that one patient might opt for the statins while another declines and **both may be right**. This is a tacit admission that there are rarely clear cut medical decisions.

Wennberg calls these relatively few obvious medical decisions 'effective care' defined as services that, on the basis of reasonably sound medical evidence, are known to work better than any alternative. [193] This group of treatments accounts, based on his research, for only about 15% of all medical care.

It's the category in which Flexner's analysis applies and probably flourishes. Examples include childhood immunizations, lifesaving drugs for patients with heart attacks, and regular blood tests and eye exams for diabetics.

A far larger category is 'preference sensitive' care meaning care for which there is more than one option and in which different people can make different decisions and all be correct. Preference sensitive care requires judgment to evaluate the risk-benefit tradeoffs. Wennberg estimates it's at least 25% of medical care. [194]

We've already discussed preventive services – statins as primary prevention. Now consider treatment for torn or injured rotator cuffs. A surgeon will likely recommend surgery after examining the patient and identifying a rotator cuff tear. But a physical therapist, reviewing the same data on the same patient, might well suggest PT.

That rotator cuff situation arose for a student of mine. He recounted that he first saw an orthopedic surgeon who took an MRI, identified the cuff tear, showed him the picture and recommended surgery. 'I would have agreed to surgery' he went on to say, 'prior to hearing your discussions about preference sensitive decision making.' (See – there actually is some value to continuing education classes!)

'But I asked the surgeon if all physicians would agree with that analysis and recommendation.' (In other words, was this an effective care situation in Wennberg's terms?) The surgeon 'answered with a snort that some clinicians might suggest physical

[193] Wennberg, Tracking Medicine, pages 8 – 10, then Parts II and III

[194] Wennberg's definitions of 'preference sensitive' and 'supply sensitive' care overlap. According to some interpretations, 'preference sensitive' may describe 85% of medical care. The exact definition and amount doesn't matter for this analysis; it's a lot no matter how we define the terms.

therapy but that would be a waste of time and that I'd be back in his office shortly thereafter.' (In other words, this was a preference sensitive decision.)

My former student decided to try PT and reported when next I saw him that his shoulder was pain free and that he had regained 99%+ range of motion – it might have been 100% but he wanted to be conservative - in the same time as surgical recovery but without the costs and risks of surgery. 'Thanks' he smiled as he relayed the story.

Was the surgeon wrong? Probably not. Surgery probably would have worked.

Was the patient right to ask about therapy? Clearly. Not only did it solve his problem but he preferred it. His choice defined the best medical treatment.

None of this makes sense in Flexner's the-human-body-is-a-big-mechanical-device world view. There's an answer in the Flexnerian world and the doctor's job is to find it.

But in the real world, doctors have foibles. They don't always diagnose and prescribe correctly because the human body is so complex. They frequently overreach because of their desire to help, combined with their economic incentives. And often misunderstand their patients' preferences.

Together these three problems doom Flexner and his Germanic approach.

Atul Gawande summarized the modern physician's role more appropriately by acknowledging that emotion complements science and that each patient has individual hopes, aspirations, fears and conditions:

> The ideal modern doctor should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them.[195]

That approach, far more than Flexner's, warms my heart as a patient.

[195] Sheri Fink, Atul Gawande's Being Mortal, NY Times Book Review, Nov 6, 2014

Review Questions

Answers on next page

1. What is medical reversal?

    a. Stop providing medical care when studies show that it doesn't benefit patients
    b. Save a dying patient. In other words, reverse the biological process
    c. Have a different specialist undo the treatment you previously received
    d. Have a doctor change his/her mind as in 'I thought that Treatment A would help you but I was wrong, so now we'll try Treatment B.'

2. What is one definition of low quality care?

    a. Care that generates some benefit to a clearly specified group of patients according to studies but that is offered to a wider group so likely generates little to no benefit to the wider population.
    b. Cheaper care when more expensive care is available
    c. Care based on virtually any non-state of the art equipment
    d. Low technology care when higher technology care is available

3. What is the NNT or Number Needed to Treat?

    a. The number of patients who need to receive a treatment or test in order for 1 patient to benefit
    b. The number of physicians who need to treat a patient for the patient to benefit
    c. The number of times a physicians must perform a test or treatment in order to achieve excellence at it
    d. The number of patients a hospital must treat in order to avoid harming any

4. What is a definition of unnecessary care?

    a. Care that does not generate any patient benefit
    b. Care that does not generate any physician income
    c. Care that does not generate any hospital income
    d. More expensive care when less expensive care is available

5. What lesson can we learn from Atul Gawande's analysis of cystic fibrosis treatments?

    a. That beneficial medical care is a combination of science, art, human interactions and emotion
    b. That physicians who follow the guidelines most closely generate the best patient outcomes
    c. That physicians who ignore guidelines generate the best patient outcomes
    d. That medicine is almost exclusively a science and the best physicians are those who understand the underlying biological, physiological and anatomical processes the best

6. What does preference-sensitive mean in medical care?

a. That different patients, with the same medical condition, can choose different treatments and all be right
b. That different patients, with the same medical condition, should always choose the same treatment
c. That there is 1 correct treatment for a given medical condition and dozens, perhaps, incorrect treatments
d. That doctors often prefer to give different treatments to similar patients simply to add variety to their professional lives

7. According to this chapter, is the human body a big mechanical device?

a. Yes
b. No. People consist of bodies and minds. The wisest physician understands this and seeks to engage both when prescribing medical care

8. This chapter suggested 3 reasons why physicians prescribe unnecessary and low quality care. Which below is not one of those reasons?

a. Physician hopes and role responsibility, basically thinking 'this treatment *might* benefit my patient and I don't want to withhold any potential benefit'
b. Tort concerns, basically 'I might get sued if I don't do it'
c. The Upton Sinclair insight that 'it's difficult to get a man to believe something when his salary depends on him not believing it.' That's why surgeons tend to recommend surgery, therapists therapy and some providers routinely recommend the most expensive interventions
d. The boredom defense, basically 'I didn't have a lot to do in the hospital that day to I decided to provide some unnecessary care to break up the boredom'

Review Questions

Correct answers in bold

1. What is medical reversal?

    a. **Stop providing medical care when studies show that it doesn't benefit patients**
    b. Save a dying patient. In other words, reverse the biological process
    c. Have a different specialist undo the treatment you previously received
    d. Have a doctor change his/her mind as in 'I thought that Treatment A would help you but I was wrong, so now we'll try Treatment B.'

2. What is one definition of low quality care?

    a. **Care that generates some benefit to a clearly specified group of patients according to studies but that is offered to a wider group so likely generates little to no benefit to the wider population.**
    b. Cheaper care when more expensive care is available
    c. Care based on virtually any non-state of the art equipment
    d. Low technology care when higher technology care is available

3. What is the NNT or Number Needed to Treat?

    a. **The number of patients who need to receive a treatment or test in order for 1 patient to benefit**
    b. The number of physicians who need to treat a patient for the patient to benefit
    c. The number of times a physicians must perform a test or treatment in order to achieve excellence at it
    d. The number of patients a hospital must treat in order to avoid harming any

4. What is a definition of unnecessary care?

    a. **Care that does not generate any patient benefit**
    b. Care that does not generate any physician income
    c. Care that does not generate any hospital income
    d. More expensive care when less expensive care is available

5. What lesson can we learn from Atul Gawande's analysis of cystic fibrosis treatments?

    a. **That beneficial medical care is a combination of science, art, human interactions and emotion**
    b. That physicians who follow the guidelines most closely generate the best patient outcomes
    c. That physicians who ignore guidelines generate the best patient outcomes
    d. That medicine is almost exclusively a science and the best physicians are those who understand the underlying biological, physiological and anatomical processes the best

6. What does preference-sensitive mean in medical care?

a. **That different patients, with the same medical condition, can choose different treatments and all be right**
b. That different patients, with the same medical condition, should always choose the same treatment
c. That there is 1 correct treatment for a given medical condition and dozens, perhaps, incorrect treatments
d. That doctors often prefer to give different treatments to similar patients simply to add variety to their professional lives

7. According to this chapter, is the human body a big mechanical device?

a. Yes
b. **No. People consist of bodies and minds. The wisest physician understands this and seeks to engage both when prescribing medical care**

8. This chapter suggested 3 reasons why physicians prescribe unnecessary and low quality care. Which below is not one of those reasons?

a. Physician hopes and role responsibility, basically thinking 'this treatment *might* benefit my patient and I don't want to withhold any potential benefit'
b. Tort concerns, basically 'I might get sued if I don't do it'
c. The Upton Sinclair insight that 'it's difficult to get a man to believe something when his salary depends on him not believing it.' That's why surgeons tend to recommend surgery, therapists therapy and some providers routinely recommend the most expensive interventions
d. **The boredom defense, basically 'I didn't have a lot to do in the hospital that day to I decided to provide some unnecessary care to break up the boredom'**

Issue 6: Deductibles and Plan Management

Successful and sustainable healthcare cost control programs require that you teach your employees how to identify and avoid unnecessary, ineffective, wasteful and low quality medical care.

Attempts to control expenses with plan design changes or ancillary programs but without this educational component never live up to their billing.

Here's a condensed 50 year history of commercial health insurance:

- Cost sharing or 'major medical' in the 1970s was inflationary so replaced by
- First dollar coverage or HMOs – the opposite of cost sharing - in the 1980s and 90s. People found these plans too restrictive so replaced by
- High deductible plans - the opposite of first dollar coverage - post 2000. People complain about the deductible size and have trouble differentiating necessary and beneficial medical expenditures from unnecessary and wasteful.
- None of these programs integrated the necessary educational component into their fabric. Any would have been far more successful with it.

You've probably tried

- Wide hospital networks figuring more competition leads to lower costs and
- Narrow hospital networks figuring more carrier control leads to lower costs,
- Defined benefit plans to give employers more plan design latitude and
- Defined contribution plans to give employees wider choice, and
- Several other things that didn't work out too well …but never with a fully integrated employee education component.

The unwritten assumptions behind all these plans and design changes: the right financing program will motivate employees either to (a) use better medical care, (b) use less medical care or (c) use less expensive medical care.

History has conclusively shown these assumptions wrong.

Your employees will always find a way to access the medical services that they believe will improve their health whether or not that belief is valid. Attempting to influence their behavior with financing restrictions annoys them, doesn't work and doesn't improve their treatment outcomes or health.

The fundamental axiom
that any effective healthcare financing program honors

Good health is cheaper than bad health. That's universally and patently true.

So is its extension: the more quickly and efficiently you can turn an employee from sick to healthy, the less it costs, especially if you factor in absenteeism and presenteeism.

Better care quality – better outcomes in other words – is cheaper than poorer care. (Yes, I understand that some MRIs cost less than others. But I wonder how many are necessary and actually improve employee health.)

If your employees choose medical care based on likely outcomes, they'll get healthier and you'll save money. It's the best possible win-win.

But if your financing program tries to get them to choose medical care based on other criteria … not so much.

This presents a new focus

I suggest that corporate healthcare programs have as their #1 priority teaching employees how to choose care based on the outcomes they're likely to enjoy.

Design and develop that program first. This book can help. So can my online education program www.TheMedicalGuide.net.

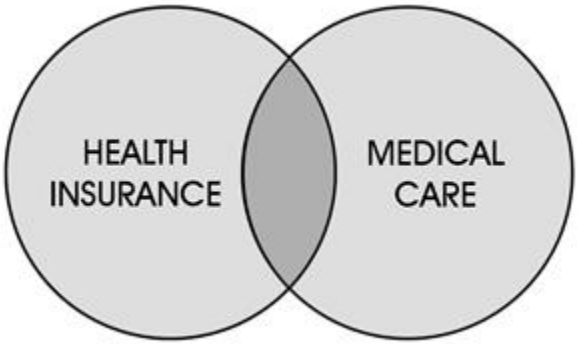
Then design a financing system to enhance and support your educational effort.

Don't do it the other way around.

The Old School approach currently in effect

Corporate engagement programs focus on understanding insurance coverage. Employees ask 'is the service covered?' and often conclude that 'if it's covered, I want it.'

The New School approach proposed in this book



The interesting work takes place in the overlap.

Corporate engagement programs include medical literacy.

Employees learn to ask 'is the service covered, *does it benefit me and do I want it*?'

What this chapter is about

Millions of well insured Americans get too many tests, take too many medications and have too many medical interventions. Our currently in-vogue benefits programs – deductibles, HSAs, wellness programs, etc. – haven't stemmed that tide.

Instead, I'll show you how to identify and avoid unnecessary, excessive, ineffective and low quality medical care.

I'll teach you the Five Most Important Questions to Ask Every Doctor, At Every Appointment, About Every Medical Intervention.

- If you learn, understand and ask these questions, you'll get better medical care with less risk. And you'll save a bunch of money along the way.
- If your company adopts this approach, it will save money and help its employees enjoy better outcomes with less intervention risk.

Too much care – and the wrong care - is bad for your health, both medical and financial. We currently waste according to many, up to $1 trillion annually. That's almost Russia's total GDP!

Consider these estimates.

- David Cordani, CEO of Cigna claims that slippage or 'things that don't work the way they're supposed to' accounts for at least 25% of all medical spending but 'probably much more'.
- Aetna's website says that 'wasteful spending likely accounts for between one-third and one-half of all US healthcare spending'.

- The Dartmouth Atlas, generally considered the bible of healthcare utilization analytics, suggests that up to about 1/3 of all US healthcare spending generates no patient benefit views this ‘as an underestimate given the potential savings even in low cost regions’.

The specifics may shock you. We Americans annually, for example,

- get 36 million prescriptions for a blood pressure lowering medication that doesn’t prevent heart attacks or save lives,
- spend $1 billion on a back procedure that works no better than a placebo,
- spend $3 billion on a knee procedure that can work less well than a placebo,
- spend over $2 billion on a cholesterol lowering drug that has not been shown to prevent heart disease or heart attacks according to its own advertising,
- and much more.

I’ll name names and provide details. I’ll also discuss some common medical procedures and show you that, for example,

- A quarter, maybe more, of the mastectomies in Connecticut generate no patient benefit.
- Half, maybe more, of the back surgeries in Fort Myers Florida generate no patient benefit.
- 30% or maybe even half of the c-sections in Florida, New Jersey and Louisiana provide no patient benefit.

This excess can lead to patient harms caused by medical care. Consider this trend:

- The 1999 Institute of Medicine report ‘To Err is Human’ found that up to 98,000 patients die annually from medical errors.
- Seventeen years later, a 2016 Johns Hopkins study found that over 250,000 Americans die annually from medical errors.

All this leads to a dismal healthcare summary:

- Americans spent $328 billion more for healthcare in 2015 than 2013. That’s about $1000 more per person.
- But we lived slightly less long in 2015. For the first time in decades, our national life expectancy actually fell despite the increased medical spending.

This gross inefficiency puts enormous responsibility on individual patients to choose healthcare wisely.

Step 1 of that process is acknowledging and understanding the problems.

Step 2 is learning how to make wise medical decisions.

How to make a wise medical decision

Follow this process to get better outcomes with less risk and at lower costs:

- First, determine how well the medical intervention works.
- Second, evaluate your treatment options. You almost always have them.
- Third, determine which doctor and hospital generates the best outcomes for your preferred treatment alternative.
- Fourth, if you find two or more equally excellent providers for your preferred option, consider price. But consider price fourth, only after you've completed the first three steps!

Asking the right questions gets you the information necessary for wise decisions.

But asking the wrong questions gets you … something else. Maybe useful information, but maybe just some of the most important information, maybe irrelevant (even if true) facts, maybe impressions, maybe incorrect information, maybe noise, who knows.

Obtaining the relevant information is a skill that most of us lack. In fact, according to the US Department of Health and Human Services, only 12% of Americans are medically literate, meaning they have the skills necessary to assess likely treatment benefits and harms though I suspect the real number – the percentage of people who understand and use the tools described in this book – is actually much lower.

Less medically literate folks have higher hospitalization rates and medical costs, and poorer health outcomes. This medical literacy problem arises because most of us haven't been taught how to approach medical investigations. This book will correct that problem.

The Goldilocks Rule
not too little, not too much, but just right

Too little medical care leads to undertreated patients and poorer-than-optimal outcomes.

Too much medical care leads to overtreated patients, higher-than-necessary treatment risks, higher-than-necessary medical costs and potentially poorer-than-optimal medical outcomes.

Inappropriate medical care leads to suboptimal outcomes, excessive costs, patient dissatisfaction and sometimes lawsuits.

Appropriate medical care minimizes your chance of medical harm but maximizes your chance of medical benefit.

Why can't I simply follow my doctor's advice and skip the rest of this chapter?

You always should consider your doctor's advice! But temper it with our questions for two main reasons:

First, doctors generally worry more about undertesting and undertreating than overtesting and overtreating patients. (This highlights a difference between advice giving and advice receiving, a situation I'll discuss in Question 4.)

- As trainees, they're upbraided for having too little information about their patients not too much information, so learn to overtest.
- As doctors, they're typically paid to do more not less, so may overtreat.
- As caring human beings, they want to do something to relieve your suffering, not nothing.
- As professionals operating in our legal system, they're more likely to be penalized for not doing something than for doing something extra.

One result is that about a third of patients annually receive one or more useless tests or treatments.

- Dr. Atul Gawande, a famous Boston area surgeon, found that 7/8ths of his patients had.
- Millions more, he writes, 'receive drugs that don't help them, operations that don't make them better and scans and tests that do nothing beneficial but often cause harm.'

Second, many doctors assume they know what patients want, their risk / reward tradeoff decisions. But studies show doctors can get this wrong.

- One, for example, showed that most doctors assume breast cancer patients rate 'living as long as possible' as their primary goal. But only 59% of patients agreed. Doctors were wrong about 40% of the time.
- A second showed that 40% of men with benign prostate disease opted against surgery once they were fully informed of surgical risks and benefits.
- A third showed that almost 20% of patients suffering from chest pain diagnosed as stable angina opted against surgery when fully informed of their treatment options and likely outcomes.

A fundamental cause of these problems is 'information asymmetry' or 'your doctor knows more about medical care than you do so thinks he or she understands your treatment goals and preferences too.' Gawande writes

We can recommend care of little or no value because it enhances our incomes, because it's our habit, or because we genuinely but incorrectly believe in it.

Patients often want to do their homework but don't know how. Some attempt to become mini-MDs through online research. That almost certainly won't protect against unnecessary, excessive or inappropriate care; the research is clear.

Instead this book will show you how.

It will put you onto a level (or, at least, a more level) field so you can participate more wisely and effectively in your own medical decision making.

The 5 Question Checklist
Medical Literacy in Practice

*If you **understand** these questions, you're medically literate.*

*If you **ask them**, you're ahead of the curve.*

*If you **get them answered**, you've maximized your chance of benefit and minimized your risk of harm.*

In a typical appointment, you and your doctor discuss a medical problem and your doctor recommends an intervention.

Ask these 5 questions about that recommendation:

- Has it been tested for the outcomes that concern me?
- Out of 100 people like me, how many benefit and how many are harmed?
- Is it overused?
- Would most physicians make the same recommendation or might some suggest something different?
- How many patients like me do you treat annually?

These deceptively simple questions are based on extensive research and analysis. The better you understand them and the more you integrate them into you medical thinking, the better care you'll get.

Ask them of every doctor, at every meeting, about every medical intervention.

You can use this list as a script. Feel free to share it with your doctors.

Question #1
Has it been tested for the outcomes that concern me?

Testing determines how well a medical intervention works in real life, on real people.

When testing, medical researchers typically divide a large group of people in half to make 2 identical smaller groups. They give one group the treatment but not the other.

Then researchers watch both groups for a time period, say 5 years, and note medical differences like the number of heart attacks, deaths or strokes. They attribute any differences to the intervention.

Simple! (Actually not simple at all. Medical research methodology is very complicated and worthy of many books, each much longer than this.)

But what happens if you don't have 5 years available? Say that a new blood pressure lowering drug just came on the market, looks promising and you, a person with high blood pressure, have a doctor's appointment the next day.

Your doctor may say 'this is the newest generation of blood pressure lowering medications and has been configured to reduce the side effects of the old drug. I suggest you try it and see how you tolerate it.'

In theory the new drug works well. But it hasn't been tested yet in real life, on real people, for years.

How well does it work?

Dr. Vinay Prasad, assistant professor of medicine at the Oregon Health and Sciences University, studies that issue. He asks 'how well do medical interventions work if they haven't been tested over long time periods on real people?'

How well, in other words, did medical theory hold up to subsequent testing?

Prasad and his team conducted a fascinating study. They reviewed every article in the New England Journal of Medicine between 2001 and 2010 and pulled out those that studied and tested an established medical practice, one commonly used on patients like intensively lowering blood sugar in Type 2 diabetics to reduce cardiovascular events … interventions, in other words, that made medical sense and that the medical community embraced.

363 studies qualified.

Prasad then asked 'Of those 363 studies, how many affirmed the practice?' i.e. found that it benefited patients.

38% affirmed the practice, 40% negated the practice, (found it ineffective or harmful) and 22% were ambiguous.

Dr. Prasad's research shows that if you base your medical decisions on biology, physiology, anatomy and logic – but not on test results – you are wrong about as often as you are right.

We'll call this Prasad's Law and refer to it throughout this book.

According to Dr. Prasad, rather than focusing on outcomes, patients often

> *gravitate toward the nuts and bolts — what does it do, how does it work?*
>
> *But the real question is: Does it work? What evidence is there that it does what you say it does? What trials show that it actually works?*
>
> *You shouldn't ask how does it work, but whether it works at all.*

Why is this the case?

Our bodies are enormously complicated and our understanding of medical risks, causality and treatment impacts is surprisingly limited. Sometimes (often?) rather than using the most important biological or anatomical factors in our medical theories, we use the most easily accessible and measurable.

Here's an analogy to illustrate:

Assume that our bodies are controlled by a wizard located in our brain, more or less like the fellow behind the curtain in the Wizard of Oz.

The wizard in our brain has a wall of knobs that control body parts and functions - one controls cholesterol levels, another blood pressure, a third bone density, a fourth eye ball pressure, etc.

If each knob is 1 inch in diameter and 1 inch apart (so the wizard can get his fingers around it) the wall is six and a half feet high and half a mile long!

Turning any one knob affects the value of some others, which in turn affect still others.

We simply can't anticipate all the initial effects, rebound effects, interactions and modifications from turning a knob or two.

Medicine rarely works in the simplified 'if A causes B, and B causes C, then A causes C' scenario. That's why we need to test.

Wise patients always ask 'has it been tested for the outcomes that concern me?'

If it has been tested, then your doctor can tell you how well it works. All physicians today can access extensive databases of medical studies…in their offices…in real time so they can answer this question.

If answers exist.

Asking this question may motivate your doctor to refresh his or her memory and look for new studies that have been published since the last time he or she checked.

You and your doctor can then decide if the intervention works well enough for you. I'll show you how in the next section.

But you may learn that the intervention has not been appropriately tested. In that case, you know your chance of benefit is only 50/50. Prasad's Law tells us that.

And even if it benefits you, it might not benefit you very much.

Examples of medical care that should work, but doesn't; Case studies that illustrate the power of asking this question

I'll present 6 case studies to show the power of asking 'has it been tested for the outcomes that concern me?' and why you need to ask this question about every medical intervention:

- Extended release niacin, a 'good cholesterol' boosting drug
- Atenolol, a blood pressure lowering drug
- Ezetimibe, a cholesterol lowering drug
- Vertebroplasty, a back surgery technique
- Arthroscopic knee surgery, a knee osteoarthritis remedy
- Rest after heart surgery, an historical example to tie everything together

Extended release niacin. Niacin, a B vitamin, has been shown in tests to raise good (HDL) cholesterol. More good cholesterol is associated with a lower heart attack risk, so artificially raising it should benefit patients.

Niacin doesn't lower total cholesterol like commonly prescribed statin drugs.

Cardiologists have prescribed various niacin products for years. One, Niaspin manufactured by Abbott Labs, generated about $900 million in 2009 sales.

Then in 2011, the AIM-High trial of niacin effectiveness showed that, while extended release niacin is associated with higher HDL levels and lower triglyceride levels, there was no significant reduction in cardiovascular events.

In 2013, a second study, this time of Merck's niacin drug Tredaptive found the same thing: no difference in coronary event rates between people taking Tredaptive with a statin, and those just taking the statin.

Two studies on two different niacin based drugs arrived at the same conclusion: niacin doesn't reduce rates of heart attacks or strokes.

This is an example of Prasad's Law: interventions that appear to make biological sense and that are adopted before publication of comparative tests are proven ineffective or harmful about half the time when they finally are tested.

Atenolol, a blood pressure lowering drug. High blood pressure is a common condition in which the long-term force of the blood against your artery walls is high

enough that it may eventually cause health problems such as heart disease. High blood pressure can damage the heart and coronary arteries and lead to heart attacks, strokes and death, among other events.

Lowering blood pressure, therefore, should reduce the number of heart attacks, strokes and deaths. So strongly do physicians subscribe to this theory that they write millions of blood pressure lowering medication prescriptions annually, worth billions of dollars, including 36 million prescriptions for Atenolol in 2010.

Atenolol recorded $161 million in 2014 sales.

Unfortunately comparative study hard outcomes do not always support the theory.

Start in 2002 with publication of the LIFE study on two of the most commonly prescribed blood pressure lowering medications called beta blockers, Losartan and Atenolol. Atenolol placed 2nd in preventing heart attacks and strokes.

Was that because Losantan was superior or because Atenolol was actually ineffective?

That question was answered in a 2004 meta review (a compilation that integrates results from several different studies to develop a single conclusion) in the Lancet entitled ‘Atenolol in hypertension: is it a wise choice?’

Those reviewers found that

> there were no outcome differences between Atenolol and placebo in the four studies, comprising 6825 patients, who were followed up for a mean of 4.6 years on all-cause mortality, cardiovascular mortality, or myocardial infarction [heart attacks].

The PubMed abstract summary concludes:

> Our results cast doubts on atenolol as a suitable drug for hypertensive patients.

The theme was then picked up in the March 15, 2005 issue of The American Family Physician, a publication of the American Association of Family Physicians. Dr. Henry Barry’s article ‘Should Atenolol Be Used for Hypertension?’ concluded that, though atenolol did lower blood pressure,

> It does not appear to reduce the rates of cardiovascular mortality or morbidity.

Let’s summarize:

- One major, high quality comparative study in 2002 concluded Atenolol is ‘inefficient’
- A large meta study in 2004 concluded ‘no outcome differences’ as compared to a placebo and cast doubts on Atenolol as a suitable drug for hypertensive patients.

- At least one article in a professional publication in 2005 seriously questioned the use of Atenolol.
- Five years later, docs wrote 36 million Atenolol prescriptions and nine years later Atenolol achieved $161 million in annual sales.

Medically literate folks – the ones who ask the questions in this book – could have saved those millions of dollars by avoiding Atenolol.

Would they have made wise decisions?

In January 2017, Cochrane released an update on beta blocker research. Cochrane researchers reviewed all relevant beta blocker studies published through June 2016, most of which focused on Atenolol. Their conclusions were entirely in line with the research discussed above, specifically that beta-blockers have little to no effect on heart attacks or mortality and are inferior to other anti-hypertension drugs.

I hope you're beginning to understand why you need to ask 'has it been tested for the outcomes that concern me?' about every medication. Even for medications that have been around for a long time.

Ezetimibe, a cholesterol lowering drug. Lower cholesterol is associated with fewer heart attacks. Ezetimibe, typically marketed as Zetia, blocks cholesterol absorption in the small intestine, unlike the more commonly prescribed statins that block absorption in the liver.

- Some patients can't tolerate statins.
- Others might not achieve their desired cholesterol reduction goals with statins and lifestyle changes alone.

Ezetimibe offers benefits to both types of patients. Consider this statement on Zetia's website, zetia.com from about 2011 – 2016.

Adding Zetia to a statin is proven to help reduce cholesterol more than a statin alone.

Zetia's sales exceeded $3 billion annually from 2013 - 2016.

But read the next sentence on Zetia.com, this one in bold:

Unlike some statins, Zetia has not been shown to prevent heart disease or heart attacks.

The New York Times review of Zetia's 2008 clinical trial, for example, concluded that no trial has ever shown that it can reduce heart attacks and strokes.

Note the difference between cholesterol lowering (Zetia has been shown to be good at this) and heart attack prevention (Zetia has not been shown to be good at this).

Then in 2014, the IMPROVE-IT study showed a ‘modest’ though statistically significant benefit of Vytorin (combination of Zetia and Zocor, a statin) over a statin only, but just for a very select group: patients who had already suffered a heart attack or experienced chest pain.

This underscores the need to ask your doctor regularly ‘Has it been tested for the outcomes that concern me?’ Be clear about the outcomes that concern you – heart attack reduction or cholesterol lowering. They’re not necessarily the same.

- Patients who conflated the two and focused on Zetia.com’s first claim that Zetia reduces cholesterol might have opted to take the medication but then only have received the cholesterol lowering benefit, not the heart attack reduction one. On the other hand
- Patients who relied only on the website’s second sentence ‘Zetia has not been shown to prevent heart disease or heart attacks’ - and who had previously had a heart attack - might have missed the heart attack prevention benefit discovered in 2014.

See why being medically literate is so important?

Vertebroplasty to relieve back pain Let’s switch focus now from medications to procedures. Consider vertebroplasty, a procedure to inject medical grade cement into fractured vertebra (back bones) to reduce back pain.

In 2008, the US market for vertebroplasty was $245 million.

Then in 2009 the New England Journal of Medicine published two studies comparing vertebroplasty to a control or placebo group that received lidocaine (a topical skin numbing agent), massage and aromatherapy to reproduce operating room smells.

- The Australian study found ‘no beneficial effect’ of vertebroplasty compared to the control group.
- The Mayo study concluded that patient improvements were similar in the placebo and experimental groups.

Vertebroplasty, in other words, worked as well as, but no better than, the safer and far cheaper placebo.

$245 million on a procedure that works no better than a placebo?

See why asking the ‘has it been subjected to comparative studies?’ question is so important?

Surgery for Knee Osteoarthritis Knee osteoarthritis is a degenerative disease that causes pain, stiffness and decreased knee function.

Arthroscopic surgery, including lavage (removal of particulate material such as cartilage fragments and calcium crystals) and debridement (surgical smoothing of articular surfaces and osteophytes) was the widely used treatment in the early 2000s despite the fact that, according to the New England Journal of Medicine in 2008 ‘scientific evidence to support its efficacy is lacking’.

Estimates of the number of knee arthroscopies performed annually in the US vary, and not all address osteoarthritis so we’ll have to estimate the size of this problem:

- A 2002 New England Journal of Medicine study estimated 650,000 procedures at $5,000 each, creating a $3.25 billion market.
- A 2014 NEJM study estimated the market at 500,000 knee arthroscopies at about $20,000, generating a $10 billion market.
- Vinay Prasad in his 2015 book Ending Medical Reversal estimated the market at 700,000 patients spending $4 billion.

How poorly does the scientific evidence support the efficacy of arthroscopic surgery to treat knee osteoarthritis?

- A 2008 New England Journal of Medicine published study concluded that they ‘failed to show a benefit of arthroscopic surgery for the treatment of osteoarthritis of the knee.’
- This followed a 2002 comparative study which concluded ‘At no point did [the] arthroscopic-intervention group have greater pain relief than the placebo group.’
- The 2002 study concluded ‘This study provides strong evidence that arthroscopic lavage with or without debridement is not better than and appears equal to a placebo procedure in improving knee pain and self-reported function.’

Those disagreeing with these study conclusions present the usual ‘weak study methodology’ case, primarily, I would suggest, to protect their incomes. Even at our lowest market estimate - $3 billion – that’s certainly a big incentive for lots of people to protect their turfs.

These studies raise some uncomfortable questions:

- Why, after the 2002 paper, did doctors continue to prescribe this procedure and patients have it?
- Why after the 2008 study did both parties continue to use it?

This is an extension of Prasad’s Law that says treatments adopted absent testing are proven ineffective or harmful about half the time. Here we have treatments used even after studies showed no patient benefit, underscoring the need for you to ask this question and insist on a clear answer about every medication and procedure.

Asking encourages your doctor to check (again?).

Never hurts but may help.

A lot!

Rest after heart surgery, an historical example to tie all this together.

We'll start in the early 1900s with Dr. James Herrick's advice then fast forward to today's protocols.

Herrick was an extraordinarily influential coronary care researcher who received impressive accolades from both the Association of American Physicians and the American Medical Association.

In his major 1912 paper, Herrick wrote that, after having a heart attack or heart surgery 'the importance of absolute rest in bed for several days is clear'.

Herrick's recommendations were adopted by most hospitals. Over time they extended Herrick's advice of absolute bedrest from several days to a few weeks.

Indeed, thirty four years after Herrick's paper, Dr. Thomas Lewis published his own coronary care textbook Diseases of the Heart and elaborated on Herrick's prescription:

Rest in bed should continue for 4 – 6 weeks to ensure firm cicatrisation of the ventricular wall … Patients have lost their lives … by neglect of these precautions.

Lewis' justification came from pathological studies showing that it can take 6 to 8 weeks for firm scarring of the lesion to occur. Rest for that amount of time was considered necessary to minimize ventricular rupture risks.

Dr. Paul Woods, another coronary care authority, reinforced that message in his textbook Diseases of the Heart and Circulation in 1959, 13 years later, recommending 3 – 6 weeks of bedrest or more depending on the severity of the heart attack.

Thus at least three medical textbooks written between 1912 and 1959 agreed: post heart attack and heart surgery, patients should rest, pretty much for as long as possible.

But by the 1960s medical opinion reversed. Eugene Braunwald, author of his own 2007 cardiology textbook, claims doctors began to realize that

Prolonged bed rest, which had been routine since Herrick's day, could actually be harmful in some patients by leading to venous thrombosis and fatal pulmonary thromboembolism. In uncomplicated cases, the duration of absolute bed rest was shortened to about five days.

Patients who asked 'what do you recommend doc?' in the 1940s and 50s would have received the long bedrest recommendation.

But patients who asked the same questions in the 1960s and 70s would have received the short bedrest advice.

And today, patients are advised to walk every day during the first 6 – 8 weeks post heart surgery, the exact opposite of Herrick's, Lewis's and Woods' recommendations.

How can 'rest' and 'don't rest' both be right? They obviously can't. At least one is wrong. Drs. Herrick, Thomas and Woods offered their best guesses backed up with biological justifications. In effect, they said 'our best guess is that the risk of ventricular rupture exceeds the risk of venous thrombosis and fatal pulmonary thromboembolism.'

Their guesses were really testable propositions which, apparently, weren't actually tested until relatively recently. When tested, they learned that thrombosis risks exceed ventricular rupture risks. Thrombosis and embolism risks are so high in fact that today's patients are advised not even to stand in one place for more than 15 minutes! The exact opposite of Herrick's, Thomas's and Woods' advice.

That's why wise patients don't research why a specific medical recommendation makes sense. Doctors and scientists can justify a wide range of (often conflicting) recommendations, just as we've seen here. Prasad's Law tells us that absent testing for specific outcomes of concern, those recommendations are wrong about half the time.

Instead of relying on theory, wise patients rely on test data, the facts.

The tragedy of this story is that some heart attack recovery patients presumably died in the last century from following the established protocols and textbook advice.

They didn't ask if the recommendations had been tested.

****

Dozens, hundreds, perhaps even thousands of other 'makes sense but doesn't work' situations exist. Here are some relatively-easy-to-understand additional examples of Prasad's Law from his book Ending Medical Reversal.

- Estrogen replacement to reduce heart attacks in postmenopausal women. Testing showed no heart attack rate reduction.
- Coronary stent insertion to prevent heart attacks in patients with stable angina. Testing showed no impact on heart attack rates over time.
- Prophylactic antibiotics for people with persistent Lyme disease symptoms and a history of Lyme disease. Testing showed no symptom reduction.
- Lowering diabetic's blood sugar (A1c) below 7% to prevent heart attacks with an intensive drug regimen. Testing showed an increase in mortality rates.
- Calcium plus vitamin D to reduce the risk of hip fractures. Testing showed no hip fracture rate reduction but an increase in kidney stone risk.
- Withholding birth control pills for women with lupus to reduce the rate of lupus flares. Testing showed no increase in flares.

- Saw palmetto for benign prostatic hyperplasia. Testing showed no benefit measuring multiple outcomes despite more than 2 million men using it.

****

ChoosingWisely, a program organized by the American Board of Internal Medicine Foundation to combat wasteful, unnecessary and harmful medical care lists 300+ more examples of medical practices that, according to testing, should not be used. ChoosingWisely is a wonderful resource for well informed patients. Here are a few examples for illustration purposes.

Don't automatically use CT scans to evaluate children's minor head injuries.

Avoid doing stress tests using echocardiographic images to assess cardiovascular risk in persons who have no symptoms and a low risk of having coronary disease.

Don't perform EEGs (electroencephalography) on patients with recurrent headaches.

Don't routinely treat acid reflux in infants with acid suppression therapy.

Don't recommend prolonged or frequent use of over-¬the-¬counter (OTC) pain medications for headache.

Don't routinely prescribe antibiotics for inflamed epidermal cysts.

Don't use systemic (oral or injected) corticosteroids as a long-term treatment for dermatitis.

****

When you ask 'has it been tested for the outcomes that concern me?' you may learn how well it works. In that case you and your doctor can determine if the benefits are substantial enough, and risks low enough, for you to have the treatment. I'll show you how in the next section.

But you may learn that the treatment has not been tested in real life, on real people.

In that case, remember Prasad's Law.

Applying Prasad's Law to long term medication use

Some medications may have been tested for 1 year, say, but be prescribed for longer. What are the 8, 15 or 20 year effects, both positive and negative? We often don't know.

This is a version of Prasad's Law. In this case, the untested treatment is the time horizon. A medication with few side effects over 6 months may have major side effects over 10 years.

You can rephrase the testing question to 'Has it been tested for the length of time that I'm likely to be on it?'

Summary of Question 1
What We Have Learned So Far

Comparative tests tell us how well medical interventions work.

Wise patients ask ‘Has it been tested for the outcomes that concern me?’ and base their medical decisions on comparative test results. I’ll show you how in the next section.

Importantly, we also learned that interventions that make biological and anatomical sense are shown to be ineffective or harmful about half the time in comparative tests.

Patients who base their medical decisions on biology and logic – but not test results – are wrong about as often as they’re right.

Question #2
Out of 100 people like me, how many benefit and are harmed?

Determining how well care works from medical tests

Once you learn that a treatment has been tested, you and your doctor can discuss the impact. Use this phrasing:

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

This tells you how well the treatment works in testing circumstances. We’ll discuss how well it may work in real life circumstances in the next chapter.

****

Ask ‘out of 100’ to get a number for your answer. ‘16’ conveys more information than ‘some’, ‘many’, ‘a few’ or ‘quite a few’.

Some patients may decide that 16 people benefiting is good enough to have the treatment while others say ‘only 16? That’s not very many.’ Different people can reasonably disagree.

Statements like ‘this treatment cuts your risk by 36%’ don’t answer the question! 36% of what? Percentage answers may confuse more than they illuminate.

Remember that Prasad’s Law applies if your doctor can’t answer the ‘of what’ question above.

Ask about ‘people like me’ because treatments can have different impacts on different demographic groups. Consider these examples.

Age: The American Academy of Pediatrics recommends against prescribing cough and cold medications for respiratory illnesses in children under 4 saying ‘these products

offer little benefit to young children and can have potentially serious side effects'. They're apparently fine for 6 or 8 year olds though.

… out of 100 people … these medications work, but

… like me … not if you're under 4 years old

Gender: In 2014, the Food and Drug Administration cut the recommended dose of Ambien, a sleep aid, in half for women after determining that men and women metabolize it differently. Women, it turns out, have more of the drug in their bodies the next morning, putting them at higher risk of impaired driving.

… out of 100 people … the medication works, but

… like me … not so well for women

Other patient differences exist but we don't always know how frequently. You and your doctor may have to estimate the impact on people like you.

Identify the benefits of interest to you. If you take a heart attack prevention medication ask 'out of 100 people like me, how many avoid a heart attack by taking this medication?'

- Remember our discussion of Atenolol and Zetia in the last section.

If you want to reduce your back pain, ask 'out of 100 people like me, how many enjoy less back pain as a result of this procedure?'

- Remember our discussion of vertebroplasty and knee surgery in the last section.

Beware of listing 'lower my cholesterol' or 'lower my blood pressure' as the benefit you hope to achieve. We discussed earlier how these 'test benefits' may or may not correlate closely to 'patient' or 'event' benefits. Focus on the benefits you hope to achieve.

And be as specific as possible.

Some case studies to indicate the power of asking this question

Out of 100 people like me, how many benefit and are harmed?

Consider antibiotics to treat pediatric ear infections, a quite common childhood problem. Ear infections can be painful to the child and frightening to the parents who, not unreasonably, want to do something to help.

Ear aches are sometimes viral and sometimes bacterial. Doctors often prescribe antibiotics.

This intervention – antibiotics to treat pediatric ear aches - has been studied so Prasad's Law doesn't apply.

A meta review – that's a compendium of several individual studies – of 15 studies on 4100 kids concluded that 6 in 100 who took antibiotics reported less ear pain after 2 – 7 days; 94 in 100 did not enjoy less ear pain as a result of the antibiotics. Most had a complete recovery within 2 – 7 days without the medication.

But 11 in 100 who took antibiotics suffered uncomfortable side effects like diarrhea.

- Out of 100 kids who take antibiotics to treat ear infections, how many benefit by enjoying less ear pain in 2 – 7 days? 6
- Out of 100 kids who take antibiotics to treat ear infections, how many are harmed by diarrhea or other uncomfortable side effects? 11

Now you have sufficient information to discuss this intervention with your pediatrician. Does it work well enough for your child? Some parents may decide yes, others no.

But in both cases, it's an informed decision made by a parent in light of the facts.

Dozens of similar cases exist. One website www.TheNNT.com lists about a hundred. ChoosingWisely www.ChoosingWisely.org takes a slightly different approach and lists hundreds more. Both sites will provide good information for you to discuss with your doctor.

Out of 100 people like me how many benefit and are harmed?

We already discussed how age and gender can impact outcomes. I'd like to explore a different, infrequently discussed but vitally important like me category: social status.

I'll define social status ambiguously as a combination of wealth, income and sense of control over your life, analogous to the way former US Supreme Court Justice Potter Stewart defined pornography: you know it when you see it.

The Whitehall studies in Britain first identified and quantified social status' impact on health. These studies tracked disease and death rates by job and rank in the British civil service and their conclusions have been reproduced in other studies, in other countries.

Whitehall found that low social status folks had higher disease and death rates than high status folks. Surprisingly – and this is the big deal - this was not only due to measureable factors like cholesterol, blood pressure, blood sugar, smoking, obesity or exercise rates.

After correcting for those factors, the lowest status folks were about twice as likely to have heart attacks, develop other diseases and die as the highest status ones.

Whitehall also found a gradient: the higher you are on the social status scale, the lower your disease and death rates and the reverse, the lower you are on the social scale, the higher your disease and death rates.

Over and above specific disease risk factors, Whitehall concluded, there is something about social status independently that impacts people's health. Harvard School of Public Health Professor Nancy Kreiger, whose own work affirms Whitehall's conclusions, put it this way:

> An individual's health can't be torn from context and history. We are both social and biological beings—and the social is every bit as "real" as the biological.

In line with this analysis, a major 2016 study in JAMA, the Journal of the American Medical Association found that the life expectancy gap

between the richest 1% of Americans and the poorest was about 12 years on a gradient similar to Whitehall's. In an accompanying editorial, Nobel laureate Angus Deaton emphasized the impact of income and social status on health and castigated traditional medical thinking:

The finding that income predicts mortality has a long history… the mortality gradient by income is found wherever and whenever it is sought…but the medical mainstream emphasizes biology, genetic factors, specific diseases, individual behavior, health care, and health insurance.

Consider the medical impacts of your own social status. Imagine your doctor says 'your cholesterol level is slightly high. The guidelines suggest lowering it. I'll prescribe a medication.'

- If you're a low status person (thus facing higher than average heart attack risks) you may be undermedicated, leaving you exposed to disease harms.
- But if you're a high status person (thus facing lower than average heart attack risks) you may be overmedicated, exposing you unnecessarily to medication harms.

Try to include social status factors in your 'like me' discussions with your doctor along with age, gender, general health status, family history etc. One good information source is the 2004 report 'Work, Stress and Health: The Whitehall II Study'. Share it with your doctor. It's surprisingly easy to read and it may change the way you think about medical care.

It certainly did for me.

'Out of 100 people like me…' or 'The guidelines say…' Case study of hypertension

The American Heart Association recommends that people over 60 years old begin treatment for high blood pressure when their readings exceed 150/90.

But out of 100 people like that, how many benefit by following those guidelines?

Some answers come from a 2009 Cochrane report that summarized 15 trials totaling 25,000 subjects over age 60 with moderate to acute hypertension followed for average 4.5 years.

Out of 100 people over 60 years old with moderate to acute hypertension, how many avoid cardiovascular disease or death over 4.5 years?

Answer: About 4

Here are Cochran's numbers:

- Risk of cardiovascular death or disease without taking hypertensive medication: 14.9/hundred. This is the control group.
- Risk of cardiovascular death or disease among patients taking hypertensive medications: 10.6/hundred. This is the test group.
- Medication benefit: 4.3 fewer deaths or diseased patients/hundred (4.3%)

I don't know how many, if any, were harmed by the medication.

Which question gives you the best information and best helps you make the wisest decision: 'Out of 100 people like me, how many benefit?' or 'What do the guidelines say?'

It's your call.

Summary of Question 2
What We Have Learned So Far

Question 2 builds upon the lessons of Question 1.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

We also learned

- Why to ask ‘out of 100’ and not to accept answers like ‘this treatment reduces you risk by 36%’.
- Why to ask about ‘people like me’, including about people in your socio-economic demographic.
- Why ‘patient outcomes’ always matter but ‘test outcomes’ may not.

Question #3
Is it overused?

Sometimes beneficial care is overused so may not benefit you

This question acts as a yellow warning light to wise patients: proceed but proceed cautiously.

****

Testing sometimes shows that a treatment works well on a narrowly specified group of patients but, in the real world, doctors may offer it more widely, perhaps hoping to benefit even more patients.

Examples include mastectomies, back surgery, c-sections (I’ll discuss these three in some detail below), tonsillectomies, antibiotic prescription, prostate surgery, MRI use, coronary angioplasty and many more.

This results in treatment variation meaning that different doctors may treat similar patients differently.

Vast amounts of research into this phenomenon have identified three significant issues.

First, about 85% of the time, two or more treatments can generate the same patient outcomes.

Mastectomy or lumpectomy for early stage breast cancer, surgery or physical therapy for back pain, injections or physical therapy for frozen shoulder, etc. Though the outcomes may be the same, the process, pain, risk, recovery period, family impact and cost can vary widely.

Second, when faced with care options, many patients delegate decision making to their doctors. This forces the doctor’s preferences, not the patient’s, to define the treatment decisions and doesn’t always serve the patient’s best interests.

We’ll explore some implications in Question 4, the next section.

Third, the higher the supply of medical services in a region, the more frequently patients access those services: the more hospital beds, the more hospitalizations, the more MRI units, the more MRI tests, the more orthopedic specialists, the more orthopedic surgeries etc.

We'll discuss some implications in this section.

Excessive utilization raises costs and risks but doesn't improve patient outcomes. It may even worsen them since patients expose themselves only to potential treatment harms, not benefits.

We'll explore three case studies of treatment variation. Two are based on Dartmouth Atlas of Healthcare information: early stage breast cancer treatment in Massachusetts and Connecticut and back surgery in southwestern and southeastern Florida. The third is hospital baby delivery patterns, specifically c-section rates.

These are 3 of dozens I could have chosen. As you read them, consider how patients who have the more aggressive, excessive and overused treatments may actually end up worse off.

Case Study: Mastectomy Rates in Massachusetts and Connecticut

Female Medicare beneficiaries in Connecticut, using Connecticut hospitals, get about 40% more mastectomies per 100,000 than do similar women in Massachusetts. This has been roughly constant since 2008.

How can we determine if these surgical rate differences are driven by patient health differences or physician treatment orientation differences?

We'll first consider patient differences. The American Cancer Society tracks cancer incidence and mortality rates by state. They show that the breast cancer incidence rates for 2011 per 100,000 women are virtually identical in both states:

Based on breast cancer incidence rates alone the treatment variation appears driven by physician orientation, not patient disease rate differences.

Did the Connecticut women benefit from more mastectomies?

The American Cancer Society also tracks breast cancer mortality rates in each state. That's the rate at which women die of breast cancer. Again, they're virtually identical in both states.

If the higher rate of mastectomies in Connecticut from 2008 – 2011 generated patient benefit, we would expect to see lower Connecticut breast cancer mortality rates in 2011-2012 than in Massachusetts. That didn't happen.

Women asking the standard treatment questions – is this a good treatment? Do you get good results? Would you recommend this treatment for your wife, daughter or sister? – would get the same answers in Massachusetts and Connecticut.

But the Connecticut women wouldn't avoid those additional mastectomies.

The higher mastectomy rate in Connecticut generates no patient mortality reduction benefit. It only raises patient risks and costs.

Asking the ‘is it overused in this hospital or region’ question would help motivate physicians and well informed patients to review these kinds of data.

Follow up with ‘out of 100 women like me, how many benefit and are harmed by mastectomies?’

Really well informed women might also ask ‘would most physicians make the same treatment recommendation or might some suggest something different?’ I’ll introduce that question in the next chapter.

Case Study: Back Surgery in Florida

Medicare beneficiaries in southeastern Florida, around Miami, are about half as likely to have back surgery as Medicare beneficiaries in southwestern Florida, around Fort Myers.

Are retirees in Miami medically different from retirees in Fort Myers? John Wennberg, founder of the Dartmouth Atlas and professor emeritus at the Geisel School of Medicine at Dartmouth, answers with a resounding ‘no’ saying

There is no epidemiologic evidence that illness rates vary as sharply from one health care region to another as does surgery.

Do retirees in Miami prefer more aggressive care than retirees in Fort Myers? In other words, do Miami patients routinely ask for physical therapy for their back pain while Fort Myers patients typically ask for surgery?

Again ‘no’ but this time from Dr. James Weinstein, former Chairman of the Orthopedics Department at Dartmouth’s Geisel School of Medicine who has studied treatment variation for years:

It's highly improbable that Medicare retirees living in Fort Myers prefer back surgery two times as often as residents of Miami.

What causes the treatment variation? Wennberg again provides the answer:

Doctors decide who needs health care, what kind, and how much.

And the key patient benefit question: Do retirees in Fort Myers benefit from the extra back surgeries? In other words, do Miami retirees suffer unnecessarily from receiving too few back surgeries?

Though I was unable to find solid academic studies that specifically answer this question (!), Dr. Elliott Fisher and his Dartmouth colleagues addressed this issue in general in their massive 2003 study, ‘The Implications of Regional Variations in Medicare Spending’. One observation, paraphrased for readability here:

For every 10% increase in medical spending, the relative risk of death increased.

In none of the regions studied did the higher per capita expenditures lead to a statistically significant mortality decrease.

In other words more care, or care above the minimum available in any US region, led to more harm not more benefit.

Wise patients don't stop their questioning when they learn that a treatment is beneficial, as spinal surgery and mastectomy sometimes are.

Wise patients want to ensure that the treatment provides benefit to them. That takes additional questioning.

Acceptable and Unacceptable Answers to 'Is it overused?'

Acceptable answers include 'yes', 'no' and 'I don't know'. All can lead to a useful, additional discussion.

Unacceptable answers include 'we never perform unnecessary back surgery.' Fort Myers orthopedists and Miami orthopedists would say this about as frequently!

So would Connecticut and Massachusetts oncologists.

See the somewhat-famous-party-trick discussion coming up for further explanation.

Case study: C-section delivery rates at different hospitals

C-section rates vary tremendously among hospitals and regions. Some hospitals routinely deliver 40% or more of babies by c-section while others deliver 20% or less.

Similarly some states exhibit far higher average c-section rates than others.

We'll start our analysis with a 2011 New Hampshire Insurance Department study 'A commercial study of vaginal delivery and cesarean section rates at New Hampshire hospitals' that showed c-section rates varied between 15% and 47% of deliveries by New Hampshire hospital. That study concluded

There are no obvious reasons that explain why c-section rates are higher at one NH hospital than another …

there does not appear to be a relationship between c-section rates and health status among hospitals …

statistics show essentially no relationship between hospital population health and health status and c-section rates.

The NH study did not note outcome differences among hospitals suggesting similarity. (Major outcome differences would have been headline news and almost certainly included in this study.)

That raises the question: Do hospitals that perform more c-sections on similar populations generate healthier babies?

A second 2011 study addressed that, this time of 30,000 births at 10 upstate New York hospitals without specialized neo-natal intensive care units but with varying c-section rates. It found no difference in outcomes for babies born in the hospitals with the highest c-section rates and those with the lowest when outcomes are measured by Apgar scores, need for assisted ventilation, or need to move to intensive care hospitals.

Two studies, both showing different c-section rates by hospital without apparent patient health reasons or outcome differences.

Fast forward to 2013 and consider the conclusion of a Harvard School of Public Health study of 228,000 births in 49 different Massachusetts hospitals:

The same woman would have a different chance of undergoing a c-section based on the hospital she chooses …

Certain hospitals' high rates of cesarean births have more to do with characteristics of the hospitals themselves than with characteristics of their patients.

Harvard goes on to issue this caution:

While c-sections can be a lifesaving procedure for an infant in distress, or when there are multiple births or other labor complications, c-sections that are not medically necessary can put mothers and babies at avoidable risk of infection, extend hospital stays and recoveries, and increase health costs.

Again a beneficial medical intervention is overused and when 'not medically necessary' (Harvard's words) puts patients at unnecessary risk.

The same year, 2013, a different study by Dr. Katy Kozhimannil and others of 817,000 births in 593 hospitals nationally arrived at the same general conclusion. Kozhimannil found that c-section rates varied from 7 to 70 percent of all deliveries by hospital and suggested that provider practice patterns were a key driver of this rate variation.

Surgical variation rates were not, according to Kozhimannil, explained by hospital size, geographic location or teaching status…

The scale of this variation signals potential quality issues that should be quite alarming to women, clinicians, hospitals and policymakers.

More or less like the New Hampshire study, the New York study and the Harvard study.

Four different studies arrived at the same conclusion: c-sections benefit some patients but are overused so may not benefit – and may even harm – others.

To summarize:

- The hospital that you choose has a significant impact on your likelihood of delivering by c-section.
- Hospitals with the highest c-section rates don't necessarily serve the sickest, most at-risk populations.
- C-section rates vary significantly even among low risk mothers.
- Hospitals performing the highest rates of c-sections do not generate better outcomes than hospitals performing lower rates.

These treatment variation situations get replayed for dozens of procedures including

- tonsillectomies
- coronary stent insertions
- heart valve replacements
- referrals for CT scans
- hip replacements
- radical prostatectomies, and others.

Dartmouth researchers estimate that if you add all the excesses above the minimum, for lots and lots of procedures, you'll arrive at about 1/3 of all medical spending. I'd recommend that anyone interested in this topic visit the Dartmouth Atlas website and click around. It's packed with fascinating, potentially life-saving information.

A somewhat famous medical party trick story
showing that even great doctors in great hospitals practice differently

John Wennberg, more or less the godfather of treatment variation analytics in this country, performed a party trick of sorts to show how doctors practicing at highly regarded hospitals can treat similar patients differently.

He used Boston, home to Harvard Medical School affiliated teaching hospitals, and New Haven, home to Yale Medical School affiliated hospitals, as his case study.

Wennberg learned that Boston area patients spent about 40% more time in the hospital:

- A Boston patient suffering from gallstones would be 40% more likely to be hospitalized than a similar patient in New Haven.
- A patient hospitalized for surgery that required 1 night in a New Haven hospital would often have spent 2 nights in a Boston hospital.

He wondered if the New Haven docs felt they undertreated patients or if Boston docs thought they overtreated. When asked, doctors in both cities claimed to treat patients appropriately.

Which were right? They can't both be.

To answer that question, Wennberg presented his findings at New Haven and Boston medical conferences, but he accidently-on-purpose switched the data!

He showed the Boston docs that their patients spent 40% less time in the hospital and therefore received less care than New Haven patients, and vice versa, and asked for explanations.

- The Boston docs came up with lots of reasons why the New Haven ones erred by overtreating their patients, admitting too many to hospitals and therefore exposing them to unnecessary treatment risks and financial costs.
- The New Haven docs explained why the Boston ones erred by undertreating their patients, admitting too few to hospitals and therefore exposing them to unnecessary disease risks.

Wennberg then admitted his data mistake and went through the (presumably uncomfortable) analysis of the doctors' faulty reasoning.

The bottom line: though doctors all want to treat appropriately – and claim to - they are often unaware of their own assumptions and treatment patterns.

That's why wise patients always ask our questions and demand answers…

Even from the most experienced doctors who graduated from the most famous medical schools and work at the most prestigious hospitals!

Summary of Question 3
What We Have Learned So Far

Question 3 builds upon the lessons of Questions 1 and 2.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused. We learned to ask

- Is it overused?

Appropriate answers include ‘yes’, ‘no’ and ‘I don’t know’.

Inappropriate answers include ‘we never perform excessive or unnecessary treatments.’

We’ll move now to Question 4 ‘Would most physicians make the same recommendation or might some suggest something different?’ This helps you identify your treatment options.

While always important to ask, this question is particularly critical for patients who learn that the answer to Question 3 is ‘yes, we sometimes perform this procedure too often’.

Question #4
Would most physicians make the same recommendation or might some suggest something different?

How to get and evaluate a second opinion

We learned earlier that patients have care options about 85% of the time. Often two or more treatment processes generate the same patient outcomes.

But the treatment processes can involve quite different pain levels, family impacts, recovery periods, costs and other factors.

Researchers have learned that, for the 85% of care that allows for choice, wise and well informed patients may prefer treatments different from that recommended by their doctors.

And two different patients with the same medical problem can choose different treatments and both be right.

Unfortunately, since patients today often delegate decision making to doctors, physician preference rather than patient preference often determines which treatment patients ultimately receive. That’s not always such a good thing.

Preference-sensitive decision making among patients with access to good information

Various studies have assessed the impact of patient education on preference-sensitive decision making and have generally arrived at the same conclusion: when provided with good information about both outcomes and processes, patients tend to prefer less invasive and lower risk care.

The general trend is about a 20 – 25% shift.

Coincidentally, less invasive / lower risk care tends to be less expensive.

One 2012 study in Washington State found that patients who went through a thorough treatment comparison process had 26% fewer hip replacement surgeries, 38% fewer knee replacements and cost about 15% less than patients who did not go through the same process.

Other studies have indicated

- 20% fewer stent insertions
- 40% fewer prostate removal surgeries
- 40% fewer spinal fusion surgeries for herniated disks

These studies and others suggest that physicians need to diagnose both the medical condition and the patient to prescribe the appropriate intervention. A classic analysis, Patient Preferences Matter, written by two medical school professors and one business school prof, highlights the impact:

> Health care may be the only industry in which giving customers what they really want would save money.
>
> Well-informed patients consume less medicine – and not just a little bit less, but much less.
>
> When doctors accurately diagnose patient preferences, an enormous source of waste – the delivery of unwanted services – is eliminated.

In other words, when doctors assume they know which treatment process a patient wants, they substitute their own preferences for the patient's.

That's not always wise because there's a huge difference between advice giving and advice receiving. The advice recipient may or may not agree with the advice giver.

Here's a list of some potential preference-sensitive considerations that affect physician 'advice givers' differently from patient 'advice receivers'. It's not exhaustive. I didn't include 'success' since it's obviously the most important consideration of both doctors and patients.

Some physician issues and concerns	**Some patient issues and concerns**
Regulations and guidelines	Pain
Fear of lawsuit	Recovery period
Local / regional / hospital norms	Family impact
Income	Self image
Experience with treatment alternatives	Personal preference (e.g. religious)
Avoid feeling guilty	Cost

The question ‘what would you do if you were me, doc?’ is unfair. The physician-advice-giver can’t remove him or herself entirely from the constraints imposed by that role.

How to proceed after getting a second (or even third) opinion

Once you’ve had a second (or third) physician make treatment recommendations, use this chart to compare benefits and harms. Try to fill in as many boxes as possible. Include Treatments C and D as appropriate

	Treatment A	Treatment B
Benefits and harms at intervention		
Benefits and harms over the short term		
Benefits and harms over the long term		

Each patient can define benefits and harms as those most important to him or her, as well as the short and long term. Typically short term means the first few months and long term 3 – 5 years, though you can modify these definitions as you see fit.

Here are some issues in a hypothetical comparison of surgery and physical therapy for illustration purposes only. You may have different concerns.

First, benefits and harms of the intervention.

Surgery	Physical therapy
How long will I be hospitalized?	How many sessions will I need?
How much pain will I feel and for how long?	How much pain is associated with the therapy process?
How much work will I miss?	When will I know if the therapy is working?
How long will I be incapacitated?	
How likely is an infection or complication?	

Second, benefits and harms over the short term.

Surgery	Physical therapy
How long before I regain my strength and range of motion?	How often do patients report satisfaction at 3 and 12 months?
How many patients report satisfaction with the outcomes at 3 and 12 months?	How many patients quit PT and opt for surgery in the short term?
How often do patients need a second surgery?	

Third, benefits and harms over the long term

Surgery	Physical therapy
How many patients need a second surgery within 48 months?	How many patients report satisfaction with the PT outcome at 48 months?
How many patients report satisfaction with the outcome at 48 months?	How many patients who start with PT ultimately end up with surgery within 48 months?

This comparative process isn't limited to surgery and PT: you can use it to compare any medical interventions, though the specific questions in each box may differ.

Try to format your treatment comparisons this way. It will help you focus on the most critical issues and streamline your decision making process.

Feel free to show a chart like this but with your own questions to your doctor. It may facilitate your discussions.

****

Case Study: How John decided on physical therapy for his torn rotator cuff

John, a 69 year old insurance broker, walked up to me in a lecture hall one day with his arms high in the air, smiling and saying 'my shoulder feels fine'.

Odd behavior and greeting in a professional setting. I hadn't seen or talked with him in the previous year or two.

His right shoulder had been so weak, he said, that he couldn't shift gears in his pick-up: he had to reach over the steering wheel with his left hand to shift.

His scans clearly showed a torn right rotator cuff and his orthopedic surgeon recommended surgery. All fairly routine.

But his story then took a surprising turn. I'll quote him:

'I probably would have said yes to surgery prior to hearing your lectures. Instead I asked your questions and decided to try PT first.

I regained 95%+ range of motion without pain in same time period as surgical recovery.

Same outcome as surgery at far lower cost, risk and hassle.'

The key questions:

Out of 100 people like me, how many benefit from, and are harmed by, rotator cuff surgery?

Would most physicians recommend rotator cuff surgery or might some suggest something different?

Interestingly John, a well-educated, knowledgeable, regular attendee at insurance seminars, wouldn't have asked those questions absent specific instruction and a script.

I suspect a similar situation exists for most patients like the Fort Myers back surgery folks and Connecticut mastectomy women we discussed earlier.

They all might have made different choices had they simply been taught to ask the right questions.

****

Another patient's experience asking the 'out of 100 people like me' and the 'would most physicians agree' questions.

'Preference-sensitive' applies to physicians too!

A fellow called me with this poignant story one day, completely out of the blue. He had attended a lecture and read my book Transparency Metrics.

I have a good relationship with my cardiologist, so I felt comfortable asking your 'out of 100 people like me' questions. So I did.

He put down his pen, looked at me and said 'no one has ever asked me that. I don't know the answer. Let's figure it out' and he started typing on his computer.

The process of finding answers got me involved and I ended up feeling more comfortable with his treatment recommendations as a result. I feel like I now have an even better working relationship with him than I did before.

I'm also more inclined to comply with his recommendations.

I asked a few questions then he announced 'now I have to tell you about my next experience'.

I asked my dermatologist the same questions including 'would most physicians agree with your recommendation?'

His response: 'you come into my house and ask me those questions? If you don't trust my judgment, I think you should get another dermatologist.'

Different doctors for different patients.

Preference sensitive works for physician choice also.

Choose the doctor whose style and professional demeanor work for you.

Summary of Question 4:
What We Have Learned So Far

Question 4 builds upon the lessons of Questions 1, 2 and 3.

Question 1 was 'Has it been tested for the outcomes that concern me?' We learned that comparative tests identify the benefits and harms of a medical intervention.

- Importantly, we also learned that medical interventions that have not been subjected to comparative testing are ineffective or harmful about half the time. We called this Prasad's Law.

Question 2 showed how to quantify the benefit and harm impacts. We learned to ask

- Out of 100 people like me, how many benefit? And
- Out of 100 people like me, how many are harmed?

Question 3 moved us out of the laboratory and into the real world. We learned that sometimes beneficial medical interventions are overused and learned to ask

- Is it overused?

The answer helps identify at least one critical reason for asking Question 4 'Would most physicians make the same recommendation or might some suggestion something different?'

There are several additional reasons for posing this question to your physician including:

- It helps you get a second opinion that differs from the first thus exposing you to a range of treatment options.
- It helps you differentiate personal preferences from medical imperatives.

Once you identify the treatment option that you prefer, you'll want to identify the physician and hospital that does it the best. Ask Question 5 'How many patients like me do you treat annually?'

Question #5:
How Many Patients Like Me Do You Treat Annually?

The more experience a specialist or hospital has treating patients with your medical condition, the better your likely outcomes

Research has identified a pretty strong (but not perfect!) correlation between the volume of similar patients treated by a specialist or hospital and the outcomes for those patients: The higher the volume, the better your chances.

This is not a perfect predictor but it's about the best predictor currently available.

One classic study on the impact of hospital volume on mortality rates was published by Dr. John Birkmeyer of the Dartmouth-Hitchcock Health System and his colleagues. They analyzed the impact of hospital volume on mortality rates for 2.5 million patients who underwent 14 different medical procedures over a 5 year period.

Patients, they concluded, can significantly reduce their operative mortality risk by choosing a high volume hospital. Though the specific mortality rate reduction varied by procedure, Birkmeyer and his colleagues identified a surgical quality gap between high and low volume hospitals.

They concluded three things about this gap:

First, it is large enough to concern patients.

Second, it is consistent across different medical specialties and research studies, and

Third, it makes sense. High volume hospitals, they reason, tend to have more consistent processes for postoperative care, better-staffed intensive care units, and greater resources for dealing with postoperative complications.

Other research pretty strongly supports Birkmeyer's conclusions:

A 2011 study of heart failure patients estimated that 20,000 lives could be saved annually if patients at low volume hospitals switched to high volume hospitals.

A study of bariatric surgery found that hospitals treating more than 100 patients annually had shorter lengths of stay, lower mortality rates and decreased costs. In particular, bariatric surgical mortality rates at low volume hospitals were up to 3x higher than at high volume hospitals for patients over 55 years old.

A 2013 study of high risk patients found those undergoing aortic valve replacement at high volume hospitals enjoyed better outcomes.

Studies of breast cancer treatment, knee surgery and other medical care finds pretty much the same things.

By contrast, studies comparing patient outcomes from newer vs. older technologies, or from academic medical centers vs. other hospitals, do not always find such a gap.

One such newer vs. older technology study found that physicians need to perform 1600 robotic assisted prostate removal surgeries to achieve excellence. Experience with the technology, often more than the technology itself, correlates with quality outcomes.

We find the same thing for surgeons – the higher their volume of a particular type of surgery, the better their outcomes. Dr. Paul Ruggieri summarized the literature on this topic in Chapter 5 of his book The Cost of Cutting:

> The message is becoming clearer with each published study. High volume surgeons operating out of high volume hospitals give patients the best chance for quality outcomes.

Based on the data, the high volume surgeon part of the equation seems to be the most important factor.

Ruggieri, a surgeon, might be slightly biased.

But Birkmeyer, the Dartmouth physician, agrees with Ruggieri's assessment, concluding that patients can improve their chances of survival substantially, even at high volume hospitals, by choosing high volume surgeons.

Thresholds

Some organizations publish 'thresholds' or recommendations for the minimum experience a surgeon or hospital needs to achieve excellence. Treating fewer than the threshold number of patients tends to increase mortality rates but treating more doesn't decrease those risks.

The Leapfroggroup, for example, has developed hospital threshold recommendations for several procedures such as

- Coronary artery bypass graft, minimum 450 procedures/year.
- Abdominal aortic aneurysm repair, minimum 50 procedures/year.
- Percutaneous coronary intervention, minimum 400 procedures/year.

Johns Hopkins, Dartmouth-Hitchcock and the University of Michigan go one step further and have developed minimum hospital and surgeon requirements for their affiliated hospitals including

- At least 20 pancreatic cancer surgeries per hospital per year, and at least 5 for each surgeon.
- At least 50 knee or hip replacements per hospital per year, and at least 25 per surgeon.
- At least 10 carotid stent insertions per hospital per year, and at least 5 per surgeon.

John Birkmeyer, the leader of the Dartmouth effort, suggests the impact. If all US hospitals adopted this standard, he says, about half the hospitals that perform many of these procedures would be prohibited from continuing to do them.

Wise patients choose specialists and hospitals working at or above the recommended threshold.

Why is experience so important?

The common sense answer that 'practice makes perfect' is only part of the reason, and the least important part. Physicians learn the process of cutting, suturing, etc. relatively quickly. Though these mechanical skills may improve slightly over time, this doesn't address the significant mortality reduction evidenced by high volume surgeons and hospitals. Few patients, it seems, die from faulty incisions.

Instead, I suggest that the true benefit of dealing with high volume surgeons and hospitals comes from their ability to identify patients who are 'out of bounds' more quickly and address their problems more appropriately. With volume a surgeon can sense, almost even without testing, that something is wrong.

Without the experience that volume brings, the surgeon is unsure if the patient's blood loss or reactions are within the normal range. This applies at a systemic level to hospitals also: nurses and technicians can develop the same sense from experience.

Atul Gawande wrote insightfully about this process in his article 'The Computer and the Hernia Factory', a study of Shouldice Hernia Hospital in Canada. Shouldice only performs hernia surgeries. Each Shouldice surgeon performs about 700 annually or, over their medical career, perhaps 20,000 similar surgeries. Gawande estimated, in 2002, that Shouldice's hernia surgery failure rate was 'an astonishing 1.0%.' He revised that figure in 2008 to 'closer to 0.1%'.

By comparison, some studies suggest an average 10-year hernia repair failure rate outside of Souldice at around 11%.

With repetition, Gawande found, 'a lot of mental functioning becomes automatic and effortless, as when you drive a car'. This allows experienced practitioners to focus on novel or abnormal situations and essentially ignore all that is normal and routine. A surgeon, he writes, for which most activities become automatic has a significant advantage.

He described a Shouldice operation:

- The surgeon performed each step ‘almost absently’
- The assistant knew ‘precisely which issues to retract’
- The nurse handed over ‘exactly the right instruments; instructions were completely unnecessary’
- The doctor slowed down only once, to check ‘meticulously’ for another hernia. He found one that ‘if it had been missed, would almost certainly have caused a recurrence’

This ‘almost absent attention to routine features’ but intense focus on potential abnormalities comes only from experience. That’s why higher volumes identify better quality surgeons and hospitals.

Just like why more experienced drivers have fewer car accidents!

When you consider hiring a specialist or using a hospital, be sure to ask the volume question. It just may save your life.

Summary

Let’s review what we’ve learned:

Patients who follow the Goldilocks principle enjoy better outcomes than patients who do not.

- Too little medical care can expose you unnecessarily to disease harms
- Too much medical care can expose you unnecessarily to treatment harms
- Inappropriate medical care can expose you to more risks, higher costs and lower satisfaction than optimal

We introduced 5 questions to ask all doctors about all medical interventions.

- Has it been tested for the outcomes that concern me?
- Out of 100 people like me, how many benefit and are harmed?
- Is it overused?
- Would most physicians make the same recommendation or might some suggest something different?
- How many patients like me do you treat annually?

You can, of course, ask plenty of your own questions too: you may have specific concerns about pain, cost, time off from work, impact on your family, etc.

But I hope you ask the questions listed here. They'll help you differentiate better from poorer care, reduce your chance of receiving unnecessary and non-beneficial care and increase your likelihood of satisfaction with your own medical care.

Review Questions

Answers on next page

1. What is a comparative study?

    a. A study that compares two very similar groups of people, one of which gets the medical intervention and the other of which does not
    b. A study that looks at only 1 group of people
    c. A study that predicts outcomes based on biological theory
    d. A study that compares the biological and physiological make up of different people

2. What is a well informed patient according to the medical definition of ‘well informed’?

    a. Understanding how well care works, what treatment options exist and which provider generates the best outcomes
    b. Understanding deductibles, insurance regulations and prices
    c. Understanding the biological processes in each treatment option
    d. Someone who reads lots of articles online

3. Which do doctors generally worry about the most?

    a. Performing too few tests and undertreating patients
    b. Having patients wait longer in their waiting rooms
    c. Providing interesting magazines for patients to read
    d. Performing too many tests and overtreating patients

4. Which is the cheapest?

    a. Good health
    b. The lowest cost knee surgeon
    c. A hospital-based MRI
    d. A free-standing MRI

5. Which strategy is generally the cheapest after factoring in all costs including patient out-of-pocket, deductibles, insurance premiums, time off of work, productivity losses and rehab expenses?

    a. Getting the best treatment outcomes
    b. Getting care from the lowest cost surgeon
    c. Paying cash for your treatment
    d. Negotiating the best deal you can with each provider

6. Why would a wise patient ask a physician if a proposed treatment has been subjected to comparative testing?

    a. Because treatments that have not been subjected to comparative testing are ineffective or harmful about half the time

b. Because it makes you sound smart to your doctor
c. Because you want to show your doctor who's really running the meeting
d. Because you want to waste time before making an important decision

7. What is Prasad's Law?

a. Medical treatments that have not been subjected to comparative testing are ineffective or harmful about half the time
b. A hospital room built is a hospital room occupied
c. The most expensive surgeon is the best
d. The most expensive hospital generates the best patient outcomes

8. Which benefits more people?

a. A treatment that prevents heart attacks 3 out of 100 people
b. A treatment that cuts the heart attack rate by 25%
c. A treatment that reduces total cholesterol levels by 10 points
d. We have insufficient information in (a), (b) and (c) above to answer the question

9. Which benefit interests a wise patient the most?

a. A reduction in heart attacks
b. A reduction in cholesterol levels
c. A reduction in blood pressure levels
d. An improvement in blood oxidation rates

10. This chapter suggests that patients who base their medical decisions on biology, physiology, anatomy and logic – but not comparative studies – are what?

a. Wrong about as often as they are right
b. Wise and thoughtful
c. Using the best possible information
d. Likely to enjoy the best outcomes

11. As the number of medical services in a community – like MRI machines, vascular surgeons or hospital beds – rises, what tends to happen?

a. More patients use those services
b. Fewer patients use those services
c. Service prices tend to fall
d. Care quality tends to decline

12. Wise patients sometimes ask if a particular treatment is overused. Which below in an inappropriate answer to that question?

a. Yes
b. No

c. I don’t know
d. I never provide unnecessary care

13. What is a ‘preference sensitive’ medical decision?

a. A decision that’s right *for you*. Different patients with the same medical condition can choose different treatments and all be right.
b. A decision that your doctor would prefer that you make, not him or her
c. Delegating your decisions to your doctor
d. Delegating your care decisions to your hospital

14. What is the general trend among patients who explore their treatment options?

a. They tend to choose less risky, less invasive and consequently less expensive care by about 25 – 30%
b. They get confused
c. They ultimately do what their doctor tells them to do
d. They cost the most

15. What is the main purpose of second opinions?

a. Expose patients to a range of treatment alternatives
b. Waste time
c. Increase physician billing opportunities
d. Confuse patients

16. Which surgeon generally generates the best patient outcomes?

a. The surgeon who does a specific type of surgery most frequently
b. The surgeon who graduated from the most prestigious medical school
c. The surgeon who charges the most
d. The surgeon who uses the newest technology

Review Questions

Correct answers in bold

1. What is a comparative study?

    a. **A study that compares two very similar groups of people, one of which gets the medical intervention and the other of which does not**
    b. A study that looks at only 1 group of people
    c. A study that predicts outcomes based on biological theory
    d. A study that compares the biological and physiological make up of different people

2. What is a well informed patient according to the medical definition of ‘well informed’?

    a. **Understanding how well care works, what treatment options exist and which provider generates the best outcomes**
    b. Understanding deductibles, insurance regulations and prices
    c. Understanding the biological processes in each treatment option
    d. Someone who reads lots of articles online

3. Which do doctors generally worry about the most?

    a. **Performing too few tests and undertreating patients**
    b. Having patients wait longer in their waiting rooms
    c. Providing interesting magazines for patients to read
    d. Performing too many tests and overtreating patients

4. Which is the cheapest?

    a. **Good health**
    b. The lowest cost knee surgeon
    c. A hospital-based MRI
    d. A free-standing MRI

5. Which strategy is generally the cheapest after factoring in all costs including patient out-of-pocket, deductibles, insurance premiums, time off of work, productivity losses and rehab expenses?

    a. **Getting the best treatment outcomes**
    b. Getting care from the lowest cost surgeon
    c. Paying cash for your treatment
    d. Negotiating the best deal you can with each provider

6. Why would a wise patient ask a physician if a proposed treatment has been subjected to comparative testing?

    a. **Because treatments that have not been subjected to comparative testing are ineffective or harmful about half the time**

b. Because it makes you sound smart to your doctor
c. Because you want to show your doctor who's really running the meeting
d. Because you want to waste time before making an important decision

7. What is Prasad's Law?

a. **Medical treatments that have not been subjected to comparative testing are ineffective or harmful about half the time**
b. A hospital room built is a hospital room occupied
c. The most expensive surgeon is the best
d. The most expensive hospital generates the best patient outcomes

8. Which benefits more people?

a. A treatment that prevents heart attacks 3 out of 100 people
b. A treatment that cuts the heart attack rate by 25%
c. A treatment that reduces total cholesterol levels by 10 points
d. **We have insufficient information in (a), (b) and (c) above to answer the question**

9. Which benefit interests a wise patient the most?

a. **A reduction in heart attacks**
b. A reduction in cholesterol levels
c. A reduction in blood pressure levels
d. An improvement in blood oxidation rates

10. This chapter suggests that patients who base their medical decisions on biology, physiology, anatomy and logic – but not comparative studies – are what?

a. **Wrong about as often as they are right**
b. Wise and thoughtful
c. Using the best possible information
d. Likely to enjoy the best outcomes

11. As the number of medical services in a community – like MRI machines, vascular surgeons or hospital beds – rises, what tends to happen?

a. **More patients use those services**
b. Fewer patients use those services
c. Service prices tend to fall
d. Care quality tends to decline

12. Wise patients sometimes ask if a particular treatment is overused. Which below in an inappropriate answer to that question?

a. Yes
b. No

c. I don't know
d**. I never provide unnecessary care**

13. What is a 'preference sensitive' medical decision?

a. **A decision that's right *for you*. Different patients with the same medical condition can choose different treatments and all be right.**
b. A decision that your doctor would prefer that you make, not him or her
c. Delegating your decisions to your doctor
d. Delegating your care decisions to your hospital

14. What is the general trend among patients who explore their treatment options?

a**. They tend to choose less risky, less invasive and consequently less expensive care by about 25 – 30%**
b. They get confused
c. They ultimately do what their doctor tells them to do
d. They cost the most

15. What is the main purpose of second opinions?

a**. Expose patients to a range of treatment alternatives**
b. Waste time
c. Increase physician billing opportunities
d. Confuse patients

16. Which surgeon generally generates the best patient outcomes?

a. **The surgeon who does a specific type of surgery most frequently**
b. The surgeon who graduated from the most prestigious medical school
c. The surgeon who charges the most
d. The surgeon who uses the newest technology

Issue 7: The Medicare Modernization Act

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 - **Title I: Medicare Prescription Drug Benefit** (Sec. 101) Amends title XVIII (Medicare) of the Social Security Act (SSA) to add a new part D (Voluntary Prescription Drug Benefit Program). Establishes a new optional Medicare prescription drug benefit program augmenting with a comprehensive, flexible, and permanent voluntary prescription drug benefit program the limited coverage of certain outpatient prescription drugs, biologicals, and vaccines currently covered under the Medicare program under its original fee-for-service component under both Medicare parts A (Hospital Insurance) and B (Supplementary Medical Insurance) and under its managed care, medical savings account (MSA), and private fee-for-service component under Medicare part C (Medicare+Choice).

Provides under this new prescription drug benefit program for offering eligible Medicare beneficiaries, regardless of income or health status, access to more coverage options, options which provide enhanced benefits, with cost-sharing, and additional beneficiary protections and assistance, such as access to negotiated prices, catastrophic coverage limits, and premium subsidies for certain low-income beneficiaries.

Provides for these options to be offered through both: (1) a new Medicare part C Medicare Advantage (MA) program that integrates basic medical coverage with added prescription drug coverage, including coverage through specialized MA plans for special needs individuals; and (2) a new separate, stand-alone Medicare Prescription Drug plan (PDP) program under Medicare part D that relies on private plans to provide coverage and to bear a portion of the financial risk for drug costs.

Makes this new program effective January 1, 2006.

Provides that until this new permanent prescription drug benefit program is effective, the Secretary of Health and Human Services (HHS) shall establish a program to endorse prescription drug discount card programs in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States and to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs. Provides that the program shall not apply to covered discount card drugs dispensed after December 31, 2005, and transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

Allows beneficiaries entitled to benefits under Medicare part A or enrolled under Medicare part B (eligible beneficiaries) to elect to enroll under new Medicare part D, and: (1) provided that they are not enrolled in an MA plan, keep their current Medicare fee-for-service coverage and receive qualified prescription drug coverage (as described below) through enrollment in Medicare part D in a new PDP that is offered in the geographic area in which the beneficiary resides; or (2) enroll in the new Medicare part

C MA program in an MA plan, give up their current Medicare fee-for-service coverage, and receive qualified prescription drug coverage under the plan along with basic and possibly enhanced medical coverage through health maintenance organization (HMO) or revised MSA coverage options under the new MA program established by this Act under Medicare part C (and as otherwise provided under Medicare+Choice under Medicare part C as discussed more fully below under title II (MedicareAdvantage) of this Act).

Provides an exception for MA enrollees: (1) enrolled in MSA plans to receive qualified coverage of prescription drugs through enrollment in a PDP; (2) enrolled in private-fee-for service plans that do not provide qualified prescription drug coverage to receive qualified coverage of prescription drugs through enrollment in PDP plans; and (3) enrolled in an MA prescription drug plan (MA-PD) to receive qualified prescription drug coverage under that plan.

Directs the Secretary to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Medicare part D eligible individuals in prescription drug plans. Establishes an initial enrollment period beginning November 15, 2005 .

Directs the Secretary to conduct activities designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage under Medicare part D, including information comparing the plans offered by eligible entities under Medicare part D that are available to eligible beneficiaries in an area.

Divides qualified prescription drug coverage into either a standard coverage benefit package or an alternative prescription drug coverage with at least actuarially equivalent benefits, both with access to negotiated drug prices. Outlines the standard coverage package, which includes, for 2006, a $250 deductible, 25 percent cost-sharing for drug costs between $250 and the initial coverage limit of $2,250, then no coverage; except that the beneficiary shall have access to negotiated prices, regardless of the fact that no benefits may be payable under the coverage, until incurring out-of-pocket costs for covered drugs in a year equal $3,600, with the beneficiary thereafter to pay five percent of the cost of a prescription, or a copayment of $2 for a generic drug and $5 for any other drug, whichever is greater. Includes as negotiated prices all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations. Increases these amounts in future years by the annual percentage increase in average per capita aggregate expenditures for covered drugs for the year ending the previous July.

Includes among the out-of-pocket costs counting toward the annual $3,600 limit any costs paid by the part D eligible individual (or by another person such as a family member) under the Medicaid program or under a State pharmaceutical assistance program for which the individual (or other person) is not reimbursed.

Allows a PDP or an MA plan to provide a different prescription drug benefit design from the standard prescription drug coverage as long as the Administrator of the Medicare Benefits Administration approves of such benefit design.

Directs the Secretary to ensure that each part D eligible individual has available a choice of enrollment in at least two qualifying plans in the area in which the individual resides, at least one of which is a prescription drug plan. Provides that in such case in which such plans are not available the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

Establishes beneficiary protection requirements for qualified prescription drug plans, such as requiring each PDP sponsor offering a prescription drug plan to: (1) have a mechanism for providing specific information on a timely basis to enrollees upon request; (2) have in place with respect to covered part D drugs a cost-effective drug utilization management program and a medication therapy management program; and (3) provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Directs the Secretary to establish, and allows the Secretary to revise PDP regions in a manner that is consistent with the requirements below for the establishment and revision of MA regions, and to the extent practicable PDP regions shall be the same as MA regions. Requires a PDP sponsor to submit to the Secretary bid and other described information with respect to each prescription drug plan it offers for review by the Secretary for the purpose of conducting negotiations concerning the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan in order for the Secretary to approve or disapprove the plan. Provides that in order to promote competition under new Medicare part D and in carrying out such part, the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponosors and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

Establishes organizational requirements for PDP sponsors, such as licenses, and requires that they enter into a contract with the Secretary to be eligible to receive payments.

Provides for premium and cost-sharing subsidies for low-income subsidy-eligible individuals.

Provides: (1) for the establishment of risk corridors for each PDP that determines the amount of risk that the PDP shall be exposed to for drug spending, and the resultant adjustment in payment attributable to this risk; and (2) that a PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits. Prohibits

adjustment in payments made by reason of this paragraph from affecting the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Medicare Prescription Drug Account for payments for low-income subsidy payments, subsidy payments, payments to qualified retiree prescription drug plans, and administrative expenses. Authorizes appropriations. Requires transfers to be made to the Medicaid account for increased administrative costs. Requires amounts withheld for late penalties to be deposited into the Fund. Requires States to make payments to the Account for dual eligibles as provided for under Medicaid.

Directs the Secretary to establish requirements for PDPs to ensure the effective coordination between a part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage and payment for supplemental prescription drug benefits for part D eligible individuals enrolled under both types of plans. Requires the Secretary to apply such coordination requirements to described Rx plans, which include Medicaid programs and group health plans and the Federal Employees Health Benefit Program (FEHBP), in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

Requires the prescription drug discount program and the transitional assistance program to be implemented by the Secretary so that interim prescription drug discount cards and transitional assistance are first available by not later than six months after the enactment of this Act in 2004 and 2005 until coverage under the new part D program becomes effective on January 1, 2006. Requires each prescription drug card sponsor that offers an endorsed discount card program to provide each discount card eligible individual entitled to benefits, or enrolled, under Medicare part A (Hospital Insurance) or part B (Supplementary Medical Insurance) with access to negotiated prices and savings on prescription drugs through enrollment in an endorsed discount card program.

Allows card sponsors to charge annual enrollment fees, not to exceed $30. Requires the fee to be uniform for all discount eligible individuals enrolled in the program. Requires a prescription drug card sponsor offering an endorsed discount card program to provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Provides that a discount card eligible individual is an individual whose income is not more than 135 percent of the poverty line and who is entitled to have payment made of any annual enrollment fee and to have payment made, up to $600 in 2004, under such endorsed program of 90 percent of the costs incurred for covered discount card drugs.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Transitional Assistance Account for payments for transitional assistance. Makes necessary appropriations.

(Sec. 103) Establishes certain requirements for States as a condition of receiving Federal Medicaid assistance, such as requiring States to provide the Secretary with Medicaid eligibility information necessary to carry out transitional prescription drug assistance verification.

Provides for: (1) Federal phase-in of the costs of premiums and cost-sharing and cost-sharing subsidies for dually eligible individuals; and (2) coordination of Medicaid with Medicare prescription drug benefits to provide that Medicare is the primary payer for covered drugs for dual eligibles.

Exempts prices negotiated from manufacturers for discount card drugs under an endorsement card program and prices negotiated by a PDP under part D, an MA-PD plan, or a qualified retiree prescription plan from the calculation of Medicaid "best price."

Extends the Qualifying-1 (Q-1) program through September 30, 2004, and expands outreach requirements for the Commissioner of Social Security to include outreach activities for transitional assistance and low-income subsidy individuals.

(Sec. 104) Prohibits, effective January 1, 2006, the selling, issuance, or renewal of Medigap Rx policies for part D enrollees, but permits the renewal of a Medigap Rx policy that was issued before January 1, 2006. Permits persons enrolling under part D during the initial enrollment period while covered under a Medigap Rx policy to enroll in a Medigap policy without prescription drug coverage or to continue the policy in effect as modified to exclude drugs. Provides that after the end of such period the individual may continue the policy in effect subject to such modification.

Guarantees issuance of a substitute Medigap policy for persons, enrolling in part D during the initial part D enrollment period, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J or a pre-standard policy that included drug coverage. Guarantees the enrollment for any policies A, B, C, and F within the same carrier of issue. Prevents the issuer from discriminating in the pricing of such policy on the basis of such individual's health status, claims experience, receipt of health care or medical condition. Prohibits the issuer from imposing an exclusion of benefits based on a pre-existing condition under such policy. Provides that the guarantee applies for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap plan H, I, or J.

Directs the Secretary to request the National Association of Insurance Commissioners to review and revise standards for benefit packages taking into account the changes in benefits resulting from the enactment of this Act and to otherwise update standards to reflect other changes in law included in such Act.

(Sec. 105) Includes additional provisions related to Medicare prescription drug discount cards and transitional assistance program, such as the exclusion of program costs from the calculation of the part B premium. Applies Medicare confidentiality provisions to drug pricing data.

(Sec. 106) Establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs as a result of the enactment of this Act.

(Sec. 107) Requires the Secretary to study and report to Congress on variations in per capita spending for covered part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids.

Requires the Secretary to conduct a review of the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings and evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care.

Directs the Secretary to enter into a contract with the Institutes of Medicine of the National Academy of Science to carry out a comprehensive study for a report to Congress on drug safety and quality issues in order to provide a blueprint for a system-wide change. Authorizes appropriations.

Directs the Secretary to provide for a study and report to Congress on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under parts C and D of title XVIII on a multi-year basis.

Requires the Comptroller General to conduct a study for a report to the Congress on the extent to which drug utilization and access to covered part D drugs by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals except for application of the assets test.

Directs the Secretary to undertake a study for a report to Congress of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually impaired individuals.

(Sec. 108) Authorizes the Secretary to make grants to physicians for the purpose of assisting them to implement electronic prescription drug programs that comply with appropriate standards. Authorizes appropriations.

(Sec. 109) Expands the work of quality improvement organizations to include part C and part D. Requires such organizations to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy.

Directs the Secretary to request the Institute of Medicine of the National Academy of Sciences to conduct an evaluation of the peer review program under SSA title XI.

(Sec. 110) Directs the Federal Trade Commission to conduct a study for a report to Congress on differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers.

(Sec. 111) Directs the Comptroller General of the United States to conduct an initial and final study for a report to Congress on trends in employment-based retiree health coverage, including coverage under FEHBP, and the options and incentives available under this Act which may have an effect on the voluntary provision of such coverage.

Title II: Medicare Advantage - Subtitle A: Implementation of Medicare Advantage Program - (Sec. 201) Amends SSA title XVIII part C (Medicare+Choice) to replace the current Medicare+Choice program with the Medicare Advantage (MA) program.

Subtitle B: Immediate Improvements - (Sec. 211) Revises the payment system, requiring all plans to be paid at a rate at least as high as the rate for traditional Medicare fee-for-service plans. Makes change in budget neutrality for blend. Increases minimum percentage increase to national growth rate. Includes costs of Department of Defense and Department of Veterans Affairs military facility services to Medicare-eligible beneficiaries in calculation of payment rates.

Directs the Medicare Payment Advisory Commission (MEDPAC) to conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC).

Requires the Secretary to submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts on the availability on Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

Requires a Medicare Payment Advisory Commission (MEDPAC) study and report to Congress with respect to authority regarding disapproval of unreasonable beneficiary cost-sharing.

Subtitle C: Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition - (Sec. 221) Directs the Secretary to establish regional plans to encourage private plans to serve Medicare beneficiaries in from ten to 50 regions, including in rural areas, within the 50 States and the District of Columbia beginning not later than January 1, 2005.

Prohibits the Secretary from offering a local preferred provider organization plan under Medicare part C during 2006 or 2007 in a service area unless such plan was offered under such part (including under a demonstration project under such part) in such area as of December 31, 2005. Includes risk corridors for plans during the first two years of the program in 2006 and 2007; a stabilization fund to encourage plan entry and limit

plan withdrawals; a blended benchmark that will allow plan bids to influence the benchmark amount; and network adequacy stabilization payments to assist plans in forming adequate networks, particularly in rural areas.

(Sec. 222) Provides that beginning in 2006, each MA organization shall submit to the Secretary for each MA plan for the service area in which it intends to be offered in the following year the monthly aggregate bid amount for the provision of all items and services under the plan for the type of plan and year involved.

Requires this monthly bid amount, with respect to which the Secretary has authority to negotiate, to be compared against respective benchmark amounts for MA local and MA regional plans, with plans that submit bids below the benchmark to be paid their bids, plus 75 percent of the difference between the benchmark and the bid which must be returned to beneficiaries in the form of additional benefits or reduced premiums. Provides that for plans that bid above the benchmark the government will pay the benchmark amount, and the beneficiary will pay the difference between the benchmark and the bid amount as a premium.

Requires the MA plan to provide an enrollee a monthly rebate equal to 75 percent of any average per capita savings as applicable to the plan and year involved. Allows the beneficiary rebate to be credited toward the provision of supplemental health care benefits, the prescription drug premium, or the Medicare part B premium. Requires the plan to disclose to the Secretary information on the form and amount of the rebate or the actuarial value in the case of supplemental health care benefits. Provides that for MA plans providing rebates the MA monthly basic beneficiary premium will be zero.

Provides that: (1) for MA plans with bids above the applicable benchmark, the MA monthly basic beneficiary premium will equal the amount by which the bid exceeds the benchmark; (2) the MA monthly prescription drug beneficiary premium is the base beneficiary premium less the amount of rebate credited toward such amount; and (3) the MA monthly supplemental beneficiary premium means the portion of the aggregate monthly bid amount for the year that is attributable to the provision of supplemental health benefits, less the amount of rebate credited toward such portion.

Allows enrollees to have their MA premiums deducted directly from their social security benefits, through an electronic funds transfer, or such other means as specified by the Secretary. Requires all premium payments withheld to be credited to the appropriate Trust Fund (or Account therof), as specified by the Secretary, and paid to the MA organization involved.

Subtitle D: Additional Reforms - (Sec. 231) Allows specialized MA plans for special needs individuals to be any type of coordinated care plan. Designates two specific segments of the Medicare population as special needs beneficiaries, but also provides the Secretary the authority to designate other chronically ill or disabled beneficiaries as special needs beneficiaries. Permits certain restriction on enrollment for specialized MA

plans for special needs individuals. Provides authority to designate other plans as specialized MA plans.

(Sec. 232) Establishes that the MA program is a Federal program operated under Federal rules. Provides that State laws do not apply except State licensing laws or State laws relating to plan solvency.

(Sec. 233) Makes the Medicare Medical Savings Account (MSA) demonstration program a permanent program option and eliminates the capacity limit and the deadline for enrollment. Provides that non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrolleees of coordinated care plans. Eliminates requirements for the Secretary to submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted.

(Sec. 234) Allows a reasonable cost reimbursement contract to operate indefinitely unless two other plans of the same type enter the cost contract's service area. Requires these two other plans to meet the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area; and (2) at least 1,500 enrollees for any other portion of such area.

(Sec. 235) Amends the Consolidated Omnibus Budget Reconciliation Act of 1985 to extend Municipal Health Services Demonstration projects through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

(Sec. 236) Amends SSA title XVIII to provide that protections against balance billing apply to PACE providers and beneficiaries enrolled with such PACE providers in the same manner as such protections apply to any individual enrolled with a Medicare +Choice organization under part C or with an eligible organization.

Provides that MA provisions relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under Medicare shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as provisions apply to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to under such provisions.

Amends SSA title XIX (Medicaid) to provide that, with respect to services covered under the State plan but not under Medicare that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, such participating provider may not require the PACE provider to pay the participating provider an amount greater than the

amount that would otherwise be payable for the service to the participating provider under the State plan.

(Sec. 237) Provides that Federally Qualified Heatlh Centers (FQHCs) will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. Raises reimbursements to FQHCs in order that when they are combined with MA payments and cost-sharing payments from beneficiaries they equal 100 percent of the reasonable costs of providing such services. Extends the safe harbor to include any remuneration between a FQHC (or entity controlled by an FQHC) and an MA organization.

(Sec. 238) Requires the Secretary to enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall conduct an evaluation (for the Secretary and Congress) of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program.

Subtitle E: Comparative Cost Adjustment (CCA) Program - (Sec. 241) Directs the Secretary to establish a program for the application of comparative cost adjustment in CCA areas, to begin January 1, 2010, and last six years, and to test whether direct competition between private plans and the original Medicare fee-for-service program will enhance competition in Medicare.

Title III: Combatting Waste, Fraud, and Abuse - (Sec. 301) Amends SSA title XVIII to allow the Secretary to make a conditional Medicare payment if a primary plan has not made or cannot reasonably be expected to make prompt payment. Requires the payment to be contingent on reimbursement by the primary plan to the appropriate Medicare trust fund. Requires a primary plan as well as an entity that receives payment from a primary plan to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. Makes other changes with regard to Medicare as a secondary payer to address the Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare secondary payer provisions.

(Sec. 302) Directs the Secretary to establish and implement quality standards for suppliers of items and services of durable medical equipment, prosthetics and orthotics, and certain other items and services. Requires the Secretary to establish standards for clinical conditions for payment for items of durable medical equipment.

Replaces the current demonstration projects for competitive acquisition of items and services with a permanent program requiring the Secretary to establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing of competitively priced described items and services (including durable medical equipment and medical

supplies) for which payment is made under Medicare part B. Allows such areas to differ for different items and services.Allows the Secretary to exempt from such programs rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service and items and services for which the application of competitive acquisition is not likely to result in significant savings.Requires payment under Medicare part B for competitively priced items and services to be based on bids submitted and accepted for such items and services, and based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area. Requires Medicare payment to be equal to 80 percent of the payment amount determined, with beneficiaries paying the remaining 20 percent (after meeting the part B deductible).

Directs the Secretary to conduct a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests.

Requires the Comptroller General to conduct a study for a report to Congress on the impact of competitive acquisition of durable medical equipment on suppliers and manufacturers of such equipment and on patients.

Provides that for durable medical equipment, prosthetic devices, prosthetics and orthotics, the update will be 0 points in 2004 through 2008, and that after 2008 for those items not included in competitive bidding the update will be the consumer price index.

Provides that for 2005 the payment amount for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses, will be reduced.

Provides that for prosthetic devices and orthotics and prosthetics in 2004, 2005, and 2006, the update will be 0 percentage points and for a subsequent year is equal to the percentage increase in the consumer price index for all urban customers for the 12-month period ending in June of the previous year.

Directs the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under Medicare are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(Sec. 303) Amends SSA title XVIII to: (1) require the Secretary, beginning in 2004, to make adjustments in practice expense relative value units for certain drug administration services when establishing the physician fee schedule; (2) require the Secretary to use the survey data submitted to the Secretary as of January 1, 2003, by a certain physician speciality organization; and (3) require the Secretary, beginning in 2005, to use supplemental survey data to adjust practice expense relative value units for certain drug administration services in the physician fee schedule if that

supplemental survey data includes information on the expenses associated with administering drugs and biologicals the administration of drugs and biologicals, the survey meets criteria for acceptance, and the survey is submitted by March 1, 2004, for 2005, or March 1, 2005, for 2006. (States that this latter provision shall apply only to a speciality that receives 40 percent or more of its Medicare payments in 2002 from drugs and biologicals and shall not apply with respect to the survey submitted by a certain physician speciality organization.) Exempts the adjustments in practical expense relative value units for certain drug administration services from the budget neutrality requirements in 2004.

Requires the Secretary to: (1) promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption; (2) make adjustments to the nonphysician work pool methodology for the determination of practice expense relative value units under the physician fee schedule so that practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology; and (3) review and appropriately modify Medicare's payment policy in effect on October 1, 2003, for the administration of more than one drug or biological to an individual on a single day through the push technique. Makes the increase in expenditures resulting from this provision exempt from the budget-neutrality requirement in 2004.

Requires a transitional adjustment or additional payment for services furnished from January 1, 2004, through December 31, 2005, to be made for drug administration services. Requires the part B payment to be made to the physician and equal a percentage of the payment otherwise made.

Directs the MEDPAC to review the payment changes made under this section insofar as they affect payments under Medicare part B for items and services furnished by oncologists and for drug administration services furnished by other specialists. Requires MEDPAC to submit a report to the Secretary and Congress and for the Secretary to make appropriate payment adjustments on the basis of such report.

Provides that the following drugs and biologicals are to be paid at 95 percent of the average wholesale price (AWP): (1) a drug or biological furnished before January 1, 2004; (2) blood clotting factors furnished during 2004; (3) a drug or biological furnished during 2004 that was not available for part B payment as of April 1, 2003; (3) pneumoccal influenza and hepatitis B vaccines furnished on or after January 1, 2004; and (4) a drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities. Provides in general that payments for other drugs furnished in 2004 will equal 85 percent of the AWP (determined as of April 1, 2003). Provides that, beginning in 2005, drugs or biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with

certain renal dialysis services, will be paid using either the average sales price methodology or through the competitive acquisition program. Provides that infusion drugs furnished through covered durable medical equipment starting January 1, 2004, will be paid at 95 percent of the AWP in effect on October 1, 2003, and that those infusion drugs which may be furnished in a competitive area starting January 1, 2007, will be paid at the competitive price. Provides that intravenous immune globulin will be paid at 95 percent of the AWP in 2004 and paid according to the average sales price method in 2005.

Authorizes the Secretary to substitute a different percent of the April 1, 2003 AWP, but not less than 80 percent.

Establishes the use of the average sales price methodology for payment for drugs and biologicals (except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services) that are furnished on or after January 1, 2005. Creates an exception to this methodology in the case of a physician who elects to participate in the newly established competition acquisition program.

Directs the Inspector General of the Department of Health and Human Services to conduct studies to determine the widely available market prices of drugs and biologicals.

Directs the Secretary to conduct a study for a report to Congress on sales of drugs and biologicals to large volume purchasers for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent investors.

Directs the Inspector General to conduct a study for a report to Congress on adequacy of reimbursement rate under average sales price methodology.

Directs the Secretary to establish and implement a competitive acquisition program to acquire and pay for competitively biddable drugs and biologicals through the establishment of competitive acquisition areas for the award of contracts. Gives each physician the opportunity annually to elect to obtain drugs and biologicals under the program, rather than the program above using average sales methodology. Directs the Secretary to begin to phase-in the program beginning in 2006.

(Sec. 304) Makes the amendments applicable above applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

(Sec. 305) Amends SSA title XVIII to provide that in the case of inhalation drugs or biologicals furnished through covered durable medical equipment that are furnished in 2004, the payment amount will be at 85 percent of AWP, and in 2005 and subsequent years, the payment amount will be the amount provided under the average sales price methodology.

Directs the Comptroller General to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program for a report to Congress.

(Sec. 306) Requires the Secretary to conduct a demonstration project to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recoupoing overpayments under the Medicare program for services for which payment is made under Medicare part A or part B. Requires a report to Congress on the demonstration program.

(Sec. 307) Directs the Secretary to establish a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees. Makes necessary appropriations.

Title IV: Rural Provisions - Subtitle A: Provisions Relating to Part A Only - (Sec. 401) Amends SSA title XVIII part A to require Medicare, for discharges during a fiscal year beginning with FY 2004, to direct the Secretary to compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year for hospitals located in a large urban area (or, beginning with FY 2005, for all hospitals in the previous year) increased by the applicable percentage increase. Directs the Secretary to compute, for discharges occuring in a fiscal year beginning with 2004, an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase for the year involved.

(Sec. 402) Provides that for discharges after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a disproportionate share (DSH) adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. Caps the DSH adjustment formula at 12 percent for any of these hospitals except rural referral centers.

(Sec. 403) Provides that for discharges on or after October 1, 2004, the Secretary is required to decrease the labor-related share to 62 percent of the standardized amount when such change results in higher total payments to the hospital. Provides that for discharges occurring on or after October 1, 2004, the Secretary is also required to decrease the labor-related share to 62 percent of the standardized amount for hospitals in Puerto Rico when such change results in higher total payments to the hospital.

(Sec. 404) Directs the Secretary, after revising the market basket weights to reflect the most current data, to establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every five years. Requires the Secretary to include in the publication of the

final rule for payment for inpatient hospital services for FY 2006, an explanation of the reasons for, and options considered, in determining such frequency.

(Sec. 405) Reimburses inpatient, outpatient, and covered skilled nursing facility services provided by a critical access hospital (CAH) at 101 percent of reasonable costs of services furnished to Medicare beneficiaries.

Expands reimbursement of on-call emergency room providers to include physician's assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services provided on or after January 1, 2005.

Allows an eligible CAH to be able to receive payments made on a periodic interim payment (PIP) basis for its inpatient services. Requires the Secretary to develop alternative methods for the timing of PIP payments to the CAHs.

Prohibits the Secretary from requiring that all physicians or practitioners providing services in a CAH assign their billing rights to the entity in order for the CAH to be paid on the basis of 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH. Prohibits a CAH from receiving payment based on 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH.

Allows a CAH to operate up to 25 beds while deleting the requirement that only 15 of the 25 beds be used for acute care at any time.

Establishes an authorization to award rural hospital flexibility grants at $35 million each year from FY 2005 through FY 2008 and in subsequent years requires a State to consult with the hospital association and rural hospitals in the State on the most appropriate way to use such funds. Prohibits a State from spending more than the lesser of 15 percent of the grant amount for administrative expenses or the State's federally negotiated indirect rate for administering the grant. Provides that in FY 2005 up to five percent of the total amount appropriated for grants will be available to the Health Resources and Services Administration for administering such grants.

Permits a CAH to establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements that would otherwise apply to the distinct part if the distinct part were established by a "subsection (d) hospital." Limits the total number of beds that may be established for a distinct part unit to no more than ten. Provides that if a distinct part unit does not meet the applicable requirements during a cost reporting period then no Medicare payment will be made to the CAH for services furnished in such unit during such period. Requires Medicare payments to resume only after the CAH demonstrates that the requirements have been met. Requires Medicare payments for services provided in the distinct part units to equal the amount of the payments that would otherwise be made on a prospective payment basis to distinct part units of a CAH.

Allows certain milage standards to be waived in the case of a facility that was designated as a CAH before January 1, 2006 and was certified by the State as being a necessary provider of health care services.

(Sec. 406) Requires the Secretary to provide for an additional payment amount to each low-volume hospital for discharges occurring during a fiscal year beginning with FY 2005.

(Sec. 407) Provides that in no case will a hospital be denied treatment as a sole community hospital or payment because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances so long as data from at least one applicable base cost reporting period is available.

(Sec. 408) Expands the definition of attending physician in hospice to include a nurse practitioner.

(Sec. 409) Directs the Secretary to conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Provides that under the project Medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs.

(Sec. 410) Excludes certain rural health clinic and Federally-qualified health center services from the prospective payment system for skilled nursing facilities.

(Sec. 410A) Directs the Secretary to establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries.

Subtitle B: Provisions Relating to Part B Only - (Sec. 411) Extends until January 1, 2006 the hold harmless provisions governing hospital outpatient department (OPD) reimbursement for small rural hospitals and sole community hospitals.

Requires the Secretary to conduct a study to determine if the costs incurred by hospitals located in rural areas by ambulatory payment classification groups exceed those costs incurred by hospitals located in urban areas. Provides that if appropriate the Secretary is required to provide for a payment adjustment to reflect the higher costs of rural providers by January 1, 2006.

(Sec. 412) Directs the Secretary to increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00 for services furnished on or after January 1, 2004, and before January 1, 2007.

(Sec. 413) Establishes a new five percent incentive payment program designed to reward both primary care and specialist care physicians for furnishing physicians'

services on or after January 1, 2005, and before January 1, 2008 in physician scarity areas.

Directs the Secretary to pay the current law ten percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify the health professional shortage area involved.

Directs the Comptroller General to conduct a study for a report to Congress on the differences in payment amounts under the Medicare physician fee schedule for physicians' services in different geographic areas.

(Sec. 414) Revises payment for ambulance services to provide for, when phasing in the application of the payment rates under the fee schedule, for each level of ground service furnished in a year, for the portion of the payment amount that is based on the fee schedule to be the greater of the amount determined under such national fee schedule or a blended rate of the national fee schedule and the regional fee schedule for the region involved, whichever resulted in a larger payment, with the blended rate to be based 100 percent on the national fee schedule.

Requires the Secretary to establish a regional fee schedule for each of the nine census divisions. Provides for adjustment in payment for certain long trips. Directs the Secretary to provide for a percentage increase in the base rate of the fee schedule for ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010 that originate in a qualified rural area. Increases by two percent the payments for ground ambulance services orginating in a rural area or a rural census tract for services furnished on or after July 1, 2004, and before January 1, 2007. Provides that the fee schedule for ambulances in other areas will by increased by one percent. Provides that these increased payments will not affect Medicare payments for covered ambulance services after 2007.

Requires the Comptroller General to submit to Congress a report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the Medicare ambulance fee schedule.

(Sec. 415) Provides that the regulations governing the use of ambulance services will provide that, to the extent that any ambulance service (whether ground or air) may be covered, that a rural air ambulance service will be reimbursed at the air ambulance rate if: (1) the air ambulance service is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary.

(Sec. 416) Provides that hospitals with fewer than 50 beds in qualified rural areas will receive 100 percent reasonable cost reimbursement for clinical diagnostic laboratory

tests covered under Medicare part B that are provided as outpatient hospital services during a cost reporting period beginning during the two year period beginning on July 1, 2004.

(Sec. 417) Amends the Balanced Budget Act of 1997 to extend the telemedicine demonstration project by 4 years and to increase total funding for the project.

(Sec. 418) Directs the Secretary to evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities are treated as originating sites for telehealth services for a report to Congress.

Subtitle C: Provisions Relating to Parts A and B - (Sec. 421) Provides that with respect to episodes and visits on or after April 1, 2004, and before April 1, 2005, in the case of home health services furnished in a rural area, the Secretary is required to increase the payment amount otherwise made for such services by five percent. Prevents such temporary additional payment increase from being used in calculating future home health payment amounts.

(Sec. 422) Provides that a teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005, if its reference resident level is less than its applicable resident limit. Exempts rural rural hospitals with fewer than 250 acute care inpatient beds from such reduction. Provides that for such other hospitals the reduction will equal 75 percent of the difference between the hospital's limit and its reference resident level. Authorizes the Secretary to increase the applicable resident limit for each qualifying applicant hospital by such numbers as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005.

Subtitle D: Other Provisions - (Sec. 431) Amends SSA title XI to provide that any remuneration in the form of a contract, lease, grant, loan, or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to health center would not be a violation of the anti-kickback statue if such agreement contributes to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population.

(Sec. 432) Amends SSA title VII to expand the functions of the Office of Rural Health Policy to include administering grants, cooperative agreements, and contracts to provide technical assistance and other necessary activities to support activities related to improving health care in rural areas.

(Sec. 433) Directs MEDPAC to conduct a study of specified rural provisions of this title for various reports to Congress.

(Sec. 434) Directs the Secretary to waive such provisions of the Medicare program as are necessary to conduct a demonstration project under which frontier extended stay

clinics in isolated rural areas are treated as providers of items and services under the Medicare program. Authorizes appropriations.

Title V: Provisions Relating to Part A - Subtitle A: Inpatient Hospital Services - (Sec. 501) Amends SSA title XVIII with respect to hospital payment updates to provide that: (1) an acute hospital will receive an update of the market basket from FY 2005 through FY 2007 if it submits data on the ten quality indicators established by the Secretary as of November 1, 2003; and (2) an acute hospital that does not submit data to the Secretary will receive an update of the market basket percentage minus 0.4 percentage points for the fiscal year in question and that the Secretary will not take this reduction into account when computing the applicable percentage increase in subsequent years.

Directs the Comptroller General to conduct a study to determine: (1) the appropriate level and distribution of Medicare payments in relation to costs for short-term general hospitals under the inpatient prospective payment system; and (2) the need for geographic adjustments to reflect legitmate differences in hospital costs across different geographic areas, kinds of hospitals, and types of cases.

(Sec. 502) Expands the formula for determining the indirect medical education adjustment percentage to cover the period from April 1, 2004 to on and after October 1, 2007.

(Sec. 503) Requires the Secretary to add new diagnosis and procedure codes in April 1 of each year without requiring the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date.

Requires the Secretary when establishing whether diagnosis related group (DRG) payment is adequate to apply a threshold that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between costs and charges) or 75 percent of one standard deviation for the diagnosis-related group involved. Requires the mechanism established to recognize the costs of new medical services and technologies under the appropriate Medicare payment system to be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under Medicare part A (Hospital Insurance).

Directs the Secretary, before establishing any add-on payment with respect to a new technology, to seek to identify one or more diagnosis-related groups associated with such technology and, within such groups, the Secretary is required to assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. Prohibits the making of an add-on payment in such case. Provides that funding for new technology will no longer be budget neutral.

(Sec. 504) Provides that hospitals in Puerto Rico will receive Medicare payments based on a 50-50 split between Federal and local amounts before April 1, 2004. Provides that starting April 1, 2004 through September 30, 2004, payment will be based on a 62.5 percent Federal amount and a 37.5 percent local amount, and that starting October 1, 2004, payment will be based on a 75 percent Federal amount and a 25 percent local amount.

(Sec. 505) Directs the Secretary to establish a process and payment adjustment to recognize commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

(Sec. 506) Requires that hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, an Indian tribal organization, or an urban Indian organization be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payment. Requires that these rates of payment must be accepted as payment in full for the items and services provided.

(Sec. 507) Modifies the "whole hospital" exception to the prohibition against physicians referring Medicare patients to entities in which they or their immediate family members have financial interests to provide for a period of 18 months from the date of enactment of this Act during which there is excluded from such exception (and thereby subjected to the prohibition) those circumstances in which a physician's ownership interest is in a "subsection d hospital"devoted primarily or exclusively to cardiac, orthopedic, surgical, or other specialties designated by the Secretary. Exempts from such provision speciality hospitals in operation or under development as of November 18, 2003.

Requires that, in order to maintain the exception, the speciality hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase the total number of beds in its facilities by more than the greater of five beds or 50 percent of the number of beds in the hospital as of November 18, 2003.

Makes a similar modification with respect to the rural provider exception.

Directs the Secretary in determining whether a hospital is under development as of November 18, 2003 to consider whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received, and other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

Directs MEDPAC to conduct a study to determine: (1) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within

specific diagnosis-related groups; (2) the extent to which speciality hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection; (3) the financial impact of physician-owned specialty hospitals on local full-service community hospitals; (4) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and (5) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

Directs the Secretary to conduct a study of a representative sample of specialty hospitals to: (1) determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest; (2) determine the referral patterns of physician owners; (3) compare the qualty of care furnished in physician-owned speciality hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and (5) assess the differences in uncompensated care between the specialty hospital and local full-service community hospitals, and the value of any tax exemption availabble to such hospitals.

(Sec. 508) Directs the Secretary to establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State to which to be reclassified. Provides that a qualifying hospital (which must be a "subsection (d) hospital" is not eligible for a change in wage index classification on the basis of distance or commuting. Requires the qualifying hospital to meet such other criteria, such as quality, as the Secretary may specify by instruction or otherwise. Provides that if the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital, the hospital shall be reclassified to the area selected. Requires such reclassification to apply with respect to discharges occurring during the three year period beginning with April 2, 2004. Limits the total aggregate amount of additional expenditures resulting from application of this paragraph to $900 million.

Subtitle B: Other Provisions - (Sec. 511) Increases the per diem RUG payment for a skilled nursing facility (SNF) resident with acquired immune deficiency syndrome (AIDS). Provides that such payment increase will not apply on and after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

(Sec. 512) Provides coverage of certain physician's services for certain terminally ill individuals who have not elected the hospice benefit and have not previously received these physician's services.

(Sec. 513) Directs the Comptroller General to conduct a study of portable diagnostic ultrasound services furnished to Medicare beneficiaries in SNFs for a report to Congress.

Title VI: Provisions Relating to Part B - Subtitle A: Provisions Relating to Physicians' Services - Amends SSA title XVIII with respect to payment for physicians' services to: (1) provide that the update to the conversion factor for 2004 and 2005 will not be less than 1.5 percent; (2) modify the formula for calculating the sustainable growth rate to provide that the gross domestic product factor will be based on the annual average change over the preceding 10 years (a 10-year rolling average); (3) provide that in calendar years 2004 and 2005, for physicians's services provided in Alaska, the Secretary is required to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense, and malpractice cost indices that would otherwise be less than 1.67; and (4) allow podiatrists, dentists, and optometrists to enter into private contracts with Medicare beneficiaries.

(Sec. 604) Directs the Comptroller General to conduct a study for a report to Congress on access of Medicare beneficiaries to physicians's services under the Medicare program.

(Sec. 605) Requires the Secretary to review and consider alternative data sources than those currently used to establsih the geographic index for the practice expense component under the Medicare physician fee schedule no later than January 1, 2005. Requires the Secretary to select two physician payment localties for such purposes, one to be a rural area and the other one will be a statewide locality that includes both urban and rural areas.

(Sec. 606) Directs MEDPAC to submit to Congress: (1) a report on the effect of refinements to the practice expense component of payments for physicians' services after the transition to a full resource-based payment system in 2002; and (2) a report on the extent to which increases in the volume of physicians' services under Medicare part B are a result of care that improves the health and well-being of Medicare beneficiaries.

Subtitle B: Preventive Services - (Sec. 611) Authorizes Medicare coverage of: (1) an initial preventive physical examination; (2) cardiovascular screening blood tests; and (3) diabetes screening tests.

(Sec. 614) Excludes screening mammography and diagnostic mammography from the outpatient prospective payment system (OPPS).

Subtitle C: Other Provisions - (Sec. 621) Provides that for specified covered OPD drugs and biologicals starting in 2004 payment would be made based on a percentage of the reference AWP for the drug or biological.

Directs the Comptroller General to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition costs for each specified covered outpatient drug.

Requires the amount of payment for an orphan drug designated by the Secretary that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 to equal such amount as the Secretary may specify. Requires the Comptroller General not later than April 1, 2005 to furnish data from such surveys to the Secretary for use in setting payment rates for 2006.

Requires the Comptroller General, no later than 30 days after the date the Secretary promulgates the proposed rules setting forth the payment rates for 2006, to evaluate such rates and submit a report to Congress on their appropriateness.

Directs MEDPAC to submit to the Secretary a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Authorizes the Secretary to adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account appropriate recommendations to such effect in the report.

Provides that the additional expenditures that result from the previous changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account for subsequent years.

Provides that with respect to payment under Medicare part B for an outpatient drug or biological covered under such part that is furnished as part of covered OPD services for which an HCPCS code has not been assigned, the amount provided for payment for such drug or biological under such part shall be equal to 95 percent of the AWP for the drug or biological.

Provides that for drugs and biologicals furnished in 2005 and 2006, the Secretary is required to reduce the threshold for establishing a separate ambulatory payment classification (APC) group for drugs or biologicals from $150 to $50 per admission. Makes these separate drug and biological APC groups ineligible for outlier payments. Provides that starting in 2004, Medicare transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average price for the drug or biological for all competitive acquisition areas calculated and adjusted by the Secretary for that year.

Requires the Secretary to make payment for each brachytherapy device furnished under the hospital outpatient prospective payment system equal to the hospital's charges for each device furnished, adjusted to costs for all brachytherapy devices furnished on or after January 1, 2004, and before January 1, 2007. Provides that charges for such devices will not be included in determining any outlier payment.

Directs the Secretary to create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under the hospital outpatient prospective payment system in a manner reflecting the number, the radioactive isotope, and the radioactive intensity of the brachytherapy devices furnished

to each patient, including the use of separate APCs for brachytherapy devices made from palladium-103 and iodine-125 devices.

Requires the Comptroller General to conduct a study for a report to Congress and the Secretary on the appropriate payment amounts needed for devices of brachytherapy. Requires the report to include specific recommendations for appropriate payments for such devices.

(Sec. 622) Prohibits the Secretary from publishing regulations that apply a functional equivalence standard to a drug or biological. Applies this prohibition to the application of a functional equivalence standard on or after the date of enactment of this Act, unless such application was made prior to enactment and the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for transitional pass-through payments.

(Sec. 623) Increases the composite rate for renal dialysis by 1.6 percent for 2005.

Provides that provisions prohibiting the Secretary from providing for an exception under provisions for Medicare coverage for end stage renal disease patients that require the Secretary to provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home, and that provisions setting a deadline of July 1, 2001, for new applications for an exception rate in the case of a facility that during 2000 did not file for an exception rate under such former provisions, shall not apply as of October 1, 2002, to pediatric facilities that do not have an exception rate in effect on such date. Requires that for purposes of this paragraph the term pediatric facility means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.

Directs the Inspector General of HHS to conduct two studies for reports to the Secretary with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the Medicare program which are separately billed by end stage reneal disease facilities.

Requires the Secretary to establish a basic case-mix adjusted prospective payment system for dialysis services. Requires the basic case-mix adjusted system to begin for services furnished on January 1, 2005. Requires the system to adjust for a limited number of patient characteristics.

Provides that payments for separately billed drugs and biologicals (other than erythropoietin) will be 95 percent of the AWP for 2004, the acquisition costs in 2005 (including for 2005), and, beginning in 2006, for such drugs and biologicals (including erythropoietin), such acquisition cost or the average sales price payment methodology for the drug or biological as the Secretary may specify.

Requires drugs and biologicals (including erythropoietin) which were separately billed on the day before the enactment of this Act to continue to be separately billed on and after such date.

Directs the Secretary to establish a demonstration project for the use of a fully case-mix adjusted, bundled payment system for end stage renal disease services, beginning January 1, 2006. Authorizes appropriations.

Requires the Secretary to submit a report to Congress detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities.

(Sec. 624) Provides for an additional two-year moratorium on therapy caps for 2004 and 2005.

Requires the Secretary to submit by March 31, 2004 overdue reports on payment and utilization of outpatient therapy services that are required by the Balanced Budget Act of 1997 and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BIPA).

Requires the Comptroller General to identify for a report to Congress conditions or diseases that may justify waiving the application of the therapy caps with respect to such conditions or diseases.

(Sec. 625) Waives the late enrollment penalty for military retirees who did not enroll in Medicare part B upon becoming eligible for Medicare. Provides that the waiver applies to the late enrollment penalty for military retirees, 65 and over, who enrolled in the TRICARE for Life program from 2001 to 2004. Requires this waiver to apply to premiums for months beginning with January 2004. Directs the Secretary to establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such waiver provision but for which a penalty was previously collected.

Directs the Secretary to provide for a special Medicare part B enrollment period for these military retirees beginning as soon as possible after enactment of this Act and ending December 31, 2004.

(Sec. 626) Provides that in FY 2004, starting April 1, 2004, the ambulatory surgery center (ASC) update will be the Consumer Price Index for all urban consumers (U.S. city average) as estimated as of March 31, 2003, minus 3.0 percentage points. Provides that in FY 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the ASC update will be zero percent.

Provides that upon implementation of the new ASC payment system, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every five years.

Provides that subject to recommendations by the General Accounting Office, the Secretary will implement a revised payment system for payment of surgical services furnished in ASCs. Requires the new system to be implemented so that it is first effective on or after January 1, 2006, and not later than January 1, 2008.

Requires the Comptroller General to conduct a study for a report to Congress that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments.

(Sec. 627) Limits payment for custom molded shoes with inserts or extra-depth shoes with inserts for an individual with severe diabetic foot disease by the amount that would be paid if they were considered to be a prosthetic or orthotic device. Allows the Secretary to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. Requires the Secretary to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

(Sec. 628) Provides that there will be no updates to the clinical diagnostic laboratory test fee schedule for 2004 through 2008.

(Sec. 629) Keeps the Medicare part B deductible at $100 through 2004, increasing it to $110 for 2005, and providing that in subsequent years the deductible will be increased by the same percentage as the Medicare part B premium increase.

(Sec. 630) Requires the Secretary to make payment under Medicare part B to a hospital or an ambulatory care clinic (whether provider-based or free standing) that is operated by the Indian Health Service or by an Indian tribe or tribal organization for all Medicare part B covered items and services furnished during the five year period beginning on January 1, 2005.

Subtitle D: Additional Demonstrations, Studies, and Other Provisions - (Sec. 641) Requires the Secretary to conduct a demonstration project under Medicare part B under which payment is made for drugs or biologicals that are prescribed as replacements for existing covered drugs and biologicals that are furnished incident to a physician's professional service which are not usually self-administered. Requires the project to provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as the cost-sharing applicable under part D for standard prescription drug coverage.

(Sec. 642) Includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare.

(Sec. 643) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of providing for payment under Medicare part B for surgical first assisting services furnished by a certified registered nurse first assistant to Medicare beneficiaries.

(Sec. 644) Requires MEDPAC to conduct a study for a report to Congress on the practice expense relative values established by the Secretary under the Medicare physician fee schedule for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

(Sec. 645) Directs the Secretary to conduct a study for a report to Congress on the feasibility and advisability of providing for payment for vision rehabiliation services furnished by vision rehabilitation professionals.

Requires the Secretary to submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries.

(Sec. 646) Amends SSA title XVIII to direct the Secretary to establish a 5-year demonstration program under which the Secretary is required to approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care.

(Sec. 647) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as a comprehensive rehabilitation facility service.

(Sec. 648) Directs the Secretary to establish demonstration projects under which the Secretary is required to evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the Medicare program on behalf of such individuals for such chronic conditions. Requires the Secretary to conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under Medicare part A, and enrolled under Medicare part B, with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(Sec. 649) Directs the Secretary to establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures

(Sec. 650) Requires the Comptroller General to conduct a study for a report to the Congress on concierge care to determine the extent to which such care is used by

Medicare beneficiaries and has impacted upon the access of Medicare beneficiaries to items and services for which reimbursement is provided under the Medicare program.

(Sec. 651) Directs the Secretary to establish demonstration projects for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the Medicare program. Requires the Secretary to conduct an evaluation of the demonstration projects for a report to Congress along with such recommendations for legislation or administrative action as the Secretary determines appropriate.

Title VII: Provisions Relating to Parts A and B - Subtitle A: Home Health Services - (Sec. 701) Amends SSA title XVIII to change the time frame for the home health update from the Federal fiscal year to a calendar year basis beginning with 2004.

Increases home health agency payments by the full market basket percentage for the last quarter of 2003 (October, November, and September) and for the first quarter of 2004 (January, February, and March). Provides that the update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points.

(Sec. 702) Directs the Secretary to conduct a two-year demonstration project under Medicare part B under which Medicare beneficiaries with chronic conditions are deemed to be homebound for purposes of receiving home health services under the Medicare program. Authorizes appropriations.

(Sec. 703) Requires the Secretary to establish a demonstration project under which the Secretary is required, as part of a plan of an episode of care for home health services established for a Medicare beneficiary, to permit a home health agency, directly or under arrangements with a medical adult day-care facility, to provide medical adult day-care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(Sec. 704) Prohibits the Secretary during a described period of suspension from requiring a home health agency to gather or submit OASIS (Outcomes and Assessment Information Set) information that relates to an individual who is not eligible for benefits under either Medicare or Medicaid (non-Medicare/Medicaid OASIS information).

Requires the Secretary to conduct a study for a report to Congress on how non-Medicare/Medicaid OASIS information is and can be used by large home health agencies.

(Sec. 705) Directs MEDPAC to conduct a study for a report to Congress on payment margins of home health agencies under the home health prospective payment system.

(Sec. 706) Allows a religious nonmedical health care institution to provide home health services to individuals meeting conditions for coverage of religious nonmedical health care institutional services.

Subtitle B: Graduate Medical Education - (Sec. 711) Provides that hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY 2004 through FY 2013.

(Sec. 712) Provides that Congress intended to provide an exception to the initial residency period for geriatric residency or fellowship programs to accomodate programs that require two years of training to initially become board eligible in the geriatric speciality.

(Sec. 713) Provides that for one year from January 1, 2004, for purposes of applying provisions for the payment of indirect medical education and direct medical education costs, the Secretary is required to allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

Requires the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress on the appropriateness of alternative payment methodologies for the costs of training residents in non-hospital settings.

Subtitle C: Chronic Care Improvement - (Sec. 721) Amends SSA title XVIII to require the Secretary to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Requires the programs to be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under Medicare for targeted beneficiaries with one or more threshold conditions. Makes necessary appropriations.

(Sec. 722) Requires each MA organization to have an ongoing quality improvement program for improving the quality of care provided to enrollees in each MA plan offered by such organization (other than an MA private fee-for-service plan or an MSA plan) effective for contract years beginning January 1, 2006. Requires as part of the quality improvement program for each MA organization to have a chronic care improvement program.

(Sec. 723) Directs the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries. Authorizes appropriations.

Subtitle D: Other Provisions - (Sec. 731) Requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. Allows for public comment in national coverage determinations. Directs the Secretary to develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be acheived among local coverage determinations. Prohibits the Secretary in the case of an individual entitled to

benefits under Medicare part A, or enrolled under part B, or both who participates in a category A clinical trial, from excluding payment for coverage of routine costs of care furnished to such individual in the trial.

Directs the Secretary to implement revised procedures for the issuance of temporary national HCPCS codes under Medicare part B.

(Sec. 732) Amends BIPA to provide that direct payment for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals will be made for services furnished during 2005 and 2006.

(Sec. 733) Directs the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Authorizes appropriations. Requires the Secretary to pay for the routine costs as well as transplantation and appropriate related items and services in the case of Medicare beneficiaries who are participating in such a clinical trial as if such transplantation were covered under Medicare.

(Sec. 734) Directs the Secretary to transfer to the Hospital Insurance Trust Fund an amount that would have been held by that fund if the clerical error had not occurred. Appropriates to the Trust Fund an amount determined by the Secretary of the Treasury to be equal to the interest income lost by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

(Sec. 735) Requires MEDPAC to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service.

Requires the Commission to conduct a study for a report to Congress on the need for current data and sources of current data available to determine the solvency and financial circumstances of hospitals and other Medicare providers of services. Requires the Commission to submit to Congress a report on investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals.

Requires the Comptroller General to appoint experts in the area of pharmaco-economics or prescription drug benefit programs to the Commission.

(Sec. 736) Makes technical corrections.

Title VIII: Cost Containment - Subtitle A: Cost Containment - Requires the Medicare Board of Trustees annual report to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for the fiscal year and each of the succeeding six fiscal years, previous fiscal years, and 10, 50, and 75 years after such fiscal year; (2) comparisons with the growth trends for the

gross domestic product, private health costs, national health expenditures, and other appropriate measures; (3) expenditures and trends in expenditures under Medicare part D; and (4) a financial analysis of the combined Medicare trust funds if general revenue funding for Medicare is limited to 45 percent of total Medicare outlays. Requires the trust fund reports to include a determination as to whether there is projected to be excess general revenue Medicare funding for any of the succeeding six fiscal years. Provides that an affirmative determination of excess general revenue funding of Medicare for two consecutive annual reports will be treated as a funding warning for Medicare in the second year for the purposes of requiring presidential submission of legislation to Congress.

(Sec. 802) Amends Federal money and finance law to provide in the event that a Medicare funding warning is made, the President is required to submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress for the succeeding year, proposed legislation to respond to such warning. Provides that if during the year in which the warning is made, legislation is enacted which eliminates excess general revenue Medicare funding for the 7-fiscal-year period, then the President is not required to make a legislative proposal.

Expresses the sense of Congress that legislation submitted in this regard should be designed to eliminate excess general revenue Medicare funding for the seven-fiscal year period that begins in such year.

(Sec. 803) Sets out the procedures for House and Senate consideration of the President's legislative proposal.

Subtitle B: Income-Related Reduction in Part B Premium Subsidy - (Sec. 811) Provides that beginning in 2007, beneficiaries with incomes over $80,000 for an individual or $160,000 for a married couple will be asked to contribute more to the cost of their Medicare benefits through payment of a higher premium since the monthly amount of the premium subsidy applicable to the premium shall be reduced by a monthly adjustment amount that is based on the product of the sliding scale percentage and the unsubsidized part B premium amount and is phased-in beginning in 2007 through 2010.

Amends the Internal Revenue Code to direct the Secretary of the Treasury, upon written request from the Commissioner of Social Security, to make appropriate disclosure of tax return information to carry out the Medicare part B premium subsidy adjustment.

Title IX: Administrative Improvements, Regulatory Reduction, and Contracting Reform - (Sec. 900) Amends SSA title XVIII (Medicare) to establish within the Centers for Medicare & Medicaid Services (CMS) a center to administer Medicare parts C and D, provide notice of Medicare benefits and related information to beneficiaries, and perform such other duties as the Secretary may specify.

Amends SSA title XI to require that an actuary within the office of Chief Actuary of CMS have duties exclusively related to parts C and D of Medicare and related provisions.

Amends Federal civil service law to increase the pay grade for the Administrator of CMS to Executive Level III, beginning January 1, 2004.

Changes references from the Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

Subtitle A: Regulatory Reform - (Sec. 901) Provides that the term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

(Sec. 902) Requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. Prohibits the timeframe established from being no longer than three years except under exceptional circumstances. Provides that if the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(Sec. 903) Bars retroactive application of any substantive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines such retroactive application is needed to comply with statutory requirements or is in the public interest. Provides that no substantive change may go into effect until 30 days after the change is issued or published unless it is needed to comply with statutory requirements or is in the public interest. Prohibits compliance action from being taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

Provides that if a provider or supplier follows written guidance provided by the Secretary or by a Medicare contractor when furnishing items or services or submitting a claim and the guidance is inaccurate, the provider or supplier is not subject to any penalty or interest (including interest on a repayment plan).

(Sec. 904) Requires the Comptroller General to conduct a study for a report to Congress to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the Medicare program.

Requires the Secretary to periodically submit to Congress a report on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation.

Subtitle B: Contracting Reform - (Sec. 911) Amends SSA title XVIII to permit the Secretary to contract competitively with any eligible entity to serve as a Medicare contractor. Eliminates the distinction between Medicare part A contractors (fiscal intermediaries) and Medicare part B contractors (carriers), and merges separate authorities for fiscal intermediaries and carriers into a single authority for the new contractor. Authorizes these new contractors, called Medicare Administrative Contractors, to assume all the functions of the current fiscal intermediaries and carriers: determining payments; making payments; providing education and outreach to beneficiaries; communicating with providers and suppliers; and additional functions as are necessary.

(Sec. 912) Requires Medicare administrative contractors to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under Medicare. Requires Medicare administrative contractors to undergo an annual independent evaluation of their information security programs.

Subtitle C: Education and Outreach - (Sec. 921) Amends SSA title XVIII to require the Secretary to: (1) coordinate the educational activities provided through Medicare administrative contractors to maximize the effectiveness of Federal education efforts for providers and suppliers; and (2) use specific claims payment error rates or similar methodology of Medicare administrative contractors in the processing or reviewing of Medicare develop and implement a methodology to measure the specific payment error rates in the processing or reviewing of Medicare claims to give such contractors an incentive to implement effective education and outreach programs for providers and suppliers.

Directs the Secretary to develop a strategy for communications with individuals entitled to benefits under Medicare part A or enrolled under Medicare part B, or both, and with providers of services and suppliers under Medicare. Requires Medicare administrative contractors, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under Medicare within 45 business days.

Directs the Secretary to ensure that Medicare administrative contractors provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled

under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under Medicare. Requires monitoring of contractor responses. Authorizes appropriations.

Authorizes appropriations to the Secretary for enhanced provider and supplier training which are to be tailored for small providers or suppliers.

Requires the Secretary, and each Medicare contractor insofar as it provides services (including claims processing) for providers of services or supppliers, to maintain an Internet website which provides answers in an easily accessible format to frequently asked questions, and includes other published materials of the contractractor, that relate to providers of services and suppliers under Medicare.

Prohibits a Medicare contractor from using a record of attendance at (or failutre to attend) educational activities or other information gathered during an educational program to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(Sec. 922) Directs the Secretary to establish a demonstration program under which described technical assistance is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under Medicare. Authorizes appropriations.

(Sec. 923) Requires the Secretary to appoint within HHS a Medicare Beneficiary Ombudsman to receive complaints and provide assistance with respect to such complaints and who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under Medicare. Authorizes appropriations.

Directs the Secretary to provide through the toll free telephone number 1-800-MEDICARE for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free numbers are transferred (without charge) to appropriate entities for the provision of such information or assistance.

Requires the Comptoller General to conduct a study for a report to Congress to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free telephone number.

(Sec. 924) Requires the Secretary to establish a demonstration program under which the Medicare specialists employed by HHS provide advice and assistance to individuals entitled to benefits under Medicare part A, or enrolled under part B, or both, regarding the Medicare program at the location of existing local offices of the Social Security Administration.

(Sec. 925) Directs the Secretary to provide information about the number of days of coverage remaining under the skilled nursing facility (SNF) benefit and the spell of illness involved in the explanation of Medicare benefits.

(Sec. 926) Requires the Secretary to publicly provide information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify skilled nursing facilities (SNFs) that are participating in the Medicare program. Requires hospital discharge planning to evaluate a patient's need for SNF care.

Subtitle D: Appeals and Recovery - (Sec. 931) Directs the Commissioner of Social Security and the Secretary to develop and transmit to Congress and the Comptroller General a transition plan under which the functions of administrative law judges responsbile for hearing cases under the Medicare program are transferred from the responsibility of the Commissioner and Social Security Administration to the Secretary and HHS.

Directs the Commissioner and the Secretary to implement the transition plan and transfer the administrative law judge functions from the Social Security Administration to the Secretary. Requires the Secretary to: (1) assure the independence of administrative law judges performing the administrative law judge functions transferred from the Centers for Medicare & Medicaid Services and its contractors; and (2) provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred throughout the United States to ensure timely access to such judges.

Authorizes additional appropriations to increase the number of administrative law judges, improve education and training opportunities for administrative law judges, and increase the staff of the Departmental Appeals Board.

(Sec. 932) Directs the Secretary to establish a process where a provider, supplier, or a beneficiary who has filed an appeal may obtain access to judicial review when a review entity determines, within 60 days of a complete written request, that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and there is no material issue of fact in dispute. Provides that the determination by such review entity shall be considered a final decision and not be subject to review by the Secretary.

Permits expedited access to judicial review for cases where the Secretary does not enter into or renew provider agreements.

Requires the Secretary to develop and implement a process to expedite appeals of provider terminations and certain other remedies imposed on SNFs, including denial of payment for new admissions and temporary management, if imposed on an immediate basis. Allows an expedited appeal where a finding of substandard quality of care has resulted in the disapproval of a skilled nursing facility's nurse aide training program.

Requires the Secretary to give priority to cases where termination has been imposed on a provider.

Allows the Secretary to waive disapproval of a nurse aide training program, upon application by a nursing facility if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility.

Provides that in addition to any amounts otherwise appropriated, such additional sums are authorized to be appropriated for FY 2004 and each subsequent fiscal year as may be necessary to reduce by 50 percent the average time for administrative determinations on appeals.

(Sec. 933) Revises the Medicare appeals process to: (1) require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QTC) unless good cause precluded the introduction of the evidence; (2) provide for the use of beneficiaries' medical records in QIC reconsiderations; (3) require that notice of decisions or determinations, redeterminations, reconsiderations, and appeals be written in a manner calculated to be understood by a beneficiary and include reasons for the decision or determination or redetermination and the process for further appeal; (4) specify the eligibility requirements for QICs and their reviewer employees that relate to medical and legal expertise, independence, and prohibitions linked to decisions being rendered; and (5) reduce the required number of QICs from 12 to four.

(Sec. 934) Permits Medicare contractors to conduct random prepayment reviews only to develop a contractor-wide or program-wide claims payment error rate or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers. Establishes limitations on initiation of non-random prepayment review.

(Sec. 935) Provides that in situations where repaying a Medicare overpayment within 30 days creates a hardship for a provider or supplier, the Secretary is required, upon the request of the provider or supplier, to enter into an extended repayment plan of at least six months duration, but not longer than three years (or five years in the case of extreme hardship, as determined by the Secretary). Provides that if the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier.

Provides that if a provider or supplier fails to make a payment in accordance with a repayment plan, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding under the repayment plan.

Provides that if post-payment audits are conducted, the Medicare contractor is required to provide the provider or supplier with written notice of the itent to conduct the audit.

Provides that if a Medicare contractor audits a provider or supplier, the contractor shall: (1) give the provider or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider or supplier and permits the development of an appropriate corrective action plan; (2) inform the provider or supplier of the appeal rights under Medicare as well as consent settlement options; (3) give the provider of services or supplier an opportunity to provide additional information to the contractor; and (4) take into account such information provided, on a timely basis, by the provider of services or supplier. Provides that such provisions shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits. Requires the Secretary to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(Sec. 936) Requires the Secretary to establish by regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal.

(Sec. 937) Requires the Secretary to develop a process so providers and suppliers can correct minor errors in claims that were submitted for payment without having to initiate an appeal.

(Sec. 938) Amends SSA title XVIII to direct the Secretary to establish a prior determination process where physicians and beneficiaries can request through the Medicare administrative contractor whether Medicare covers certain physicians' services before such services are provided only if the physician requestor is a participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under Medicare and who has consented to the physician making the request for those physician services and the beneficiary is an individual entitled to benefits under Medicare, but only with respect to a physicians' service for which the individual receives an advance beneficiary notice from a physician who receives direct payment for that service.

Requires the Secretary to establish a process for the collection of information on the instances in which an advance beneficiary notice has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished. Directs the Secretary to establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advanced beneficiary notices and coverage policies under the Medicare program.

Requires the Comptroller General to submit to Congress a report on the use of advanced beneficiary notices under Medicare. Directs the Comptroller General to submit to Congress a report on the use of the prior determination process under such section.

(Sec. 939) Directs the Secretary to permit a provider of services or supplier to appeal any determination of the Secretary relating to services rendered under Medicare to an individual who subsequently dies if there is no other party available to appeal such determination.

(Sec. 940) Adds 30 days to the timeframe for deciding an appeal at the redetermination and reconsideration levels of appeal.

Indexes the amount in controversary for appeals to the consumer price index for all urban consumers, rounded to the nearest multiple of $10 beginning in 2005.

(Sec. 940A) Directs the Secretary to establish a mediation process for local coverage determinations using a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

Requires the Secretary to include in the contract with Medicare administrative contractors the performance duties expected of a medical director of a Medicare administrative contractor.

Subtitle E: Miscellaneous Provisions - (Sec. 941) Prohibits the Secretary from implementing any new or modified documentation guidelines for evaluation and management physician services under Medicare on or after the enactment of this Act unless the Secretary: (1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines; (3) has conducted appropriate and representative pilot projects to test such guidelines; (4) finds, based on reports submitted with respect to pilot projects conducted for such or related guidelines, that described objectives for evaluation and management guidelines will be met in the implementation of such guidelines; and (5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

Directs the Secretary to carry out a study of the following for a report to Congress: (1) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under Medicare; and (2) consideration of systems other than current coding and documentation requirements for payment for such physician services. Directs the MEDPAC to conduct an analysis of the results of the study included in the report for a report to Congress.

Requires the Secretary to conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made for a report to Congress.

(Sec. 942) Requires the Secretary to establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services to coordinate the activities of

coverage, coding, and payment processes under Medicare with respect to new technologies and procedures and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

Directs the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.

Requires the Comptroller General to conduct a study for a report to Congress that analyzes which external data can be collected in a shorter timeframe by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services.

(Sec. 943) Prohibits the Secretary from requiring a hospital (including a critical access hospital) to ask questions (or obtain information) relating to Medicare secondary payor provisions in the case of reference laboratory services if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(Sec. 944) Requires emergency room services provided to screen and stabilize a Medicare beneficiary after January 1, 2004 to be evaluated for Medicare's "reasonable and necessary" requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered. Provides that except in the case where a delay would jeopardize the health or safety of individuals, the Secretary is required to request a peer review organization review before making a compliance determination that would terminate a hospital's Medicare participation because of Emergency Medical Treatment and Labor Act (EMTALA) violations.

(Sec. 945) Directs the Secretary to establish a Technical Advisory Group to review issues related to EMTALA and its implementation.

(Sec. 946) Permits a hospice to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness or other events, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements.

(Sec. 947) Requires that public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, comply with the Bloodborne Pathogens standard. Provides that a hospital that fails to comply with such requirement will be subject to a civil monetary penalty, but cannot be terminated from participating in Medicare.

(Sec. 948) Makes BIPA-related technical amendments and corrections.

(Sec. 949) Amends SSA title XI to permit the administrator of a Federal health care program to waive certain 5-year exclusions if the exclusion of a sole community physician or sole source of essential specialized services in a community will impose a hardship. Provides that the mandatory exclusions that can be waived are those related

to convictions associated with program-related crimes; health care fraud; and controlled substances.

(Sec. 950) Amends SSA title XVIII to prohibit a group health plan providing supplemental or secondary coverage to Medicare beneficiaries from requiring dentists to obtain a claim denial from Medicare for dental benefits that are not covered by Medicare before paying the claim.

(Sec. 951) Requires the Secretary to arrange to furnish to "subsection (d)" hospitals the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage for that hospital for the current cost reporting year.

(Sec. 952) Allows physicians and non-physician practitioners to reassign payment for Medicare-covered services, regardless of where the service was provided so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such services. Allows the Secretary to provide for other enrollment qualifications to assure program integrity.

(Sec. 953) Requires the Comptroller General to report to Congress on: (1) the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate formula for 2002 and subsequently; and (2) all aspects of physician compensation for services furnished under Medicare and how those aspects interact and the effect on appropriate compensation for physician services.

Directs the Secretary to provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under Medicare in the previous year and information on how to get more information with respect to such determinations.

Requires the Comptroller General to submit to Congress a report on the implications if there were flexibility in the application of the Medicare conditions of participation for home health agencies with respect to groups or types of patients who are not Medicare beneficiaries.

Directs the Inspector General of HHS to submit a report to Congress on: (1) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days under the hospital benefit; and (2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before the completely exhaust such lifetime reserve days.

Title X: Medicaid and Miscellaneous Provisions - Subtitle A: Medicaid Provisions - (Sec. 1001) Amends SSA title XIX to establish a temporary increase in DSH allotments for FY 2004 and for certain subsequent fiscal years.

Raises the temporary floor for extremely low DSH states for FY 2004 and subsequent fiscal years.

Provides for an appropriate DSH allotment adjustment for FY 2004 and 2005 for States with statewide "Section 1115" waivers which have been revoked or terminated before the end of either such fiscal year and for which there is no DSH allotment for the State. Requires the State whose waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State to identify and make payments to DSH hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs.

Directs the Secretary to require, with respect to FY 2004 and each fiscal year thereafter, a State as a condition of receiving Medicaid payments to submit to the Secretary an annual report identifying each DSH hospital that received a payment, the amount such hospital received, and such other information as the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year.

Requires the State to annually submit to the Secretary an independent certified audit that verifies: (1) the extent to which hospitals have reduced their uncompensated care costs to reflect the total amount of claimed expenditures; (2) payment compliance; (3) only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to described individuals are included in the calculation of the hospital-specific limits; (3) the State included all payments under Medicaid, including supplemental payments, in the calculation of such hospital-specific limits; and (4) the State has separately documented and retained a record of all of its costs and claimed expenditures under Medicare, uninsured costs in determining payment adjustments, and any payments made on behalf of the uninsured from payment adjustments.

(Sec. 1002) Permits certain high-volume DSH safety net providers to negotiate with pharmaceutical companies and to receive discounts on the prices of inpatient drugs for the lowest price they can get. (Currently such entities are only able to receive discounts on the prices of outpatient drugs because of a Center for Medicare and Medicaid Services interpretation of the best price exemption under the Medicaid drug rebate program). Provides for the application of specified auditing and recordkeeping requirements with respect to such high-volume DSH hospital safety net providers.

(Sec. 1003) Amends the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1993 and the Balanced Budget Act of 1997, to permanently extend the moratorium on the determination of Saginaw Community Hospital as an institution for mental disease.

Subtitle B: Miscellaneous Provisions - (Sec. 1011) Appropriates for FY 2005 through 2008 specified funding out of any funds in the Treasury not otherwise appropriated to the Secretary for the purpose of making allotments to States for payments to eligible providers for unreimbursable costs incurred by providing emergency health care services to: (1) undocumented aliens; (2) aliens who have been parolded into the United

States at a United States port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card.

(Sec. 1012) Directs the Secretary to establish the Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation. Authorizes appropriations.

(Sec. 1013) Provides that in order to improve the quality, effectiveness, and efficiency of health care delivered pursuant to Medicare, Medicaid, and the State Children's Health Insurance Program, the Secretary is required to conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to: (1) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services; and (2) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs. Requires the Secretary to establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section. Directs the Secretary to evaluate and synthesize available scientific evidence related to health care items and services identified as priorities and to disseminate such evaluations and syntheses to various prescription drug plans to enhance patient safety and quality of health care. Authorizes appropriations.

(Sec. 1014) Directs the Secretary to establish the Citizen's Health Care Working Group to hold hearings to examine: (1) the capacity of the public and private health care systems to expand coverage options; (2) the cost of health care and the effectiveness of care provided at all stages of the disease; (3) innovative State strategies used to expand health care coverage and lower health care costs; (4) local community solutions to accessing health care coverage; (5) efforts to enroll individuals currently eligible for public or private health care coverage; (6) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and the use of technology in supporting providers in improving quality of care and lowering costs; and (7) strategies to assist purchasers of health care to become more aware of the impact of costs and to lower the costs of health care. Requires the Working Group to prepare and make available to health care consumers through the Internet and other appropriate public channels a report entitled "The Health Report to the American People." Directs the Working Group to initiate health care community meetings throughout the United States to address certain topics and to prepare and make available to the public initial recommendations on health care coverage and ways to improve and strengthen the health care system. Requires the Working Group to submit to Congress for appropriate action the final set of recommendations put together after the period of public comment. Authorizes appropriations.

(Sec. 1015) Makes appropriations to carry out this Act to be transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund: (1) not to exceed $1,000,000,000 for the Centers for Medicare and Medicaid Services; and (2) not to exceed $500,000,000 for the Social Security Administration. Provides from these latter funds for the Social Security Administration to reimburse the Internal Revenue Service for expenses in carrying out this Act. Allows the President to transfer such amounts between the Centers for Medicare and Medicaid Services and the Social Security Administration.

(Sec. 1016) Amends SSA title XVIII to direct the Secretary to establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects designed to improve the cancer-related health care infrastructure of the hospital, including construction, renovation, or other capital improvements. Makes appropriations.

Title XI: Access to Affordable Pharmaceuticals - Subtitle A: Access to Affordable Pharmaceuticals - (Sec. 1101) - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions (Hatch-Waxman Act) with respect to abbreviated new drug applications (ANDAs) to require the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.

Requires the ANDA applicant to notify the patent holder and the brand name company (if different) of a paragraph IV certification within 20 days.

Prohibits the ANDA applicant from amending the application to include a drug different from that approved by the Food and Drug Administration (FDA), but allows the applicant to amend the application if seeking approval for a different strength of the same drug.

Authorizes the FDA to approve the ANDA on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed.

Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of the notification but provides however if sued that the patent holder and the brand name company (if different) may file a counter claim to require that changes be made to correct the patient information submitted.

Disallows damages from being awarded in either case.

Provides that: (1) if a declaratory judgment is pursued, the action is to be brought in the judicial district where the defendant has its principle place of business; and; (2) in a declaratory judgment the holder of an approved new drug application may obtain access to confidential information contained in the application; and (3) the 180-day exclusivity period is to begin on the date of the first commercial marketing of the generic drug by any first ANDA applicants.

Requires a first ANDA applicant to forfeit the 180-day exclusivity period under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification and failure to obtain tentative marketing approval.

Prohibits other subsequent ANDA applicants from being permitted the 180-day exclusivity period if all first ANDA applicants forfeit.

(Sec. 1103) Defines "bioavailability" as the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

Subtitle B: Federal Trade Commission Review - (Sec. 1112) Requires that agreements between brand name companies and generic firms regarding the manufacture or sale of a generic drug that is equivalent to the pharmaceutical marketed by the patent owner must be filed with the Assistant Attorney General and the Federal Trade Commission (FTC) for review within ten days after the agreements are executed.

(Sec. 1114) Exempts from disclosure under the Freedom of Information Act any information or documentary material filed with the Assisstant Attorney General or FTC pursuant to this subtitle, and prohibits such information or documentary material from being made public, except as may be relevant to any administrative or judicial action or proceeding.

(Sec. 1115) Subjects parties which fail to file such agreements to civil penalties.

(Sec. 1116) Allows the FTC to engage in rulemaking to carry out this subtitle.

Subtitle C: Importation of Prescription Drugs - (Sec. 1121) Directs the Secretary to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. Sets forth specified provisions respecting: (1) importer and foreign seller recordkeeping and information requirements; (2) qualified laboratory drug testing; (3) registration with the Secretary of Canadian sellers; and (4) approved labeling.

Declares that the Secretary should: (1) focus enforcement on cases in which individual importation poses a significant public health threat; and (2) exercise discretion to permit individuals to make such importation for non-risk personal use.

Authorizes the Secretary to grant individuals a waiver of the prohibition of importation of a prescription drug or device. Directs the Secretary to grant individuals a waiver of such prohibition for an approved prescription drug imported from Canada that is: (1) imported from a licensed pharmacy for not more than 90-day personal use; (2) accompanied by a valid prescription; (3) in a final finished dosage that was manufactured in a registered establishment; and (4) imported under such other conditions as the Secretary determines necessary to ensure public safety.

(Sec. 1122) Directs the Secretary to conduct a study on the importation of drugs into the United States for submission in a report to the Congress.

Title XII: Tax Incentives For Health And Retirement Security - (Sec. 1201) Amends the IRC to permit eligible individuals who are covered by a high deductible health plan with a deductible of at least $1,000 up to $2,250 (subject to an annual cost of living adjustment) for self-only coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $5,000, and a deductible of at least $2,000 up to $4,500 (subject to an annual cost of living adjustment) for family coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $10,000, and not covered by any other other health plan that is not a high deductible health plan (except plans for any benefit provided by permitted insurance and plans for coverage for accidents, disability, dental care, vision care, or long-term care) to establish Health Savings Accounts (HSAs) for taxable years beginning with 2004 to pay for qualified medical expenses. Provides that: (1) contribution levels are to be determined monthly based on how many months of the year the individual is covered by a HDHP; and (2) a plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care. Prohibits Medicare-eligible individuals from participating in HSAs.

Includes as qualified medical expenses any expense for coverage under: (1) a COBRA continuation plan; (2) a qualified long-term care insurance contract; (3) a health plan during a period in which the individual is receiving unemployment compensation; and (4) health insurance premiums for individuals eligible for Medicare, other than premiums for Medigap policies program

Allows an eligible individual establishing an HSA to take a tax deduction for the taxable year of an amount equal to the aggregate contributions paid during the taxable year by or on behalf of such individual to an HSA of such individual, up to the limits specified above for self-only and family coverage. Allows the deduction whether or not the individual itemizes other deductions.

Allows contributions to remain in the HSA at the end of the year and to earn tax-exempt interest until they are withdrawn for uses other than for qualified medical expenses in which case they are to be included in the gross income of the account beneficiary and subjected to a ten percent penalty, except in cases of disability or death or where the contributions are distributed after the account beneficiary attains Medicare eligibility. Requires contributions to be in cash, except in the case of certain rollover contributions. Allows additional "catch up" contributions for eligible individuals age 55 or older.

Allows an HSA trustee to be a bank, an insurance company, or another person.

Permits rollovers from Archer MSAs.

Prohibits any payment or distribution out of an HSA for qualified medical expenses from being treated as an expense paid for medical care.

Allows employers to contribute to the HSAs of their employees and excludes amounts contributed from the employee's income and from employment taxes.

Imposes an excise tax on: (1) the failure of employer to make comparable HSA contributions; and (2) excess contributions.

Allows HSAs to be offered under cafeteria plans.

(Sec. 1202) Excludes from gross income any special subsidy payment received under employer-sponsored qualified retiree prescription drug plan programs.

(Sec. 1203) Creates an exception to information reporting requirements relating to information at the source for flexible spending arrangements and a health reimbursement arrangement that is treated as employer-provided coverage.

Issue 8: Extending the Medicare Modernization Act - The Trump Proposals of 2017

This chapter consists of three discrete sections. The first and longest part was originally published in 2017 as 'Reforming America's Healthcare System Through Choice and Competition' by the US Department of Health and Human Services and endorsed by then HHS Secretary Alex Azar II, Treasury Secretary Steven Mnuchin and Labor Secretary Alexander Acosta. I present the entire report here so readers can get both the factual discussion and nuances without any potential biases from me. All footnotes appear at the end. 'Reforming America's Healthcare System' is available online at https://www.hhs.gov/about/news/2018/12/03/reforming-americas-healthcare-system-through-choice-and-competition.html.

I encourage readers to consider this as a statement of the market based / Republican approach to solving our healthcare financing problems. Read it less as a specific policy proposal and more as an overall approach.

I also present two additions to these market based reform proposals: Individual Coverage Health Reimbursement Accounts (ICHRAs) and Association Health Plans, both at the end of this chapter.

The ICHRA discussion comes from the 2019 Department of Health and Human Services FAQs on ICHRAs. It is available online at https://www.hhs.gov/about/news/2019/06/13/hhs-labor-treasury-expand-access-quality-affordable-health-coverage.html.

The Association Benefit Plan discussion comes from the 2020 CBO Paper: INCREASING SMALL-FIRM HEALTH INSURANCE COVERAGE THROUGH ASSOCIATION HEALTH PLANS AND HEALTHMARTS, January 2000. https://www.cbo.gov/publication/12066. Numbers in the text and tables of this paper may not add up to totals because of rounding. All dollar values are expressed as 1999 dollars.

The United States healthcare system increasingly imposes a bewildering array of complexity and inefficiency throughout the commercial insurance markets. In addition, our nation's healthcare system is encumbered with mandates and regulations that raise costs, decrease competition, and sometimes do little on net to improve the nation's health. These inefficiencies, mandates and regulations contribute to higher costs and higher health insurance premiums. Health insurance premiums, particularly for individual coverage (the markets most affected by the Affordable Care Act, or ACA) have soared—more than doubling in the individual market between 2013 and 20172—while out-of-pocket spending has also skyrocketed.3 Even though the ACA was supposed to hold down healthcare costs, premiums in the individual market rose after 2013 when the ACA's insurance rules took effect. The average monthly premiums for all plans rose: For the benchmark plan—the second-lowest cost silver plan—premiums

increased by 88 percent between 2014 and 2018 in states with the federally run healthcare exchange (Healthcare.gov).4 Spending by employers for employer-sponsored health benefits is also rising. The average premium for family coverage has increased 20 percent since 2013 and 55 percent since 2008.5 While private spending is increasing, so, too, is government spending. Spending on government health programs now accounts for nearly half of all U.S. healthcare expenditures, increasing the burden on taxpayers.6 Part of this increase in government spending is driven by an aging population, as the baby boomer generation shifts from private coverage to Medicare. Given the magnitude of this spending, it should not be surprising that there are growing concerns about whether the spending is producing benefits that justify the cost.

In addition to increased spending, the federal regulation of healthcare has risen sharply. Unfortunately, government bureaucracies are often slow to change and adapt to health-care innovations and new payment models. Given government's large role in the healthcare sector, this likely contributes to lower productivity in the sector. For example, the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) found that multifactor productivity—the output from joined units of capital and labor—in hospitals had a 0.1 to 0.6 percent 10-year moving average productivity growth rate from 1990 to 2013, compared to 1 percent in private nonfarm businesses.7 Slower-than-average productivity growth suggests that there is a misallocation of resources and widespread inefficiency in the healthcare system, particularly in public programs.8 Since the government share of healthcare spending is so large, government rules impose inefficiencies on private firms dependent on public funding, even if they also serve privately funded patients. Simply put, government has played a large role in limiting the value Americans obtain for their healthcare spending. The United States is spending a large and increasing share of its national income on healthcare, and much of this spending does not lead to citizens living longer, healthier lives.

One of the most important mechanisms available to enhance the value Americans receive for their healthcare spending is increased competition. Market competition should encourage healthcare providers to charge lower prices and provide higher-quality services. Although the traditional view among economists is that government should step in to correct so-called market failures, this report finds many cases where government regulation and rules prevent healthcare markets from working efficiently. This report examines many sectors of the U.S. healthcare market to assess the degree to which competition for healthcare services exists and the role government regulation plays in affecting competition for healthcare services. In doing so, the report identifies numerous government policies that inhibit choice and competition in healthcare markets, dampen productivity gains among providers, lead to increased consolidation and market concentration, and prevent the introduction of more efficient or innovative ways of delivering and paying for care.

A highly-effective and well-functioning healthcare market is important for two reasons. First, the state of health and well-being Americans enjoy contributes in economic and

non- economic ways to the quality of American life. Second, the significant resources Americans spend on healthcare crowd out resources that would otherwise be available for other individual and national priorities. The United States spends nearly one-fifth of its national income on healthcare,9 and much of this spending provides little, if any, positive value. For example, the 2018 Economic Report to the President, prepared by the Council of Economic Advisers, reviewed several studies that showed a poor relationship between government coverage expansions and health improvements.

When it comes to healthcare, Americans should expect more value for the dollars they spend. This report details many opportunities to increase the value provided throughout our healthcare system through the actions that create greater choice and competition.

The Fundamental Bases of Commercial Health Insurance Reforms

Commercial health insurance reforms are based on the concept of enhanced user / patient decision making responsibilities. Economists generally accept that free-market competition produces the most efficient production and distribution of goods and services. When consumers have choices, the incentives and information needed to optimize value, firms have the incentive to improve quality and lower costs through innovation. Competitive market forces and the incentive to innovate typically raise quality and drive down prices, including quality-adjusted prices, for goods and services over time (features observed in many well-functioning sectors of the economy but which are generally absent in the highly regulated healthcare market).10 However, when government policies and regulations suppress competition, producers may use their market power to raise prices, produce lower-quality goods and services, or become complacent in innovating. In other words, without competitive pressure, the incentive to lower prices, improve quality, and innovate diminishes. As the government share of healthcare spending has increased over time, the healthcare market has become increasingly vulnerable to rules and regulations that impede market forces.

The importance of market competition is apparent in the relevant data. Hospitals without local competitors typically charge higher prices, which could add thousands of dollars to a hospital bill.11 Since healthcare expenses largely drive insurance premiums, these costs are mostly passed on to consumers or taxpayers. The lack of insurer competition also leads to higher prices: Researchers have estimated that adding a single insurer offering to health exchange plans in 2014 reduced premiums by 4.5 percent on average.12 A recent paper in Health Affairs estimated that exchange plan premiums were 50 percent higher, on average, in rating areas with only one insurer compared to those with more than two insurers.13 The lack of competition produces similar affects within the employer market for health insurance. A paper in the American Economic Review estimated that premiums in average markets were approximately 7 percentage points higher by 2007 due to increases in local concentration of health insurers from 1998 through 2006.14 One example is that, according to one study, the merger between Aetna and Prudential in 1999 led to a 7 percent increase in premiums for large

employers.15 Similarly, according to another study, the merger of Sierra and United Health in 2008 led to an almost 14 percent increase in small group premiums.16

Perhaps more importantly, there is evidence that the lack of competition in provider markets leads to reduced quality of care.17 For example, a 2000 study of more than 500,000 Medicare beneficiaries found that those who experienced a heart attack had a statistically significant (1.5 percentage point) higher chance of dying within one year of treatment if they received care in a hospital with fewer potential competitors.18 To drive that point home, Americans have 790,000 heart attacks each year.19 Assuming that half the country lives in relatively noncompetitive hospital markets, we would expect from these findings that 5,925 premature deaths to be associated with a lack of competition. Of course, this calculation is just for heart attacks, just one of numerous diseases or conditions that kill Americans prematurely each year. Other findings demonstrate the relationship between competitive healthcare markets and improved outcomes, increased quality, and lower prices. For example, the inflation- adjusted price of LASIK eye surgery declined by 25 percent between 1999 and 2011, even as quality markedly improved.20 Notably, third-party payers (including the government) generally do not cover the procedure and so ophthalmologists have had to compete directly for consumer dollars.21 Similarly, though the price of healthcare grew at double the rate of inflation between 1992 and 2012, the price of cosmetic surgery—for which consumers pay almost exclusively out of pocket—grew at less than half the rate of inflation.22 These examples also highlight that when consumers are spending their own dollars and shopping accordingly, providers have greater incentives to improve quality and cut costs.

Unfortunately, a lack of consumer choice permeates most health insurance markets as well. Most Americans receive insurance selected by their employer or receive coverage through government programs, characterized by exceptionally heavy regulation and bureaucratic controls. Because of the ACA, insurance companies were not allowed to offer certain low- cost plans and withdrew from some markets. Although some people who were previously uninsured are covered, many with subsidies, Americans without employer or publicly- supported coverage often face limited choices in the individual market.23 Starting in 2014, new individual market plans had to satisfy ACA requirements. In 2017, people in one-third of U.S. counties could purchase health insurance only through the ACA exchanges from a single insurer.24 As additional insurers have withdrawn from government-designed and regulated markets, people in more than half of U. S. counties (representing 29 percent of exchange enrollees) have options from only a single insurer in 2018.25 Notably, government policies promote many factors that prevent the free-market from operating. Specifically, government has encouraged excessive third-party payment, created counterproductive barriers to entry, incentivized opaque pricing practices, skewed innovation activity, and placed restrictions on the reimbursement policies of government programs. Overall, these practices have resulted in less choice, less competition, and sub-optimally functioning markets that deliver higher prices and lower quality.

Some healthcare expenditures are for emergency services that are not conducive to consumer shopping. That said, the common claim that the healthcare sector as a whole cannot function under free-market principles is untrue. The vast majority of healthcare services are routine or elective services that can be organized by markets to enhance patient welfare. One study found that emergency department spending is roughly six percent of total United States health spending.26 Another study classified 43 percent of healthcare spending as “shoppable,” with another 11 percent of spending on prescription drugs, an item that is generally shoppable.27 Distinguishing between shoppable and non-shoppable healthcare services is important, and encouraging normal market economic forces to govern the shoppable transactions constituting the majority of the sector is prudent. As this report explains, government policy and regulation often does precisely the opposite, actively discouraging the application of normal market forces to the shoppable category of healthcare services, and, in effect, treating the whole sector as if it were similar to emergency services.

Another common argument contends that the gap in expertise between the sellers of healthcare services (i.e., healthcare providers) and buyers (i.e., patients) makes the idea of informed consumer choices implausible. While true to some extent, the same could be said about other markets that operate successfully under free-market principles, as anyone who has taken a car to an auto-mechanic or employed a financial adviser can attest. Indeed, the implication that healthcare providers will take advantage of patients by selling them services they do not understand or need suspects the worst of professions (such as medicine and nursing) that adopt strict ethical standards. Even if there were agreement that this risk is justified, there are other ways to solve this problem without abandoning free-market principles. For instance, in many markets where there is a gap in expertise between buyers and sellers, the less knowledgeable party will employ an unbiased consultant to help them make good decisions. In addition, third-party entities, like consumer watchdog groups, can produce reviews of actors within the healthcare system. The lack of transparent, reliable price and quality information currently inhibits such reviews.

Another reason given by some against market-based healthcare is that there are inherent economies of scale within healthcare that lead to natural monopolies and limit the extent to which markets can properly function. For example, there might be high fixed costs in building and equipping a healthcare facility. Once the facility is built, the marginal cost of extra services declines. This is why, the argument goes, it may make economic sense to have only a single hospital or nursing home in lightly-populated rural areas, and why certain healthcare mergers can increase economic efficiency by lowering production costs.28 These natural economies of scale contribute to the creation of entities with significant pricing power. One can make a similar argument with regard to disease burdens, wherein smaller communities are only likely to have a need for so many specialists of a certain type given a population size and disease incidence rate. This leads to an economic incentive for specialists to form a practice together and take advantage of their pricing power. Furthermore, it is possible that a

relatively small market cannot support the entrance of a competitor that would drive down prices since demand for the relevant type of specialist is roughly fixed among the population, meaning that the addition of another provider would merely drive prices to a point where neither entity were profitable and one ultimately would exit.

While these claims have some merit, most people live in areas with markets large enough to sustain multiple hospitals, nursing homes, or other providers. More importantly, economies of scale are inherent in many markets, yet the markets function well for consumers. Overall, there is little reason to think that these issues are so intrinsic to healthcare markets that they undermine a market-based approach. Indeed, with vigorous law enforcement to prevent unlawful consolidation and anti-competitive behavior, there is good reason to think that healthcare markets will function like most other competitive markets.

As this report will discuss, the government has actually adopted many policies that promote consolidation in the healthcare sector, favoring established incumbents at the expense of smaller providers and start-ups. Additionally, the ability to create regional monopolies in healthcare markets is largely dependent on geographic factors, which recent innovations such as telehealth could substantially disrupt. Rather than adopt policies that allow disruptive technology like telehealth to compete, the government has often intervened to create an uneven playing field that limits choice and competition to the benefit of established incumbents and at the expense of consumers. While there are economies of scale in healthcare markets, they are hardly unique and do not prevent the market as a whole from functioning well. What is unique is the extent to which the government has adopted policies that exacerbate these issues.

The Third Party Payment Environment of Commercial Health Insurance Policies

Why do healthcare markets not function like other economic markets with price transparency, clear quality metrics, shopping, and declining real, quality-adjusted prices through time? The answer is primarily because government policies have combined to produce an excessive reliance on third-party payment mechanisms and numerous barriers to entry.

Third-party payment mechanisms insulate the ultimate consumer from the direct payment for healthcare goods and services. Instead of paying for healthcare services directly, consumers rely on an intermediary to do so on their behalf. Some degree of third-party payment in healthcare is understandable and necessary since there are low-probability, hard-to-predict, and costly health events that would otherwise subject an individual or family to a large financial loss. While insurance, along with saving and financing, is an efficient mechanism to reduce the impact of unlikely and high-cost events, insurance that covers routine, predictable, or shoppable services has significant drawbacks. First, an insurance system is often administratively complex to implement and accordingly can have high administrative costs. Second, consumers are incented to extract as much value out of an insurance policy as possible (since the premium is in

effect a fixed fee), which in turn creates a coverage-induced demand for low-value products and services, and generates greater administrative costs as insurers validate claims. For these reasons, firms offer, and insurance consumers in most other markets select, policies that provide protection against improbable but high-cost events. Because routine, predictable, or shoppable services are not covered by a third party in other insurance markets, consumers have significant incentive to maximize the value they receive from these uncovered, routine services.

Auto insurance is a good example. Auto insurance typically covers a car crash and related healthcare expenses, but it does not cover gasoline or routine maintenance. Imagine if auto insurance did provide coverage for gasoline and routine maintenance. First, consumers would shop for their gas less carefully (since the insurance pool would bear the marginal cost of premium gasoline versus standard gasoline), and they would consume more maintenance. Second, in response to rising utilization and corresponding premium increases, auto insurance companies might establish preferred networks of gasoline and maintenance providers to better incentivize consumer behavior and control cost. In the long term, complex bureaucratic management schemes might emerge to tackle resource allocation with large national networks coming to dominate the market. While one could keep going with this thought experiment, the example highlights that as insurance covers more of an individual's routine expenses, consumers experience diminished incentives to obtain value.

Federal policy has a long history of subsidizing highly-comprehensive health insurance.29 In the 1940s and 1950s, the exclusion of employer-provided health insurance premiums from income and payroll taxes created incentives for employers to offer comprehensive insurance coverage to compete for workers. Notably, this incentivized employers to compensate employees with health insurance rather than wage increases or other benefits that lacked a comparably generous tax exemption. The creation of Medicare and Medicaid in 1965 led to additional government subsidization of comprehensive coverage. Most recently, the ACA mandated that individuals have comprehensive coverage or pay a tax penalty. (This penalty has been reduced to $0 as of 2019 because of the Tax Cuts and Jobs Act of 2017.) Similarly, employers with 50 or more full-time workers who do not offer comprehensive coverage pay a tax penalty if at least one of their employees receives a premium tax credit for an exchange plan. The ACA also created additional federal subsidies for comprehensive coverage through Medicaid expansion and premium tax credits and cost-sharing reduction payments for exchange plans.

Because of open-ended tax subsidies for employer-provided health insurance, health insurance in the United States generally covers routine, predictable and shoppable services in addition to low-probability events. Federal laws, including the ACA, and state laws governing health insurance policies also require coverage for specific health benefits, often with low or no copayments. The Medicaid program, with nominal or zero copays and deductibles, exemplifies this problem. As a result, consumers typically do

not have an incentive to shop for value, eliminating one mechanism that could help constrain provider prices. This set of policy choices has created a market for healthcare goods and services that is inherently inflationary.

As healthcare costs increase, insurers should feel market pressure to aggressively manage these costs on behalf of their customers. In competitive insurance markets, insurers feel the pressure of market forces to lower healthcare costs and premiums. However, some have claimed that insurers benefit from rising provider costs.30 One recent article discussed that insurers may lack adequate incentives to bring down provider charges, partly because higher provider prices translate into higher insurer profits.31 This may be particularly problematic in markets without vigorous competition among payers. Regardless of the motivation, one might ascribe to insurer actions, healthcare costs have consistently increased faster than wages and the overall economy.

Third-party payment also creates notable separation between producers and consumers, and leaves bureaucracies with the role of allocating resources. Bureaucracies are extremely susceptible to pressure from special interest groups, which lobby lawmakers to require coverage for the products they produce or services they provide. While a boon to special interests, mandated benefits cause a greater amount of healthcare services to be financed through third-party arrangements, raising premiums and taxes. The increased premiums, in turn, may incentivize some people to obtain more treatment and services so as to maximize the value received for the premium paid. This behavior drives up utilization and increases low-value spending. Moreover, excessive third-party payment results in providers serving the interest of payers—government bureaucracies and insurance companies—rather than consumers.

In conclusion, in most other markets, consumers pay the full price of what they purchase and are therefore likely to carefully consider the value of products relative to alternatives. Active shopping by consumers motivates competition on price and quality among producers. Third-party payment for routine, predictable and shoppable expenses reduces consumers' incentives to obtain maximum value and has contributed to opaque and byzantine prices and bureaucratic complexities. As a result, consumers have less ability and less incentive to carefully shop for healthcare, compare prices and quality, and select the most efficient providers. This, in turn, means that providers have a diminished incentive to innovate and increase their efficiency.

Under normal market conditions, high prices and/or high profit margins attract new producers and sellers. This increased supply leads to lower prices and higher quality over time. Without the possibility of new entrants and real competition, however, existing producers can use market power to keep prices high and quality low. While barriers to entry can be the result of normal market forces, such as economies of scale, they may also be the result of government restrictions. Government-erected barriers to entry can lead to a highly-concentrated and inefficient market. Moreover, firms protected

from competitive forces can be expected to devote resources to maintaining these rents (e.g., by erecting or maintaining entry barriers) rather than to improving efficiency and innovating.32 Some government-erected barriers, such as patents, are enacted to support a careful balance that promotes innovation and consumer options. However, many government-erected barriers harm consumers by blocking or restricting market entry.33

These harmful barriers, such as state laws requiring potential new entrants to gain governmental permission (and, occasionally, permission from established incumbents) to enter markets, or preventing healthcare professionals from practicing to their full ability, are of primary interest in this report.

Over the past few decades, there has been a substantial increase in mergers and acquisitions throughout the healthcare sector, particularly among healthcare providers. More recently, industry consolidation (fewer and larger firms in the market) and industry concentration (the extent to which a small number of firms control most of the transactions) has occurred, in part, due to the increased complexity and administrative burden resulting from the ACA34 and other government requirements. As will be discussed in Section 2 of this report, significant evidence shows that reduced competition in healthcare markets contributes to higher prices and reduced quality.

Perhaps the best evidence for why the healthcare system needs reform and that the ACA moved the system in the wrong direction was outlined in the President's 2018 Economic Report.35 This report (at pages 283-285) details the literature showing that our previous focus on expanding health insurance coverage has had mixed and surprisingly small effects on health outcomes. Probably the best investigation– the oft-cited Oregon Medicaid study– found that low-income, uninsured individuals randomly selected to enroll in Medicaid did not experience statistically significant improvement in any of the physical measures of health observed—cholesterol, blood pressure, and blood sugar–although there were some benefits for mental health.36

A subsequent Oregon Medicaid expansion study estimated that Medicaid enrollees only valued each dollar of program spending at between 20 to 40 cents, and that 60 percent of expansion costs were transfers to providers who would have otherwise provided uncompensated care to these patients.37 A separate study of how many enrollees dropped out when charged higher premiums for Medicaid-like coverage in Massachusetts found that most enrollees valued coverage at less than half the cost. The availability of uncompensated care was the central reason that enrollees place low value on the coverage – substantially less than the cost of providing that coverage.38

Notably, despite the ACA expanding coverage options to the uninsured, largely through Medicaid, American life expectancy dropped three-tenths of a year from 2014 to 2017—in part due to rising opioid abuse—something that has not happened since the 1960s.39 The Economic Report of the President outlined several explanations for why insurance, particularly expansions of public programs like the ACA's Medicaid expansion, have

limited health benefits and in many locations contribute to access problems. Some Medicaid recipients have difficulty finding providers to provide care.40 Moreover, as Atul Gawande, former adviser to President Bill Clinton, has discussed, some medical care can actually decrease health because there are separate health risks associated with the receipt of medical care, including over-testing and resulting issues like stress, radiation exposure and over-treatment (e.g. medically unnecessary surgeries), that need to be counted.41

This report discusses government-induced barriers to competition and choice and makes recommendations that would reduce or eliminate these barriers. These reforms are critical to unleashing competitive forces to improve consumer choices and spur provider and payer innovation to deliver high-value products and services to consumers. Without enacting a bold set of reforms that increase choice and competition in healthcare, government-created inefficiencies will continue to dominate the U.S. healthcare system, particularly publicly- financed care, frustrating Americans as the rising cost of healthcare squeezes family and government budgets. Reform will involve taking on entrenched special interests that maintain their advantage over consumers by lobbying government to restrain competitive forces.

In particular, this report aims to address these issues as crystalized in the following problem statement: Many government laws, regulations, guidance, requirements and policies, at both the federal and state level, have reduced incentives for price- and non-price competition, increased barriers to entry, promoted and allowed excessive consolidation, and resulted in healthcare markets that lack the benefits of vigorous competition. Increasing competition and innovation in the healthcare sector will reduce costs and increase quality of care—improving the lives of Americans.

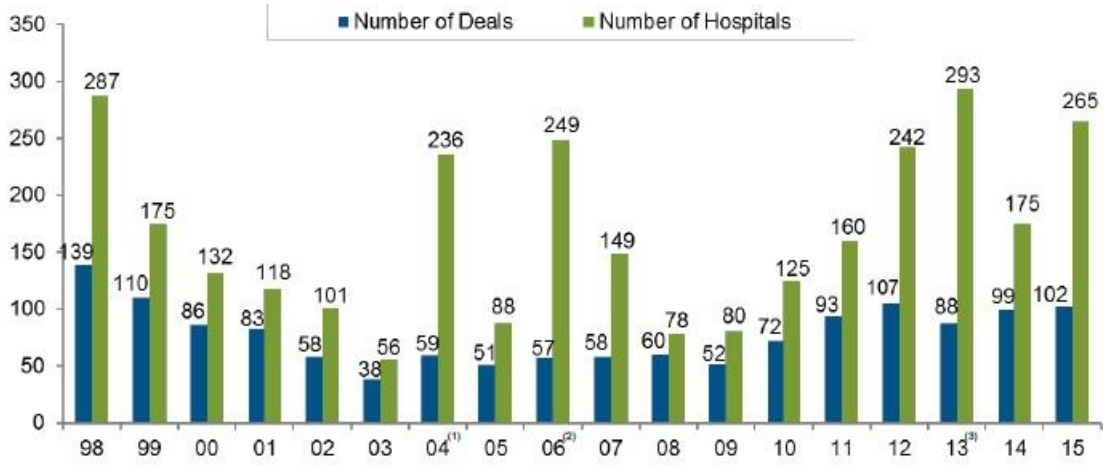
The remaining three sections of this report are devoted to analyzing these important issues with a focus on changing government regulations to improve health-market outcomes through enhancing choice and competition. Section 2 provides detailed analysis of trends in consolidation and concentration in certain healthcare markets. Section 3 provides analysis of several specific areas of federal and state policies associated with increased consolidation or reduced competition. Section 4 presents recent and emerging policy alternatives that can address these issues by facilitating more efficient allocation of healthcare dollars. The final section offers specific policy recommendations based on these analyses.

Trends in Merger Activity

According to a recent analysis of metropolitan areas that are considered single markets, roughly 77 percent of Americans in these urban markets live in highly concentrated hospital markets.45 Over the past several decades, many hospitals have consolidated into multi-hospital systems.46 According to data compiled by Irving Levin Associates, depicted by the American Hospital Association in Figure 1, the number of announced hospital transactions (including mergers and acquisitions) per year fell from 139 in 1998

to 38 in 2003, before starting to increase in 2010 and reaching 102 in 2015.47 In 2010 alone, the number of mergers jumped 40 percent to 59, with more than 60 deals in each subsequent year. The number of hospitals involved in those deals has shown more variation from year to year, although data from recent years show a rise in mergers and acquisition.

Figure 1: Announced Hospital Mergers and Acquisitions, 1998-2015



Source: Irving Levin Associates, Inc. (2016). *The Health Care Services Acquisition Report*, Twenty-Second Edition.
(1) In 2004, the privatization of Select Medical Corp., an operator of long-term and acute-care hospitals, and divestiture of hospitals by Tenet Healthcare Corporation helped to increase the number of hospitals affected.
(2) In 2006, the privatization of Hospital Corporation of America, Inc. affected 176 acute-care hospitals. The acquisition was the largest health care transaction ever announced.
(3) In 2013, consolidation of several investor-owned systems resulted in a large number of hospitals involved in acquisition activity.
Chart 2.10 in 2009 and earlier years' Chartbooks.

An acquisition that combines healthcare providers that were competing in some aspect of their business may substantially lessen competition and thereby violate Section 7 of the

Clayton Act.48 Because preservation of healthcare competition is vital to preserving

consumer choice, price containment, and quality, federal antitrust authorities, specifically the Federal Trade Commission (FTC) and the Department of Justice, have for many years maintained vigorous enforcement programs to scrutinize healthcare mergers for their potential effects on competition. Antitrust enforcers seek to identify and challenge mergers likely to have anti-competitive effects.

Empirical evidence on the impact of mergers on competition in healthcare markets—based on studies by FTC staff and independent scholars—shows that healthcare consumers benefit from competitive markets and the associated lower prices and higher quality services.49 Economic studies also consistently demonstrate that

reducing hospital competition leads to higher prices for hospital care.50 These effects are not limited to for- profit hospitals: mergers between not-for-profit hospitals can also result in substantial anti- competitive price increases.51 Economic evidence also shows that hospital competition tends to be highly localized.52

The Impact of Lost Competition

FTC merger retrospective studies, supplemented by a large and growing body of literature, strongly suggest that healthcare providers with significant market power can (and often do) negotiate higher-than-competitive payment rates.53 The price differences ultimately paid by consumers in concentrated markets can be significant.54 For example, price increases as high as 40 percent have resulted when competition was lost after one hospital system acquired a competing hospital.55

Federal antitrust agencies prevailed in some early challenges to anti-competitive hospital mergers56 and obtained a number of consent decrees that allowed problematic hospital mergers to proceed only if certain hospitals were divested.57 However, in the 1990s, several courts rejected the agencies' attempts to block hospital mergers (on the grounds that the government had not established geographic or products markets) that they claimed would harm competition.58 This string of losses led the FTC to launch a Hospital Merger.

Retrospective Project to determine whether consummated hospital mergers led to higher prices. The FTC selected four consummated hospital mergers for intensive study and published retrospective studies in early 2011.59 The study of one consummated merger in particular—the Evanston/Highland Park (Illinois) merger—led to an FTC administrative challenge determining that the acquisition had violated the antitrust laws.60

The Hospital Merger Retrospective Project led to important insights about the nature of hospital competition and the competitive effects of hospital mergers that have continued to guide FTC case selection and enforcement decisions today.61 For instance, in 2011, the FTC challenged ProMedica Health System's acquisition of its rival, St. Luke's Hospital.62 The proposed merger would have given ProMedica, already the largest hospital system in the Toledo, Ohio, area, over half the market for general acute care hospital services and over 80 percent of the market for inpatient obstetrics services. Hospital documents indicated that St. Luke's management saw the acquisition leading to higher prices by increasing its "negotiating clout" over insurers. The FTC's order required ProMedica to

undo its merger and re-establish St. Luke's as an independent competitor. The FTC has since successfully challenged other hospital mergers as well.63

The FTC has also challenged mergers between competing physician practices. For example, the FTC and the State of Idaho successfully challenged the acquisition by St. Luke's Health System of Saltzer Medical Group in Nampa, Idaho.64 St. Luke's, the

state's dominant health system, had numerous employed primary care physicians from prior acquisitions, including eight primary care physicians in Nampa, before acquiring from Saltzer 16 additional primary care physicians also practicing in Nampa. Although their prior acquisitions gave St. Luke's greater bargaining power, payers had been able to resist at least some of St. Luke's demands because of the presence of an alternative provider, Saltzer. The FTC alleged, and the court agreed, that the St. Luke's acquisition of Saltzer eliminated that remaining competitive option and would have led to higher prices for physician services.65

In sum, consolidation in well-defined antitrust markets can harm competition and consumers. Retrospective studies of healthcare mergers provide credible examples of harmful consolidation. These studies lend support for vigorous antitrust enforcement to prevent the accumulation of market power in healthcare markets. They can also help to guide case selection by the antitrust agencies and illustrate the mechanism by which excessive consolidation can stifle competition and harm healthcare consumers. However, as will be discussed in Section 3, certain state policies, such as certificate-of-need laws and certificates of public advantage, may suppress entry or prevent antitrust scrutiny of mergers that lead to increased concentration in local healthcare markets.66

Consolidation in Specific Healthcare Markets

While the evidence above demonstrates that some specific transactions have had anti-competitive consequences, it does not speak to general trends in the ownership structure of healthcare service providers. This section discusses research tracking various measures of concentration that differ from those used in antitrust analysis, generally calculating concentration in geographic areas that are broader than geographic markets consistent with antitrust standards, as well as explaining possible limitations with measures.67

Consequently, while these studies provide information about trends in changes of ownership of various types of healthcare providers, they do not reliably distinguish between concentration that may lessen competition and concentration that may be competitively benign.

Measures of Concentration

Industrial organization economists and antitrust practitioners have developed several market concentration indices. Two of the more common are the "four firm concentration ratio" (CR4) and the Herfindahl-Hirschman Index (HHI). The CR4 is the sum of the market shares of the four largest firms (as measured by market share), and the HHI is the sum of the squared share of each firm in the market, multiplied by 10,000. For example, a market with five firms each having a share of 20 percent would have a CR4 of 80 percent and an HHI of 2,000. A merger between any two of those five firms will yield a CR4 of 100 percent and an HHI of 2,800. The 2010 Department of Justice-

Federal Trade Commission Horizontal Merger Guidelines68 explain the HHI as a measure of market concentration for use in merger analysis. These guidelines generally classify markets with an HHI below 1,500 as unconcentrated and markets with an HHI exceeding 2,500 as highly concentrated. However, these thresholds apply only to well-defined antitrust markets, i.e., markets carefully defined to reflect the scope of both geographic and product/service competition that is relevant in antitrust analysis. HHIs calculated for broader geographic units, such as counties or metropolitan statistical areas (MSAs), may sometimes be informative, but considerable care is required in interpreting the results. HHIs calculated for larger geographic regions can both overstate and understate changes in the level of concentration in a relevant geographic market as it would be defined for purposes of antitrust analysis.69

Inpatient Hospital Industry

Much of the research into concentration in the healthcare sector has been focused on hospitals, largely due to data availability and the outsized role of hospitals in the healthcare system. Recent analysis suggests a noticeable shift during 2010-2016 in site of practice for primary care physicians into hospital systems, as well an increase in the number of hospital consolidations since 2009.70 One recent study by Gaynor et al.71 measured concentration in the hospital industry by calculating the HHI for each MSA in the United States. The study calculated concentration measures at the MSA level using each hospital system's share of admissions.72 It found that the mean HHI across MSAs in the inpatient hospital industry increased from 2,370 in 1987 to 3,261 in 2006—an increase of more than 900 points.73 It also found that most of this increase had occurred by the year 2000. The report found that the mean hospital HHI increased by an average of about 100 points per year over the period 1990-2000 but was largely flat over the period 2000-2006. It also found that the percentage of MSAs with an HHI that exceeded 2,500 increased from 65 percent in 1990 to 77 percent in 2006.

More recent work by Fulton measured hospital concentration over the period 2010-2016.75 Like Gaynor et al., Fulton calculated the HHI for inpatient hospitals within each MSA in the United States. He found that the mean HHI across MSAs increased from about 5,500 to about 5,786, an increase of 5.2 percent. This finding implies an average increase in the mean HHI of about 48 points per year. Fulton also reported that the percentage of MSAs with an HHI that exceeded 2,500 increased from about 87 percent in 2010 to 90 percent in 2016. The mean HHI of 5,500 in 2010 found by Fulton is substantially higher than the mean HHI of 3,261 in 2006 found earlier by Gaynor.76

Physician Services

More recently, researchers have been able to obtain data to study consolidation involving physician practices. Fulton calculated HHIs at the MSA level for primary care physicians and specialist physicians.77 He found a high degree of concentration at the MSA level for specialist physician services, but the increase over the period 2010-2016 was modest. The mean HHI across MSAs ranged from about 3,000 to about 3,400 over

the period. The mean HHI increased by about 5 percent over the period 2010-2016. This implies an average increase in the mean HHI of about 26 points per year. The percentage of MSAs with an HHI that exceeded 2,500 for specialist physicians increased from about 60 percent in 2010 to about 62 percent in 2016. Fulton also found that the levels of concentration for primary care physician services were much lower, but the increase over the period 2010-2016 was more substantial. The mean HHI for primary care services across MSAs ranged from about 1,700 to about 2,300 over the period 2010-2016, but increased by about 29 percent over this period. This implies an average increase in the mean HHI of about 87 points per year. The percentage of MSAs with an HHI greater than 2,500 for primary care physicians increased from about 21 percent in 2010 to about 35 percent in 2016.

Other research, while not examining trends in physician consolidation, also found higher concentration levels for specialist physicians than for primary care physicians. Kleiner examined shares by physician practice within specialty-specific geographic areas using 2009 patient-level Medicare data.79

Figure 3: Hospital Systems are Increasingly Acquiring Primary Care Practices78

The study found median two firm concentration ratios (CR2) across all areas of 33 percent for primary care services, but 58 percent for cardiology, 72 percent for oncology, 49 percent for orthopedics, and 57 percent for radiology. Similarly, it found a median HHI of 761 for primary care services, but 2,370 for cardiology, 3,606 for oncology, 1,751 for orthopedics, and 2,190 for radiology. These differences in concentration metrics between specialist physicians and primary care physicians may be due to higher barriers to entry faced by specialists.

Some of the consolidation in physician services might be due to the acquisition of physician practices by local hospitals, as opposed to mergers between physician practices. For example, in a market consisting of two hospitals and

ten physician practices, an acquisition of the ten practices by the two local hospitals would yield a significant increase in concentration in the market for physician services. Hospitals have increasingly been acquiring physician practices. One study reported that the share of physician practices in the United States owned by hospitals doubled over the period 2002- 2008.80 Another study examined the effect of the acquisition of physician practices by hospitals on prices and expenditures over the period 2007-2013.81 It reported that hospitals

acquired 10 percent of the physician practices in their sample during their sample period. In its 2013 Report to the Congress, the Medicare Payment Advisory Commission (MedPAC), an independent, non-partisan, Congressional support agency, similarly reported that while the number of physicians and dentists employed by hospitals was relatively constant from 1998 to 2003, it increased by 55 percent from 2003 to 2011.82 Another survey by the Medical Group Management Association found

a 75 percent increase in the employment of doctors by hospitals between 2000 and 2012.83 The overall effects of a hospital becoming the owner of a physician practice raise significant anti- competitive concerns, although in some cases they can produce pro-competitive effects.84

Need for Continued Vigilance

While the studies cited above do not definitively confirm that increased concentration has led to increased market power or increased payments, they do demonstrate a steady stream of transactions affecting the ownership of hospitals and physician services. Given the strong evidence of consumer harm from some transactions that have been shown to diminish competition, these concentration trends highlight the need for continued vigilance by the antitrust authorities to identify and prevent anti-competitive activity. Furthermore, in instances where markets have become concentrated due to a lawful accumulation of market power, elimination of regulatory barriers to entry can help to keep that in check, as will be discussed in the next section.

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

Government Healthcare Policies and Their Effects

Healthcare Workforce and Labor Markets

In competitive markets, suppliers of goods or services respond to market signals that suggest growing demand for the goods or services by increasing prices, which provides incentives to increase the supply of goods and services. Government policies that reduce the available supply of qualified healthcare service providers or the range of services they may safely offer can increase the prices paid for healthcare services, reduce access to care, and suppress the benefits of competition and innovation in healthcare delivery. Such regulations can also unnecessarily limit the types or locations of providers authorized to practice or the range of services they can provide.

Government rules restrict competition if they keep healthcare providers from practicing to the “top of their license”— i.e., to the full extent of their abilities, given their education, training, skills, and experience, consistent with the relevant standards of care. Such

rules, including restrictions on the appropriate use of telehealth technologies, unnecessarily limit the types or locations of providers authorized to practice, or the range of services they can provide, in contrast to regulations tailored to address specific and non-speculative health and safety concerns.

With respect to physicians in particular, certain policies relating to graduate medical education (GME), as well as significant restrictions on the ability of foreign-trained doctors to practice in the United States may also unnecessarily limit the supply of physicians available to provide care to Americans. Reduced competition among qualified physicians inevitably leads to higher prices for physician services and generally reduces the quality of care. Consistent with overarching patient health and safety concerns, the discussion below examines potential benefits of more flexible approaches to GME and the treatment of foreign-trained doctors that could increase physician supply and promote additional competition and consumer choice.

Scope of Practice

State licensing and scope-of-practice (SOP) restrictions are common components of state licensure statutes and regulatory codes for healthcare professions.85 Licensure regulates entry into an occupation since a worker must obtain the permission of a government agency or government-authorized regulatory board before providing certain services.86 For numerous healthcare occupations, a state licensing authority stipulates minimum education, training requirements, and certification, among other criteria, for those who seek to acquire or maintain a license to practice a given profession or provide certain services.87 SOP regulations "describe the metes-and-bounds of licensure—what a given professional license permits a person to do and, often, prohibits others from doing."88

SOP laws and regulations, like other health and safety regulations, may be justified when there are substantial risks of consumer harm.89 These regulations may be especially important with respect to certain healthcare professions, where consumers might be at risk of serious harm if they were treated by unqualified individuals, and where patients might find it difficult (if not impossible) to assess quality of care at the time of delivery.90 Still, even well-intentioned regulations may impose unnecessary restrictions on provider supply and, therefore, competition. Oftentimes, too, SOP restrictions limit provider entry and ability to practice in ways that do not address demonstrable or substantial risks to consumer health and safety.91 When this happens, these undue restrictions are likely to reduce healthcare competition and harm consumers—including patients, and taxpayers more generally.92

When state regulators impose excessive entry barriers and undue restrictions on SOP for particular types of providers, they often are not responding to legitimate consumer protection concerns. There is a risk that healthcare professionals with overlapping skill sets will seek these restrictions; they view SOP restrictions as an easy, state-sanctioned opportunity to insulate themselves from competition.93 The risk of anti-competitive harm

may be even greater when the regulatory board that imposes SOP restrictions on one occupation is controlled by members of another, overlapping occupation that provides complementary or substitute services,94 and the board members are themselves active market participants with a financial stake in the outcome.95

For example, advanced practice registered nurses (APRNs),96 physician assistants (PAs),97 pharmacists,98 optometrists, 99 and other highly trained professionals can safely and effectively provide some of the same healthcare services as physicians, in addition to providing complementary services. Similarly, dental therapists and dental hygienists can safely and effectively provide some services offered by dentists, as well as complementary services.100 SOP statutes and rules often unnecessarily limit the services these "allied health professionals"101 can offer. A 2011 Institute of Medicine (IOM) report surveyed "[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing the use of . . . APRNs in primary, chronic, and transitional care,"102 and expressed concern that SOP restrictions "have undermined the nursing profession's ability to provide and improve both general and advanced care."103 In fact, research suggests that allowing allied health professionals to practice to the full extent of their abilities is not a zero sum game for other medical professionals, and may actually improve overall health system capacity.104 The previously mentioned IOM report found that APRNs' scope of practice varies widely "for reasons that are related not to their ability, education or training, or safety concerns, but to **the political decisions of the state** in which they work."105

State decisions about scope of practice and reimbursement can also affect the development and utilization of allied health professionals, particularly in public programs. Private insurance has the flexibility to incentivize patients to find lower-cost, higher-quality provider alternatives when feasible. Public programs, more restricted by state regulations, can be less responsive to such changes in the healthcare workforce, even after scope of practice regulations accommodate them. Currently, for example, states vary widely in the degree to which they permit their Medicaid programs to reimburse allied health professionals directly for services. Services provided under the direct supervision of a physician are reimbursed as if the physician provided those services. State Medicaid programs can also pay for PA, nurse practitioner, and certified nurse midwife (CNM) services provided outside of a physician's office, but only if state scope-of-practice laws do not require onsite supervision by physicians. Some states allow allied health professionals to bill Medicaid directly, while other states require them to bill under the physician's number. For patients to realize the benefits of changes to state SOP restrictions, state Medicaid programs would need to reimburse allied health professionals independently for their services.

As noted by FTC staff, "when APRN access to the primary care market is restricted, healthcare consumers—patients and other payers—are denied some of the competitive benefits that APRNs, as additional primary care service providers, can offer."106 Slightly more than half the states require supervision and "collaborative practice"

requirements, which can operate as de facto supervision requirements. These are a particular source of concern to the extent that they raise the cost of APRN-provided services.107 In addition, rigid “collaborative practice agreement” requirements can impede collaborative care rather than foster it because they limit the ability of healthcare professionals to adapt to varied healthcare demands, thereby constraining provider innovation in team-based care.108 Economic analysis indicates that expanding APRN SOP, consistent with APRN education, training, and experience, would have clear consumer benefits, particularly in rural and poorer areas:

In underserved areas and for underserved populations, the benefits of expanding supply are clear: Consumers will have access to services that were otherwise unavailable. Even in well-served areas, the supply expansion will tend to lower prices for any given level of demand, thus lowering healthcare costs.109

Similar concerns about the competitive impact of supervision and “collaborative practice” requirements can apply to other healthcare occupations. Even when some form of collaboration or supervision might be desirable, particular requirements might be unnecessary, over-rigid, and costly barriers to the efficient delivery of healthcare services.110

Extremely rigid collaborative practice agreements and other burdensome forms of physician and dentist supervision are generally not justified by legitimate health and safety concerns. Thus, many states have granted full practice authority to APRNs, but there is significant room for improvement in other states and for other professions.111 Emerging healthcare occupations, such as dental therapy, can increase access and drive down costs for consumers, while still ensuring safe care. States should be particularly wary of undue statutory and regulatory impediments to the development of such new occupations.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.

- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Workforce Mobility

State-based licensing requirements, by their nature, inhibit provider mobility.112 These requirements add time and expense when healthcare providers seek to move or work across state lines. Markets cannot be as responsive to economic change when workers cannot easily move to meet the demand for their services.113

State-based licensing also often inhibits delivery of healthcare services across state lines by making it more difficult for qualified healthcare professionals licensed in one state to work in another state, even though most healthcare providers complete nationally certified education and training programs and sit for national qualifying exams.114 Appropriate standards of care do not differ from state to state. Yet, even when a profession's underlying standards are national in scope, and when state licensing requirements are similar throughout the United States, the process of obtaining a license in another state is often slow, burdensome, and costly.115 There is little economic justification for the redundant licensing processes that many states impose on licensed, out-of-state applicants. Even when there may be plausible consumer-protection concerns, the harm to consumers likely outweighs any benefits.116

The effects of state-based licensing are especially apparent in fields where providers routinely communicate electronically and provide services in multiple states. For this reason, state-based licensing requirements can inhibit the efficient development and use of telehealth (discussed below), as well as in-person services.117

Interstate compacts and model laws can mitigate the effects of state-based licensing requirements by enhancing license portability. Professional associations and associations of licensing boards typically draft model laws, which may be passed with minor variations between jurisdictions. Almost all states and other United States jurisdictions have adopted model laws with license portability provisions in other professions such as accountancy and pharmacy.118 By contrast, interstate compacts, which are binding contracts between two or more states authorized by the United States Constitution, must be identical and have been used only recently to improve licensure portability.119 The first interstate licensure compact, on nurse licensure, was initially implemented in 1999 and has been adopted by 30 states.120 Other licensure compacts in the health professions are in the early stages of implementation.121 Federal grants to state professional licensing boards have encouraged the development and implementation of various licensure compacts in several professions.122

Model laws and interstate compacts typically use one of two approaches to enhance licensure portability. One is reciprocity as practitioners licensed by one state are able to practice in other states without obtaining another license. Second, some states require a license in each state of practice but expedite the process.123 By making it easier to practice in multiple states, interstate compacts and model laws can enhance access to healthcare services and improve provider mobility.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.
- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Telehealth

Telehealth, the use of telecommunications to provide healthcare services, has been hailed as a significant innovation in healthcare delivery.124 It encompasses a broad variety of services and technologies, and is particularly effective when it replicates in-person care, speeds input from knowledgeable practitioners, provides information more frequently than would be possible with in-person visits, or involves conditions that can be evaluated from digital images. Examples of healthcare services that may be provided by telehealth include mental health services,125 dermatology,126 ophthalmology,127 specialist-to-provider consultations in neurology and pathology,128 and direct-to-consumer services for minor conditions.129

Telehealth often increases the virtual supply of providers and extends their reach to new locations, promoting beneficial competition. By doing so, telehealth can enhance price and non-price competition, reduce transportation expenditures, and improve access to quality care.130 Indeed, telehealth has great potential to improve access in underserved locations, reduce costs, and generate improved short- and long-term health outcomes.131

Nonetheless, a variety of regulatory barriers have kept telehealth from reaching its full potential to increase competition and access. State laws and regulations typically require that providers be licensed in the state where the patient is located, thus restricting the provision of telehealth services across state lines.132 State licensing requirements and variations in scope of practice are barriers for even well-established and natural telehealth services, such as mental and behavioral healthcare.133 Public

and private reimbursement laws and policies are also frequently cited as major impediments to the development and use of telehealth services.134 For example, Medicare fee-for-service pays for telehealth services only when patients are located at certain types of healthcare facilities ("originating sites")135 in rural areas with a shortage of health professionals.136 Another barrier is that states may require practitioners to have first provided services in person before caring for a patient by telehealth.137

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of state licensure standards and approaches to telehealth.
- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.
- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Foreign-Trained Doctors

The United States has the highest physician salaries in the world, with per-capita physician spending significantly higher than in other countries and making up about a fifth of overall healthcare spending.138 Increasing the supply of goods or services in any market is generally the best approach to lowering prices, and physician services are no exception. Expanding domestic education and training opportunities—including the opening of new medical schools is a priority—efforts should be made to reduce the

burdens on highly skilled, fully trained, foreign medical doctors looking to practice in the United States. Currently, any physician trained outside the United States or Canada must obtain an Educational Commission for Foreign Medical Graduates (ECFMG) certification, complete a United States residency program, and apply for a state license.139 140 This process is expensive (exams can cost up to $15,000). In the interim, easing the licensing pathway for highly qualified, foreign-trained doctors is one step that could be taken in the short-run to expand the supply of medical practitioners and thus constrain the price of physician services and lower overall healthcare costs for American consumers.

While increasing the supply of high-skilled, domestically trained United States medical professionals might help to constrain salaries for specialty physicians, facilitating the entry of additional foreign-trained doctors would be particularly helpful in alleviating the country's shortage of primary care physicians (PCPs). On average, PCPs earn 46 percent less than medical specialists. Because American medical school students graduate with an average of $180,000 of debt, many of them pursue higher paid specialties rather than the much needed primary-care fields.141 While forecasts are often inaccurate, it is projected that by 2025, the United States will face a shortage of between 14,900 and 35,600 PCPs.142 Foreign-trained doctors have already helped meet this growing need—over 40 percent of current American PCPs were trained abroad; however, if it were easier for foreign-trained doctors to enter the United States marketplace, this percentage would likely rise.143

Highly skilled, foreign-trained doctors could also be encouraged to practice in underserved regions of the country, where Americans often are unwilling to practice. For example, under the Conrad 30 Waiver Program, foreign-trained doctors can receive sponsorship to work in the United States if they commit to spend at least three years in an underserved region.144 Over the past decade, this program has attracted more than 10,000 foreign-trained doctors to practice in areas faced with physician shortages.145

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted "residency waivers," allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign- trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Federal Funding of Medical Education

Spending on physician services comprises approximately 20 percent of all healthcare expenditures in the United States, and prices for physician services tend to be substantially higher in the U.S. than in other wealthy countries.146 As mentioned above, one option to reduce prices is to increase the supply of physicians. Physician supply in the United States, measured as physicians per 1,000 population, is well below the OECD median and is lower than 8 of 10 other OECD countries.147 Unlike many other professions, in which market forces determine supply, the number of persons trained to be physicians is limited by organizations that are themselves often run by physicians, which creates natural conflict- of-interest concerns and raises questions concerning cartel-style rent seeking. Some barriers to entry in the physician sector (such as extensive educational, training and testing requirements, including state licensing and specialty board certification), may be justified to ensure professional competence. Nonetheless, this does not warrant non-market-based limits placed on the number of persons seeking to enter the medical field. Medical schools admit only a fraction of applicants, with many qualified individuals unable to enter due to the sharply limited spaces available.

Not only is the supply of potential physician practitioners limited, federal policy currently subsidizes medical training for an artificially low number of persons. The Department of Education administers loan programs that are available to medical school students, including private loans guaranteed by the federal government and direct loans from the

federal government through the students' schools. The Health Resources and Services Administration (HRSA), part of HHS, administers National Health Service Corps (NHSC) scholarships and loan repayment programs for health professionals who commit to practice in underserved areas and to train in primary care. An even larger amount of federal support is directed toward Graduate Medical Education (GME)—residency and fellowship programs that provide further training for medical school graduates. As of 2015, federal taxpayers paid $287 million to support the NHSC, $10.3 billion for Medicare GME, and

$2.4 billion for Medicaid GME, and $265 million for the Children's Hospital Graduate Medical Education Payment Program.148 Medical education is costly, but its estimated rate of financial return is high and clearly sufficient to entice many qualified individuals to seek admission to medical school. Current subsidies of medical education are generally regressive by reducing the cost to the very persons who can expect high financial returns to their valuable education and training.

The Structure of Medical Education

Medical education in the United States generally consists of four years of college education, followed by four years of medical school (undergraduate medical education), followed by graduate medical education (GME) consisting of three to six years of

residency training in a medical specialty that is sometimes followed by a year or more of additional fellowship training. Medical school graduates must complete at least a year of residency training (often called an internship), depending on the state, to be licensed.

Medical students attend either allopathic medical schools (granting M.D. degrees) or osteopathic schools of medicine (granting D.O. degrees). The Liaison Committee on Medical Education (LCME), jointly sponsored by the Association of American Medical Colleges (AAMC) and the American Medical Association (AMA), is the United States Department of Education's recognized body for accrediting allopathic medical schools.149 The American Osteopathic Association's (AOA) Commission on Osteopathic College Accreditation accredits osteopathic schools. In 2017-2018 there were 118,885 United States medical students including 46,315 men and 43,571 women at allopathic schools150 and 15,904 men and 13,076 women at osteopathic schools.151 Residents and fellows train at programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) or programs jointly accredited by the ACGME and the AOA. The Department

of Veterans Affairs, through affiliation agreements with medical schools and teaching hospitals, is the largest single provider of medical training in the United States, providing the site of training for medical students, residents and a small number of fellows.152

To receive postgraduate training medical students must participate in a "match" process that determines where they receive residency training. This process is administered by the National Resident Matching Program that is sponsored in part by the AAMC. Applicants and training programs both submit rank-ordered preference lists, and then an algorithm matches applicants to programs to produce stable matchings as favorable as possible to

applicants.153 In 2004—in response to a lawsuit alleging that operating the match and

accrediting residency programs was anti-competitive and violated the anti-trust statutes by limiting the number of residency positions and driving down resident choices and salaries—Congress granted the matching program an anti-trust exemption.154

Graduate Medical Education (GME) Funding

Funding for GME subsidizes training for medical school graduates in hospitals and other teaching institutions in what are commonly known as residency and fellowship training programs. In 2015, federal agencies and state Medicaid programs provided $16.3 billion to support GME. Five federal agencies (see Table 1) spent $14.5 billion with the bulk of federal funding coming through Medicare (71 percent), Medicaid (16 percent), and the VA (10 percent); 45 state Medicaid agencies spent an additional $1.8 billion on GME.155

About 30 percent of Medicare GME spending is for direct graduate medical education (DGME) to pay the salaries of residents and supervising physicians. Another 70 percent

goes for indirect medical education (IME) to provide funding to hospitals that run training programs.156 DGME payments are based on a per-resident amount and the number of full- time-equivalent (FTE) residents. IME Medicare payments are an add-on to the predetermined amount paid under the inpatient prospective payment system for each discharge with an adjustment for the number of FTE residents per hospital bed to represent the incremental care costs of providing GME training. DGME payments are also adjusted for the share of hospitals' patients covered by Medicare. The Balanced Budget Amendment of 1997 capped the number of FTE residents that programs may count for DGME and IME payment at the number of FTE residents working at the end of 1996.157

While GME programs undoubtedly generate indirect costs, they also produce benefits for teaching institutions. Residents are an inexpensive source of labor. They work longer, more irregular hours than more experienced health professionals. They also increase attending

physicians' productivity by enabling them to increase the amount of patient services they can perform and for which they can bill.158

The Medicare Payment Advisory Commission (MedPAC), an independent agency that advises Congress about Medicare, estimates that indirect graduate medical education payments are at least twice as high as actual costs, exceeding actual costs by $3.5 billion each year.159 Similarly, an HHS-sponsored study found that Medicare is overpaying for IME costs.160 Some residency programs generate profits for hospitals. Hospitals value residency programs enough that they self-finance 12,000 residency positions.161

The current number of first year residency positions (30,232) exceeds the number of American medical school graduates (18,818 allopathic graduates and 4,617 osteopathic graduates) applying for them. The balance of positions are largely filled with foreign-born or U.S. citizen graduates of foreign medical schools, or in some cases, they go unfilled.162

Physician Supply in the United States

There is likely an inadequate supply of physicians in the United States. Moreover, there is an uneven distribution in physician supply (both geographically and across specialties), GME training slots, and in government support for GME.163 Yet there is inadequate information to assess overall physician needs, and for different specialties in different geographic areas.164 GME slots are currently determined by the industry accrediting bodies and the hospitals or medical schools themselves. Similarly, medical school positions are accredited by physician industry groups.

These findings suggest several areas for policy research and potential change. First, as requested in the FY 2019 President's Budget, the federal government should more efficiently spend taxpayer resources by streamlining federal Health and Human

Services spending on graduate medical education into a single graduate medical education grant program. Under this Budget proposal, total funds available for graduate medical education in FY 2019 would equal the sum of Medicare's 2016 payments for DGME and IME, Medicaid's 2016 payments for GME, and the Children's Hospital GME Payment Program, adjusted for inflation. This amount would increase annually with inflation as measured by the consumer price index for all urban consumers (CPI-U) minus one percentage point per year. The new grant program would be funded out of the Treasury and jointly operated by the administrators of CMS and HRSA. This proposal is estimated to save $48.1 billion between 2019 and 2028. The Budget proposal also provides the HHS Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities. This flexibility will allow the federal government to more effectively target funding to those hospitals that are committed to building a strong medical workforce and to addressing medically underserved communities and health professional shortages.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President's Budget, the federal government should streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities.
- The administration should continue the work done by the HRSA's National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
    - The administration's workforce development programs.
    - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Healthcare Provider Markets

Certificate of Need (CON) Requirements

State "certificate-of-need" ("CON") laws require healthcare providers to obtain permission from a state (or state-authorized) agency to construct new healthcare facilities, expand existing ones, or offer certain healthcare services.165 States initially

adopted CON laws to further laudable policy goals, including cost control and access to care. The evidence to date, however, suggests that CON laws are frequently costly barriers to entry for healthcare providers rather than successful tools for controlling costs or improving healthcare quality. Based on that evidence and their enforcement experience, the two federal antitrust agencies–the FTC and the Antitrust Division of the Justice Department—have long suggested that states should repeal or retrench their CON laws.166

Most states adopted CON programs in response to a since-repealed federal mandate, the National Health Planning and Resources Development Act of 1974,167 which offered the states powerful incentives to adopt CON programs.168 CON programs were supposed to control healthcare costs and mitigate incentives for an arms race in healthcare spending fostered by cost-based healthcare reimbursement systems.169 Although both public and commercial reimbursement systems have changed significantly over time, many states have maintained substantial CON requirements. Congress repealed the 1974 Development Act in 1986, and a number of states have since repealed or revised their CON laws.170

Fifteen states have eliminated their CON requirements altogether.171 Although most other states maintain CON programs,172 some remaining CON laws address only specific types of healthcare facilities (such as hospitals or nursing homes),173 exempt certain types of healthcare facilities,174 or apply only to facilities of a certain size.175 Some CON laws are subject to sunset provisions.176

CON proponents continue to raise cost control as a justification for CON programs; they also argue that CON laws improve the quality of healthcare services and assure access to healthcare services by disadvantaged citizens. However, available evidence suggests that CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved communities or in underserved areas.

CON Laws Impose Costs, Including Loss of Beneficial Competition

Empirical evidence on competition in healthcare markets generally demonstrates that consumers benefit from lower prices when provider markets are more competitive.177 Scrutiny of hospital mergers by the FTC and the Antitrust Division has been particularly useful in understanding concentrated provider markets, and retrospective studies of the effects of provider consolidation by agency staff and independent scholars suggest that

> “increases in hospital market concentration lead to increases in the price of hospital care.”178

FTC and Antitrust Division staff have examined the competitive impact of CON laws for several decades. For example, staff from the FTC’s Bureau of Economics conducted several studies of CON laws in the late 1980s, both before and after repeal of the federal law that had encouraged their adoption.179 In addition, the agencies jointly

conducted 27 days of hearings on healthcare competition matters in 2003, receiving testimony about CON laws and market entry, hospital provider concentration, and other pertinent aspects of healthcare competition;180 they jointly released a substantial report on healthcare competition issues, including those related to CON laws, in 2004.181 Finally, through their competition advocacy programs, the Agencies have reviewed numerous state CON laws and encouraged states to consider the competitive impact of those laws.182

The best empirical evidence suggests that greater competition incentivizes providers to become more efficient. Recent work shows that hospitals faced with a more competitive environment have better management practices.183 Consistent with this is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of healthcare.184 Studies have found no empirical evidence that CON laws have restricted "over-investment."185 However, CON laws can restrict investments that would benefit consumers and lower costs in the long term and are likely to increase, rather than constrain, healthcare costs. This is because CON regimes impose the legal and regulatory costs of preparing an application, then seeing that application through an often-lengthy approval process and potential third-party challenges.186 As a result, healthcare providers must spend resources on administrative processes rather than on constructing healthcare facilities or delivering healthcare services. In addition, those regulatory costs can be a barrier to entry, discouraging some would-be providers from entering certain healthcare markets, and discouraging some incumbent providers from expanding or innovating in ways that would make business sense but for the costs of the CON system. Even for providers willing to bear those regulatory costs, CON requirements may be hard barriers to entry if their applications are denied. Hence, CON laws can diminish the supply of healthcare facilities and services while exacerbating concentration in provider markets.

CON Laws Have Not Improved Healthcare Quality or Access

CON proponents have argued that CON laws support policy goals relating to healthcare quality and access. However, CON laws would be an indirect—and likely inefficient—way to achieve these goals. Moreover, the evidence suggests CON laws are ineffective. There is no compelling evidence suggesting that CON laws improve quality or access, inefficiently or otherwise.

Quality-based arguments on behalf of CON laws typically refer to evidence on volume/outcome relationships (i.e., the extent to which quality of care is related to how often a particular healthcare institution or provider performs a given procedure), rather than direct evidence of CON laws' impact on care quality. Even this volume/outcome evidence is mixed. Pronounced effects may be limited to certain relatively complicated procedures;187 and even there, where certain studies have shown a volume/outcome relationship (e.g., coronary artery bypass graft surgery188), evidence suggests that volume effects may not offset CON laws' larger negative impact on

quality.189 Studies that directly analyze the impact of changes in CON laws on health outcomes provide a more complete picture; the weight of that research has found that repealing or narrowing CON laws is generally unlikely to lower quality of care, and may improve the quality of certain types of care.190 Moreover, CON programs can tend to foster or sustain undue provider concentration; and additional empirical evidence suggests that, "[a]t least for some procedures, hospital concentration reduces quality."191

Evidence also fails to support the claim that CON programs would increase access to care for the indigent, or in medically underserved areas. The general argument has been that CON laws, by limiting competition, allow incumbent healthcare providers to earn greater profits—by charging higher prices and preserving their volume of lucrative procedures— than they would earn in a competitive environment. It is posited that those extra profits will be used to cross-subsidize care for the underserved. There are inherent weaknesses in this supposition. First, the charity-care rationale is at odds with the cost-control rationale. The notion that CON-protected incumbents would use their market power and profits to cross- subsidize charity care presumes that those providers will charge supra-competitive prices for non-charity care. Such supra-competitive pricing might harm many healthcare consumers, including low-income or under-insured patients who are ineligible for charity care. Second, because CON programs impede entry, expansion, and innovation, they can impede access to care for all patients, including low-income patients. Finally, the evidence does not show that CON laws promote charity care. Research suggests that safety-net hospitals are no stronger financially in CON states than in non-CON states.192 There is also empirical evidence contradicting the notion that dominant providers use their market power to cross-subsidize charity care, including an empirical study of the relationship between competition and charity care that found a "complete lack of support for the 'cross-subsidization hypothesis.'"193

CON Laws Can Foster Competition Problems Missed By Benefit/Cost Analysis

Not only may CON laws impose costly barriers to provider entry, but by interfering with market forces that normally determine the supply of facilities and services, they can suppress supply, misallocate resources, and shield incumbent healthcare providers from competition from new entrants.194 In addition, incumbent firms may use CON laws to thwart or delay entry or expansion by new or existing competitors.195 CON programs have also facilitated anti-competitive agreements among competitors. For example, in 2006, a hospital in Charleston, West Virginia, used the threat of objection during the CON process to keep a potentially competitive hospital from expanding.196

Finally, as illustrated by the FTC's experience in the *Phoebe Putney* case, CON laws can entrench anti-competitive mergers by limiting the government's ability to implement effective structural remedies to consummated transactions. *Phoebe Putney* involved a challenge to the merger of two hospitals in Albany, Georgia.197 Seeking a preliminary

injunction in federal court, the FTC alleged that the merger would create a monopoly of inpatient general acute care hospital services sold to commercial health plans in Albany and surrounding areas. The district court dismissed the suit, finding that the merger was protected from antitrust scrutiny by the "state action doctrine."198 The United States Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal on state action grounds, although finding that "the joint operation of [the two hospitals] would substantially lessen competition or tend to create, if not create, a monopoly."199 The Supreme Court reversed this decision, unanimously holding that "state action immunity" did not apply.200 However, the merging parties already had consummated the transaction while appeals were pending, and Georgia's CON regime precluded structural relief for the anticompetitive merger.201 As the Commission explained, "[W]hile [divestiture] would have been the most appropriate and effective remedy to restore the lost competition in Albany and the surrounding six-county area from this merger to monopoly, Georgia's [CON] laws and regulations unfortunately render a divestiture in this case virtually impossible."202

Certificates of Public Advantage

Certificate-of-public-advantage (COPA) regulations allow healthcare providers to enter into cooperative agreements that might otherwise be subject to antitrust scrutiny and can cover a wide range of provider collaboration and merger activity.203 COPA schemes displace competition in favor of state regulatory oversight and may, under the state action doctrine, immunize provider activity for conduct that might otherwise violate federal antitrust laws.204 Typically, states have the authority to approve COPA proposals if they determine that the likely benefits of the cooperative agreement outweigh any disadvantages attributable to a reduction in competition.205 In practical terms, COPAs significantly limit the ability of antitrust enforcement agencies to challenge collaborations and mergers that create or enhance provider market power, and therefore are likely to harm consumers.206

Moreover, COPA review and oversight frequently are subject to the influence of special interests through state political processes.

As a condition for COPA approval, states often impose terms and conditions on the COPA recipient intended to mitigate the potential for anti-competitive harms. Such regimes may include rate regulation, prohibitions on certain contracting practices, and commitments to improve quality or return cost savings to the local community. These types of regulatory conditions are often difficult to implement and monitor and may not accomplish intended goals. In addition, some states that have approved COPA schemes have later repealed or revised the COPA statutes allowing them, effectively terminating the state regulatory oversight that was supposed to constrain the exercise of market power and potentially empowering an unrestrained monopolist.207 For these reasons, the FTC has raised concerns that COPAs may create or enhance provider

market power without offering sufficient mechanisms for mitigating potential harms to competition and consumers.208

As discussed in Section 1, compelling empirical research suggests that market-based competition among healthcare providers yields positive results for consumers such as reduced prices and improved quality of care. Conversely, there is limited empirical research regarding the impact of COPA regulations. For this reason, FTC staff are currently assessing the potential benefits and disadvantages of COPAs and recently issued a notice requesting empirical research and public comments on these issues.209

The antitrust laws are intended to achieve the goals of reduced prices, improved quality, and greater innovation and access for healthcare services and not prevent procompetitive provider collaborations that would generate efficiencies and benefit consumers.210 COPAs that immunize otherwise anti-competitive collaborations and mergers from antitrust scrutiny pose a substantial risk of consumer harm.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example by ensuring that competitors of CON applicants cannot weigh in on these applications.
- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the benefits and disadvantages of CON and COPA statutes and regimes.
- States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Nonprofit Exemption from Federal Trade Commission Jurisdiction

Currently, the FTC Act limits the FTC's jurisdiction over nonprofits. The FTC Act applies to "persons, partnerships, or corporations,"211 and the act defines "corporation" as an entity that "is organized to carry on business for its own profit or that of its members."212 In healthcare provider markets, where the FTC has particular expertise, the inability to regulate conduct by various nonprofit entities has prevented the agency from taking action

against potentially anti-competitive behavior of nonprofits engaged in business.213 Economic research suggests that antitrust law and policy could yield significant efficiency gains for nonprofit firms; therefore, the promotion of competition for both nonprofit and for-profit organizations would yield significant social value.214 The FTC

has jurisdiction over nonprofit entities for purposes of the Clayton Act, most notably Section 7, which prohibits mergers or acquisitions where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."215 The FTC has accordingly challenged a number of healthcare mergers involving a nonprofit entity,216 and courts generally recognize that the nonprofit status of a healthcare provider does not mitigate the potential for anti-competitive harm arising from the merger.217

Nonetheless, the jurisdictional limitation contained in the FTC Act creates an arbitrary and inefficient burden on the FTC's ability to enforce the antitrust laws to prevent anti-competitive conduct by certain nonprofit entities. For example, nonprofit healthcare entities may structure an affiliation that has the economic effect of a merger but is technically an agreement between competitors—thus subject to Section one of the Sherman Act rather than a merger subject to the Clayton Act. Similarly, while investigating a merger involving nonprofit healthcare providers, FTC staff may discover an anti-competitive agreement subject to the Sherman Act. In both instances, because the FTC's ability to enforce the Sherman Act through the FTC Act is limited to for-profit corporations, the FTC would have to refer these cases to the Antitrust Division at Justice, which has direct authority to enforce the Sherman Act without the limitations related to nonprofit entities.218 This referral process serves no public interest objective, but prevents the federal government from making the best use of the FTC's valuable institutional knowledge and experience. Removing the nonprofit limitation from the FTC Act would streamline the competition investigation and enforcement process.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Employment Agreement Non-Compete Clauses

Non-compete clauses were first found to be anti-competitive in 1414.219 Legal scholars suggest that the point of these clauses was "shoring up the crumbling values of the medieval economic system against enterprising master craftsmen," aka entrepreneurs. These clauses can have dramatic economic consequences: California's public policy against enforcement of non-compete clauses, for example, is credited with fostering Silicon's Valley's rapid growth and innovation, outpacing the rival high-tech district around Boston.220

In the healthcare industry, some hospitals and physician groups continue to use these restrictive covenants to limit providers from practicing, typically in a certain geographical area for a given period after the provider leaves employment of the contracting hospital or physician group.221 A survey of physicians found that roughly 45 percent of

physicians in group practices were bound by non-compete agreements.222 The AMA suggests that these contracts may disrupt competition and the continuity of care, and could constrain a patient's choice of provider. However, recent empirical analysis found evidence consistent with these agreements being used to prevent patients from being poached by departing doctors.223

At least one case has viewed a non-compete clause in the healthcare industry with skepticism. The Tennessee Supreme Court opined on a non-compete clause between a physician and a private medical practice that had employed him in the 2005 case Murfreesboro Medical Clinic (MMC) v. David Udom.*224* Here, the court ruled that certain provisions in non-compete clauses can be harmful to public policy and therefore unenforceable. The court indicated that the non-compete clause in question had been too broad and was not based on the extent to which MMC would compete with a provider (in this case, David Udom).

While there is not a large body of case law on non-compete clauses in the healthcare industry, cases in other industries also suggest that non-compete clauses that are unreasonable in scope and duration may not be enforceable. The enforceability of non-compete clauses, including those clauses and contractual provisions related to healthcare, is typically an issue of state law.

Legal experts have suggested that a non-compete clause may be defensible where it is reasonable in scope and duration and necessary to protect against a former employee who had access to trade secret information or closely-guarded customer relationships injuring a business by utilizing that information or those customer relationships upon leaving.225,226 Employers that invest in substantial training for their provider employees might also seek to protect the investment that they make in their human capital. However, it is not clear that healthcare industry non-compete clauses are always proportionate to or even based on these concerns. In fact, other experts suggest that these clauses reduce bargaining power for employees because they reduce worker mobility.227

Various reports on non-compete clauses have also suggested that they are overly burdensome and restrictive on providers. Further scrutiny of these and other restrictive covenants is warranted, particularly where they impede patient access to care and limit the supply of providers. By suppressing competition, these clauses may inflate healthcare prices, elevating patient and federal spending on healthcare goods and services.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Health Insurance Markets

"Any-Willing-Provider" (AWP) Laws

"Any-willing-provider" (AWP) laws, like related "freedom of choice" (FOC) laws, are restrictions on certain types of selective contracting practices by health plans or pharmacy benefit plans. AWP laws require plan sponsors—or sometimes intermediaries, such as pharmacy benefit managers (PBMs)—to contract with any healthcare provider willing to meet the terms of participation in that plan's network agreements.228 FOC laws permit plan beneficiaries (or enrollees) to choose their providers, regardless of whether a chosen provider is part of their plan's network.229 Research suggests that AWP (and, perhaps to a lesser extent, FOC) laws can suppress pro-competitive forms of health and pharmacy benefit plan contracting.230

Basic economic theory suggests that a buyer can obtain a negotiating advantage by contracting selectively with a subset of providers, or at least having a credible option to do so, because providers will compete aggressively to be included. For that reason, health plans and pharmacy benefit plans often seek to employ some form of selective contracting, entering into agreements with limited networks of providers. Commonly, plans also offer tiered benefits to incent the use of lower-cost (or otherwise more efficient) providers, services, or prescription drugs by plan beneficiaries.231 Incentives to use a preferred tier may include (a) lower copayments, (b) lower co-insurance percentages, or (c) lower deductibles.232 In effect, such tools differentiate the out-of-pocket prices associated with different providers, services, or drugs—tier by tier—for the beneficiaries of plans that employ tiering.233

Selective contracting and tiered benefits are not always efficiency-enhancing or procompetitive. They can also limit consumer choice. To guard against such concerns and potential conflicts of interest,234 some states have enacted AWP or FOC laws, but, as will be explained below, these rules raise their own set of issues.

Medicare includes a type of AWP restriction—an "any willing pharmacy" provision—while also permitting selective contracting and tiered benefits. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 173, 117 Stat. 2066, requires that Medicare part D plans "permit the participation of any pharmacy that meets the terms and conditions under the plan," but permits them to, "notwithstanding… [that requirement] reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required." That is, part D plans cannot wholly exclude participation by "willing" pharmacies but can engage in tiering—a form of selective contracting (and selective benefits).235 In 2018, the Centers for Medicare and Medicaid Services clarified the Part D AWP rules and their expectations regarding statutorily required AWP provisions, including the ability of plans to maintain preferred networks. CMS's intent was "to ensure that Part D plan sponsors could continue to develop and maintain preferred networks while complying with the any willing pharmacy requirement, which applies to standard terms and conditions."236

AWP Laws are Costly Restraints on Plan Contracting

Although limited or “narrow” networks may limit patient choice and are not necessarily efficiency-enhancing or procompetitive, empirical evidence suggests that AWP and FOC laws broadening networks can make it more difficult for health insurers, health plans, or PBMs to negotiate discounts from providers, and that these laws tend to result in higher costs. Evidence also suggests that selective contracting—which AWP laws constrain— tends to lower healthcare costs and expenditures.237

Empirical Evidence on AWP

Several studies have analyzed state-by-state policy variation to measure the effects of AWP laws, finding that such laws undercut negotiating strategies whereby providers compete for inclusion in a network or a preferred tier. For example, one recent study examined state- level per capita health expenditure data from 1991-2009 and associated

AWP laws with approximately 5 percent higher per-capita drug expenditures.238 A 2009 study similarly examined variations in state AWP laws applicable to drug purchases. It found that AWP states have higher prescription drug spending than states without AWP laws. The conclusion was the same, even when using different econometric techniques to control for variations across the states, such as differences in demographics, market structure, and regulatory environment.239 An earlier study, looking at both the imposition and relative stringency of health plan AWP laws, found that AWP laws generally undermine the ability of managed care organizations to lower healthcare spending by extracting discounts in return for inclusion in a limited network. Specifically, the study found that per capita total healthcare expenditures are higher in states with relatively strong AWP laws, observing an impact on both hospital and physician expenditures.240

Empirical research on these laws has focused on the impacts on costs, not prices.241 A 2005 Maryland study, however, examined the impact of AWP/FOC types of restrictions on mail- order provision of, for example, maintenance drugs. The Maryland report estimated that greater use of mail-order maintenance drugs—enabled by liberalizing Maryland insurance law—would save Maryland consumers 2-to-6 percent on retail drug purchases overall, with 5-to-10 percent savings for third-party carriers.242

Empirical Evidence on Selective Contracting

Related research has examined the effect of selective contracting, more generally, in connection with healthcare provider markets. For example, a study of limited network health plans in Massachusetts found that large premium differences between broad and limited network plans were driven by real reductions in spending by those beneficiaries who switched from broad to narrow network plans; the study did not find reduced access to care or any adverse impact on beneficiary health.243 An earlier study of Massachusetts health plans, based on different data sources, also found savings

associated with selective contracting.244 Another study concluded that Connecticut health plans' ability to negotiate discounts with hospitals increased with a plan's willingness and/or ability to channel patients to selected hospitals, consistent with the predictions of a theoretical model introduced in the same study.245 These studies show that buyers in health insurance markets can and do use selective contracting, harnessing the benefits of competition to negotiate lower prices.

More recently, CMS released two studies analyzing prescription drug data from March 2012 for Medicare Part D plans.246 In both studies, CMS found substantial savings on average associated with preferred pharmacies and mail-order pharmacies. It has been noted that those CMS studies do not control for product mix, which can vary substantially across types of pharmacies.247 Acknowledging that limitation, the findings are generally consistent with the independent research on selective contracting discussed above.248

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Network Adequacy Requirements

Due to increased federal regulation of insurance through the ACA, premiums and deductibles have soared, forcing insurers to narrow provider networks to temper those prices. In 2017, 9 percent of firms with at least 200 employees offered their employees a health plan with a narrow network that included fewer providers than a typical Health Maintenance Organization,249 an increase of 2 percentage points from 2016.250 Among ACA-compliant individual market health plans offered on exchanges in 2016, nearly one- third had fewer than 25 percent of physicians within their service area participating as in- network providers.251

Narrow network plans bolster competition among hospitals and physician groups vying to be included in networks to secure patient volume. Furthermore, narrow network plans offer lower premiums relative to broader network plans.252 This feature is particularly beneficial to lower-income consumers, who tend to be extremely price sensitive,253 suggesting they are more interested in the size of the premium relative to the breadth of the provider network.

A potential concern regarding narrow networks is that enrollees may not have adequate choice or access to providers. Networks may lack the capacity to serve all enrollees within a health plan or lack specific specialists, leading some enrollees with only the option of more expensive care from out-of-network providers.254 These issues pertain to private insurance (group and individual markets) as well as Medicaid managed care and Medicare Advantage plans, where insurers generally contract with a limited number

of providers. This discussion applies generally to issues across these markets except where noted.

Regulations, primarily through state authority, have attempted to achieve network adequacy by requiring health plans to show sufficient capacity and access, often defined by quantitative standards (e.g., physician-to-enrollee ratios, distance, and wait times). For example, CMS requires states to develop standards for travel time and distance from enrollees' homes to providers to regulate Medicaid managed care plans. In private markets, states are primarily responsible for the enforcement of network adequacy standards. CMS's 2017 market stabilization final rule relieved burden on issuers by relying on states to regulate network adequacy for qualified health plans in the individual and small-group markets. Across states, there is substantial variation in the number and types of network adequacy measures used.

Impact on Competition and Choice

Measures used to determine network adequacy may not align with a network's ability to meet enrollees' preferences, may discourage innovative ways to meet those preferences, and may ultimately limit consumers' choices. For example, using proximity measures to regulate network adequacy may discourage insurers and providers from developing telemedicine capabilities255 or utilizing regional or national centers of excellence outside the residency area.256 Relying on current measures may also restrict entry into the insurance market by insurers with innovative plan designs. For example, vertically integrated health systems may be less likely to enter a market if network adequacy standards would force them to compete with other providers.257

Inadequate or erroneous provider directories in network plans may also discourage providers from competing on price or quality to attract patients. If consumers cannot accurately identify in-network providers, or compare networks of competing insurers, it is more difficult for them to make informed choices. In addition, without proper information, enrollees may be more likely to unknowingly receive care out of network, leading to instances of "surprise billing." Of patients aged 18-64 who receive out-of-network care, nearly 70 percent are unaware that the provider is outside their plan's network prior to receiving care.258

While CMS requires Medicare Advantage, Medicaid managed-care plans, and qualified health plans in the exchange to update and provide consumer-accessible provider directories, ensuring that enrollees receive accurate information in real-time may still be difficult. In a review of provider locations from online directories, CMS found errors in over half of the locations for Medicare Advantage providers, with 33 percent of errors due to the provider not working at or not accepting the plan at the listed location (CMS 2018).259

The provision of accurate and timely information would also bolster competition. To facilitate more competition and innovation, network adequacy standards should place

greater emphasis on network outcomes while giving states flexibility to meet their specific needs. In 2015, the National Association of Insurance Commissioners opposed blanket federal network adequacy requirements in its Health Benefit Plan Network Access and Adequacy Model Act, especially as strict quantitative measure are unlikely to meet varying needs across states. Current quantitative standards could be less restrictive and used primarily as minimum thresholds to determine whether an insurer can enter a market or when a network has actually failed an enrollee.260 These standards should take into account alternative network designs and be used alongside external review by physicians when networks fail to provide adequate access to enrollees.261 Insurers could be allowed to have more flexibility with provider contractors, such as “spot contracts,” to fill in network gaps as needed.262

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.
- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

The ACA Rules Limit Choice

The Affordable Care Act introduced a number of mandates and burdensome requirements that significantly reduced choice and competition in insurance markets and caused premiums, particularly in the individual market, to soar. This occurred to a significant extent because government rules and price controls on health insurance premiums, designed to assist some people with higher anticipated health expenditures, inhibited the application of actuarially determined pricing and created an adverse selection spiral in the individual market. These requirements also produced a significant reduction in coverage options for most consumers. In addition to reducing consumer choice and competition between insurers, the higher administrative costs associated with the ACA mandates disproportionately hurt smaller employers, in part because smaller employers were unable to spread these costs as broadly as larger employers and in part because the large-group market is not bound by all of the ACA’s mandates. Therefore, as a general matter, smaller employers that continued to offer coverage were forced to disproportionately raise premium contributions paid by covered workers, making them less competitive with larger employers and with other smaller employers that chose not to offer health coverage to their employees.263

ACA’s Harmful Insurance Rules

The ACA forces insurers offering coverage in the individual and small-group markets to offer a mandated set of government-defined benefits.264 This mandate reduces

consumer choice and represents a hidden cost on the majority of consumers by forcing them to pay for more coverage – and the corresponding expense – than many customers would otherwise choose to buy voluntarily in insurance packages. Excessive mandates hinder innovation in plan design and greater access to coverage; they also limit public efforts to assure affordability without substantial government subsidies. This leaves significant swathes of consumers with coverage that includes numerous items they do not want or need and contributes to pricing others out of the market, including some of the 6.5 million people who paid the penalty for not having minimum essential coverage under the ACA.265 The ACA further restricts choice and competition through a prohibition on people over the age of 30 purchasing catastrophic insurance (unless they qualify for a hardship exemption).

The ACA also requires insurers to cover numerous preventive services without cost sharing under the premise that a government-imposed system-wide increase in "free" preventive care will lower overall healthcare costs.266 Under the ACA, the U. S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the CDC, and HRSA are tasked with determining the required preventive services.267 However, a New England Journal of Medicine study found that "sweeping statements about the cost- saving potential of prevention…are overreaching. Studies have concluded that preventing illness can in some cases save money but in other cases can add to healthcare costs."268 Other research finds that 80 percent of preventive services add more to future expenditures than they save in healthcare costs.269 These findings suggest that the ACA's coverage mandates, while certainly providing some benefit, increase premiums, as well as lead to unnecessary utilization. Atul Gawande, former adviser to President Bill Clinton and President Barack Obama, has warned about the risks of over-testing and over-treating.270 Over-testing leads to problems like additional radiation exposure and stress from the abundance of false positive results, and over-treating leads to problems like medical errors and hospital-acquired infections.

The Medical Loss Ratio (MLR) is an ACA mandate requiring that insurers in the individual and small-group markets spend at least 80 percent of premiums on healthcare costs, allowing 20 percent for administrative costs and profit.271 The MLR was intended to provide a minimum guaranty of value to customers, as companies that fail to meet this ratio are obligated to pay a rebate to their customers.272 However, the MLR may create a perverse incentive that encourages insurance companies, particularly in the absence of competition, to increase premiums.273 Some health policy experts also believe that the MLR regulations will harm the ability of some insurers, particularly smaller insurers, to compete, thus reducing consumer choices.274

A number of ACA rules have contributed to large increases in average premiums and have driven down choices in the individual and small-group markets. In 2013, the year before many of the ACA rules took effect, 395 insurers operated in the individual

market.275 By 2017, this number had fallen to 218, and 70 percent of counties (including 36 percent of U.S. residents) had no more than two insurers selling individual plans in the exchange.276 In the exchanges in 2018, 29 percent of enrollees had only one issuer to choose from, up from 20 percent in 2017; 55 percent of enrollees had at most two insurers to choose from, up from 44 percent in 2017.277 This problem is most pronounced in rural counties. As a result of high and rising premiums, relatively young and healthy people, particularly those in the middle-class who earn too much to qualify for a premium subsidy, have largely avoided the exchanges. Moreover, the ACA's special enrollment periods created an incentive for people to wait until they need healthcare to seek insurance in the exchanges, an incentive that has exacerbated adverse selection and led to spikes in premiums.278 In an attempt to mitigate this problem, the Department of Health and Human Services issued an April 2017 rule aimed at significantly restricting peoples' ability to game the special enrollment periods.279

The administration has taken two major actions to provide Americans, particularly middle- class Americans without employer-sponsored insurance, with additional and more affordable health insurance choices. In June, the Labor Department released a final rule expanding the ability of employers, including sole proprietors without common law employees, to join together to form an association health plan (AHP).280 In August, the departments of Health and Human Services, the Treasury, and Labor released a final rule expanding the ability of consumers to purchase short-term, limited-duration insurance— much more affordable products that can better serve many consumers' needs.281 According to the Congressional Budget Office, about 6 million Americans will benefit from these actions and enroll in these plans within a few years.282

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.
- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

ACA Rules Restricting Physician-Owned Hospitals Reduce Competition

The ACA placed an effective moratorium on the opening and expansion of physician-owned hospitals.283 According to the Physician Hospitals of America, 37 planned hospitals have not been constructed, and over 30,000 planned healthcare jobs have gone uncreated because of these ACA restrictions on physician-owned hospitals.284 These restrictions, which were favored by the American Hospital Association, were included to address potential financial conflicts of interest with doctors referring patients to their own hospitals and concerns that physicians may be referring the healthiest patients to their own hospitals.285 Those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provider higher-quality care and that patients benefit when traditional hospitals have greater competition.

Physician-owned hospitals, furthermore, have been shown to provide patients with high-quality care. According to a study published by the Journal of the American College of Surgeons, physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.286 More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the Centers for Medicare and Medicaid Services (CMS), compared to only 5 percent of general hospitals.287, 288 Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital than at a general hospital.289

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

ACA Section 1557 (Nondiscrimination Requirements)

ACA Section 1557 has been implemented in such a way that creates a number of burdens on healthcare providers and payers. For example, current rules concerning persons with limited English proficiency require covered entities to include a notice of the right to translation services in 15 languages in nearly all “significant communications” that go to because of these ACA restrictions on physician-owned hospitals.284 These restrictions, which were favored by the American Hospital Association, were included to address potential financial conflicts of interest with doctors referring patients to their own hospitals and concerns that physicians may be referring the healthiest patients to their own hospitals.285 Those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provider higher-quality care and that patients benefit when traditional hospitals have greater competition.

Physician-owned hospitals, furthermore, have been shown to provide patients with high-quality care. According to a study published by the Journal of the American College of Surgeons, physician-owned surgical hospitals outperform other hospitals in the

Medicare value-based purchasing program.286 More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the Centers for Medicare and Medicaid Services (CMS), compared to only 5 percent of general hospitals.287, 288 Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital than at a general hospital.289

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

ACA Section 1557 (Nondiscrimination Requirements)

ACA Section 1557 has been implemented in such a way that creates a number of burdens on healthcare providers and payers. For example, current rules concerning persons with limited English proficiency require covered entities to include a notice of the right to translation services in 15 languages in nearly all "significant communications" that go to beneficiaries, enrollees, applicants, and members of the public.290 As a result, covered entities have printed and mailed additional "tagline" sheets they are required to include in documents they frequently mail to customers such as explanations of benefits.291 Entities have not been permitted to have online translations alone without mailing "tagline" sheets. Entities covered by the Section 1557 regulation are required to repeatedly notify a population of primarily English and Spanish speakers in multiple languages that they have a right to request translations repeatedly.

It is critical to structure anti-discrimination provisions so they are not barriers to entry that favor larger entities who can better absorb these types of costs and thereby limit competition. However, these and other new requirements imposed on the healthcare industry by the Section 1557 regulations were estimated to cost covered entities $637.5 million over the first two years.292 This burden is especially hard for smaller entities to enact because unlike larger market players, they cannot take advantage of economies of scale by spreading the additional costs incurred over their larger enrollee population.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Giving Americans Control over Their Healthcare Spending

The introduction to this report highlights how third-party payment distorts healthcare markets, increases spending and premiums, and reduces consumers' incentives to seek value from their healthcare decisions. Federal law currently favors third-party

control and payment through the federal exclusion of employer-sponsored insurance (ESI) premiums, including employer contributions for self-insured plans, from both income and payroll taxes, the design of the Medicare and Medicaid programs, and the ACA premium tax credits. Easing restrictions on other types of arrangements available for this tax preference could put more control in the hands of consumers and could thus promote cost-conscious consumer behavior.

The primary vehicles that put more control in the hands of consumers and reduce the bias toward third-party payment are high deductible health plans (HDHPs) paired with HSAs

and Health Reimbursement Arrangements (HRAs). Research demonstrates that consumer- directed health plans, such as these, can lower healthcare spending, largely through reductions in usage of outpatient care and pharmaceuticals.293

Benefits of Expanding Health Savings Accounts

Under tax provisions originally enacted in 2003, persons enrolled in certain HDHPs—which are generally referred to here as HSA-qualified plans— may contribute to savings accounts to pay for healthcare expenses on a tax-preferred basis. Contributions made by an individual's employer or by an individual through payroll deduction are excluded from wages for purposes of income and payroll taxes. Contributions made directly by an individual are deductible for income-tax purposes. Individuals must be enrolled in an HSA- qualified plan and generally cannot be enrolled in any health plan other than the HSA- qualified plan to be allowed to make HSA contributions. Annual HSA contributions are limited to $3,450 for persons enrolled in single coverage under an HSA-qualified plan ($6,900 for persons enrolled in family coverage) for 2018.294 HSA-qualified plans are required to meet the following requirements295:

1. Minimum deductibles ($1,350 for self-only coverage or $2,700 for family coverage in 2018).
2. An annual limit on the sum of the deductible and out-of-pocket expenses ($6,550 for self-only coverage and $13,300 for family coverage).
3. The out-of-pocket expense limits do not apply to any out-of-network benefits if the plan uses a network (that is, the out-of-pocket cap applies to the deductible and cost sharing only on in-network benefits).
4. Only preventive care benefits as defined in applicable guidance296 may be

provided before the minimum deductible is met.

5. The health plan coverage must not be not limited to vision, dental, disability, workers compensation or other specified types of limited insurance coverage.

HSA funds not used to pay health expenses over the course of the year may be saved for future use, and any funds unspent when individuals turn 65 may be withdrawn for any use without penalty.297 Thus, HSAs promote savings for later healthcare expenses, an extremely beneficial feature since healthcare expenditures tend to grow with age.

Unfortunately, many people—likely around 60 percent—who have deductibles exceeding the required minimum deductibles for HSA-qualified plans do not have HSA-qualified plans.298 Some of the common reasons that plans are not HSA-qualified plans are because of 1) separate drug coverage based on a tiered copayment structure with no or a low deductible, 2) coverage of generic drugs before the deductible is met, or 3) coverage of primary care visits (for free or with a copayment) before the deductible is met. Thus, certain innovative insurance products, which attempt to incentivize cost-effective health treatments and health behaviors, cannot be coupled with HSAs.

For example, an insurer looking to prudently manage the costs of diabetes by offering insulin coverage before the deductible with the goal of reducing much larger future costs that might occur from mismanagement of the disease could preclude its enrollees from contributing to an HSA. Alternatively, an insurer might offer a plan with an actuarial value299 similar to that of an HSA-qualified plan, but with a low deductible combined with higher copays. This plan could provide even more of an incentive for individuals to be as cost-conscious as the HSA-qualified plan requirements provide but would not be an HSA- qualified plan.

A third example of an arrangement that might not meet the current HSA requirements is a fixed-fee arrangement between providers and consumers, such as a direct primary care arrangement with a primary care physician where the patient pays a monthly fee in exchange for a set number of visits as well as basic treatments. Some or all fees under such fixed-fee arrangements might not be healthcare expenses under section 213(d) of the Internal Revenue Code (the “Code”). If so, HSA funds used for paying these fees could be subject to income taxes and a penalty.300 Also, if the fixed-fee arrangement is determined to be insurance for tax purposes, the arrangement would likely be considered a health plan and preclude the individual from contributing to an HSA during the year because individuals who have a health plan in addition to an HSA-qualified plan cannot contribute to an HSA.301

These constraints on HSA-qualified plans and the requirement that prevents an HSA contributor from having any health plan other than an HSA-qualified plan, limit the popularity of HSAs, reduce choice, and potentially increase healthcare spending as people eschew HSA-qualified plans and instead choose plans with greater third-party

payment. An alternative standard for determining HSA-qualified plans would allow individuals with certain cost-conscious plan features to benefit from HSAs.

One such proposal would be to allow anyone enrolled in a health insurance plan with a 70 percent actuarial value (AV) or below to contribute to an HSA. This will incentivize employers whose current plans have an actuarial value above the threshold to switch to offer a plan or plans with a somewhat higher deductible and copayments (and a lower actuarial value) because their workers could then newly participate in an HSA. Economic theory suggests employers would fund employees' HSAs with premium savings. Expanding HSAs and the corresponding incentive to obtain greater value from healthcare spending could lead to less consumption of healthcare, particularly lower-value services and treatments, and further premium reductions.

Individuals whose current plans are at or below 70 percent AV that are not currently paired with HSAs would have an expanded tax-preference for out-of-pocket spending causing some of them to spend more although this incentive is limited since unspent HSA amounts roll over from one year to the next. However, some, but not all, of those whose current plans are above 70 percent AV and who switch to 70 percent or lower AV plans would bear higher after-tax, out-of-pocket costs for services and therefore have an increased incentive to seek value for their healthcare spending. In these situations, providers would be subject to more pressure to set transparent prices and to compete for customer business by lowering prices and improving quality. In addition, unlike with current HSA-qualified plans, insurers would have flexibility to include highly cost-effective care before the deductible is met.302

As noted above, an additional constraint on the availability and use of HSAs is the requirement that HSA-qualified plans can only provide certain preventive care benefits before the minimum deductible is met. Reconsideration of the scope of care that qualifies as preventive could make HSA-qualified plans more attractive and thus enhance access to HSAs. Short of creating a new statutory standard for HSA-qualified plans, the existing regulatory definition of preventive care could reasonably be interpreted more expansively for purposes of the HSA and related HSA-qualified plan rules. A broader interpretation could improve cost-effectiveness and give consumers greater options for financing their healthcare. One reasonable approach would be to consider treatments preventive if they are highly cost-effective and treat a chronic condition that would, in a relatively high share of cases, become more severe or develop into a new condition that is considerably more expensive to treat, if the original condition were left untreated.

Another HSA reform that would reduce the bias in favor of comprehensive, employer-sponsored coverage would be allowing people with an HSA-qualified plan who also choose consumer-provider, fixed-fee arrangements, such as direct primary care arrangements, to contribute to an HSA. Doing so would provide another avenue for first-party payment of healthcare services, thereby expanding choice and making HSA-

qualified plans more attractive relative to comprehensive insurance. Some of these types of arrangements are simply pre-payment, outside of traditional insurance arrangements with all the corresponding administrative costs, for certain healthcare services that are known and regular in nature. For example, a patient with diabetes might purchase a fixed-fee arrangement that supplied insulin, testing equipment, and a quarterly visit with a healthcare provider specializing in treating diabetes patients. Healthcare providers would then have an incentive to compete with respect to price and quality to attract patients with HSAs.

Another limitation of current law is that Medicare beneficiaries in HDHPs are not allowed to make tax-deductible contributions to their HSAs or Medicare Savings Accounts (MSAs) even if Medicare serves as their secondary coverage. This limitation reduces the ability of working seniors to save for future healthcare expenses and leads them to rely more upon third-party payment for healthcare services in retirement. The FY2019 President's Budget proposed to give Medicare beneficiaries greater flexibility to take control of their healthcare. The Budget proposal would allow beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs. These beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Medicare beneficiaries who have an employer-sponsored HDHP would be allowed to make contributions to their HSAs, although Medicare would not cover any expenses before the HDHP deductible is met. The Budget estimated that this proposal would reduce government revenue by about $11 billion, over 10 years.

Although the premiums for employer-sponsored coverage—both the premiums paid by the employer and employee—are generally excluded from federal income and payroll taxes, the premiums paid for non-group coverage do not receive this same tax treatment. The ACA's premium tax credits provide assistance for the purchase of individual market plans, but this assistance declines rapidly as household income rises and does not extend to people in households with income above 400 percent of the federal poverty line. As part of its proposal to replace the ACA, the President's FY2019 Budget recommended increasing HSA contribution limits and allowing the use of tax-preferred HSA funds to pay HDHP premiums. The Treasury Department's budget estimates suggest that, as part of ACA repeal, raising the HSA contribution limits to the out-of-pocket maximums and allowing the purchase of HDHP premiums from HSAs would reduce government revenue by $28 billion over 10 years.

Another option to increase consumer control through HSA expansion would be to allow persons enrolled in Healthcare Sharing Ministries as defined in Code section 5000A(d)(2)(B)(ii) to contribute to HSAs. Healthcare Sharing Ministries are organizations in which people with shared religious or ethical beliefs help pay each other's medical costs. Contributions to HSAs by participants in Health Sharing Ministries would be permissible provided that the individuals (1) remain responsible for an amount

of their own (or their family's own) healthcare expenses equal to the applicable annual deductible for an HSA- qualified plan, and (2) with respect to any particular medical expense, are not eligible for payment, sharing, or reimbursement of the expense in any manner by both the Healthcare Sharing Ministry and the HSA. In other words, the HSA-qualified plan deductible would still apply and a medical expense could not be reimbursed twice. These arrangements would encourage individuals to keep medical spending low by encouraging less costly behaviors and greater negotiation with medical providers. In expanding the flexibility of these arrangements, however, distinguishing genuine Healthcare Sharing Ministries from plans and organizations that mischaracterize themselves as such would be essential.

Benefit of Expanding Health Reimbursement Arrangements

Since HSAs are the property of the individual, increasing consumers' ability to use HSAs is likely the best way to encourage first-party payment. Expanding HRAs could also encourage more efficiency through greater consumer control over their healthcare and somewhat reduced third-party payment.

Originally described in IRS guidance in 2002,303 HRAs allow employers to reimburse their employees' medical expenses. An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical expenses incurred by the employee or his or her family up to a maximum dollar amount for a period. Historically, HRAs have often been used by employers that did not choose to offer group insurance to their workers, as well as to supplement group coverage.

As a result of the interpretation of some ACA provisions, HRAs can currently only be offered if employers also offer ACA-compliant group health insurance plans. In implementing the ACA, the Obama administration determined that standalone HRAs violated the ACA prohibition on annual dollar limits and the requirement that group health plans provide certain preventive care without cost sharing. Although the Obama administration issued regulations allowing HRAs to be offered as long as the employee had other group health insurance coverage, the Obama administration restricted individuals' ability to use an HRA to purchase individual market insurance of their own choosing, even if the insurance did not have annual and lifetime dollar limits and covered preventive care without cost sharing.

The following two expansions of HRAs, both proposed in a notice of proposed rule-making issue on October 23, 2018, would increase their usability and provide employers, and their employees, with a greater set of alternatives for financing health coverage. First, reversing the Obama administration restriction on HRAs for individuals with individual market insurance would encourage more employers to offer HRAs, increase consumer choice, and provide equal tax treatment for employee-selected coverage in the individual market as for traditional employer-selected group coverage.304 In essence, allowing HRAs to be integrated with non-group coverage that does not have annual dollar limits and that covers the necessary

preventive care without cost sharing would allow employers to provide a tax-advantaged, defined contribution arrangement for each employee to select the health insurance that best works for his or her circumstances. In addition to the benefit for workers, the proposed rule would better enable businesses to focus on what they do best— serve their customers—and not on navigating and managing complex health benefit designs.

This proposed rule is increasingly important as fewer employees at small and mid-sized firms are enrolled in employer coverage and most employers that do offer a plan only provide their workers a single option. For firms that employ 3-24 workers, the percentage of workers covered by employer health benefits has fallen from 44% in 2010 to 30% in 2018. For firms that employ 25-49 workers, the percentage of workers covered by employer health benefits has fallen from 59 percent in 2010 to 44 percent in 2018. 81 percent of small to midsized employers (fewer than 200 employees), and even 42 percent of larger employers (at least 200 employees), offering health benefits only provide a single coverage option for their employees. Economists have found that increasing plans available to employees is extremely valuable, providing the median consumer equivalent benefit as a 13 percent premium reduction.305

An additional way to expand the use of HRAs is to allow a limited "excepted benefit" HRA that, as with all excepted benefits, would not be subject to the ACA's market rules (such as the prohibition on annual dollar limits and the requirement to cover preventive care without cost sharing) or certain other requirements for group health plans under the Code and the Employee Retirement Income Security Act of 1974 (ERISA). Providing an excepted benefit HRA would reduce the bias toward comprehensive ESI and allow employees another tax-advantaged arrangement to finance limited healthcare expenses. The proposed regulation would permit employers that offer traditional group coverage to provide an HRA of up to $1,800 per year (indexed to inflation) to reimburse an employee for certain qualified medical expenses, including standalone dental benefits and premiums for a short-term health insurance plan.

According to preliminary estimates from the Treasury Department, once fully phased in, roughly 800,000 employers are expected to provide HRAs to pay for individual health insurance coverage to over 10 million employees. Some experts, such as Harvard Business School professor Regina Herzlinger, suggest the effect could be larger since expanded HRAs will create a more efficient healthcare system as consumerism will be unleashed.306 This phenomenon could lead to increased workforce investment and higher wages as less is spent on health insurance and could spur innovation among providers and insurers as they directly compete for consumer dollars.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value

below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA-qualified non-group premiums, allowing Medicare beneficiaries in enrolled high-deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.

- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.

- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to their employees, and to allow HRAs to be used in conjunction with non-group coverage.

The Unintended Consequences of Federal Policies

Delivery System Reform

Policymakers generally agree that the U. S. healthcare system's reliance on fee-for-service, third-party financing has contributed to a system that produces high costs with uneven quality. The increasing recognition among policymakers of this dynamic has led to recent reimbursement policies that attempt to move away from rewarding volume (fee-for- service) to rewarding value. Many delivery system reform efforts to date have sought to transfer risk to entities with better incentives for managing costs and delivering value to patients. One of the most successful examples of this has been Medicare Advantage, which has moved away from a fee-for-service model, improved incentives, and has generally produced higher value (better care per unit of cost) for patients. The success of Medicare Advantage is based on better empowering consumers—letting them determine what constitutes value, as opposed to deferring the judgement to Washington. As HHS Secretary Azar has stated, if the government writes the equation for value, the answer is never going to be cheap or simple, and special interests will find a way to manipulate it. Relying on the free exchange of information between buyers and sellers, among competing interests, can deliver better outcomes from our healthcare system at a lower cost with patients, not the government, in charge.307

ACOs

Various structures have been tried in different settings by the prior administration. However, they have often relied on the government (rather than patients and the private

sector) to define value, rather than allowing patient choice. One such approach has been the development of Accountable Care Organizations (ACOs), groups of doctors, hospitals and other providers that work together to manage and coordinate care for Medicare fee- for-service beneficiaries through an accountable care organization, whose performance is evaluated according to quality standards established by the government. ACOs were intended to improve coordination of care between primary care providers, specialists, and hospitals by holding providers accountable for patient outcomes and total costs. When considering the future of ACOs and broader delivery system reform efforts, it is critical to understand the history of ACOs and their effect on provider competition.

The largest Medicare ACO program is the Medicare Shared Savings Program (MSSP), in which Medicare shares in the financial savings and losses generated by ACOs. In 2018, there were 561 MSSP ACOs, which enrolled 10.5 million beneficiaries.308 Importantly, most MSSP participants are not responsible for financial risk if their spending is above established targets (i.e., one-sided financial risk). New payment models such as Medicare's Next Generation ACOs require providers to take on both shared savings and shared losses. (309). These models may offer important learning opportunities to test public-private initiatives that aim to increase value since two-sided financial risk represents better incentives to achieve value than one-sided financial risk. Over time, two-sided financial risk should be paired with some control over the inputs to match outcome accountability.

ACO Impact on Provider Competition

While changes such as ACOs and other alternative payment models (APMs) may hold the promise of improved care coordination and better aligned financial incentives, they may also encourage provider consolidation that increases market concentration, drives up prices, and decreases competition between providers. This may occur as hospitals purchase physician practices (vertical integration), or through mergers between hospitals or between physician practices (horizontal integration). Although a causal link has not yet been identified, some studies have found that vertical integration has been associated with higher prices and spending in some markets and for some providers.311 In California, hospital- owned physician practices have higher per-patient spending than physician-owned practices.312 Most economists believe that horizontal integration threatens consumers with higher prices as well as reduced options.

Some experts have suggested that hospital-acquired practices increase the use of evidence- based care such as disease registries, nurse care managers, and reminders to patients that can improve quality of care and outcomes more than physician-owned practices that do not use such care management practices.313 However, hospital-owned practices may have higher rates of emergency department visits and higher Medicare spending per patient.314

This may be why greater physician-hospital integration has been linked to higher commercial prices for outpatient care315 and hospital prices.316

The FTC and the Justice Department worked closely with CMS to develop ACO eligibility criteria so Medicare Shared Savings Program ACO applicants meet clinical integration requirements, avoiding antitrust concerns.317 In order to facilitate compliance with antitrust rules, the FTC and DOJ developed antitrust guidance and policy for ACOs,318 defining antitrust safety zones as well as areas of potential concern where providers have high market power based on their share of the primary service area. The antitrust authorities continue to monitor ACOs for potential antitrust violations.

Research to date indicates that ACOs tend to develop in competitive markets; and only in a minority of markets have ACOs increased physician concentration.319 One recent study found that markets with higher ACO penetration did not experience differential changes in physician-hospital integration, practice size, or market concentration of physicians or hospitals from 2008 to 2013.320 The study also found high ACO penetration markets had more competitive hospital and insurance markets and higher commercial HMO penetration. The authors did note that continued consolidation might be a defensive response to the potential threat from new payment models, as larger health systems may be able to resist payer pressures to enter into risk contracts.

Importantly, provider consolidation began prior to the start of delivery system reform efforts. In one study of hospital acquisition of practices between 2006 and 2013, vertical integration peaked in 2011. Hospitals mostly bought small primary care, multi-specialty, or cardiology practices; case studies of hospitals indicated the primary motivation was to increase referrals and negotiate higher payment rates with insurers.321

A Robert Wood Johnson Foundation project on the impact of hospital consolidation concluded that early trends in consolidation were primarily to improve bargaining power and did not necessarily involve clinical integration.322 Some potential factors related to delivery-system reform that may be contributing to provider consolidation include large health system economies of scale and ability to handle increasing quality and cost measurement reporting. The capital and resource requirements to transform a primary care practice, even within a practice, are substantial. The financial and administrative demands of delivery system reform may incentivize small practices and solo practitioners to accept buy-outs by hospitals and health systems or leave the profession prematurely. The trend toward large systems is likely not be better for patients. A 2013 study found that larger health systems participating in payment reform have not shown better patient outcomes or lower spending,323 whereas small practices have seen lower rates of preventable admissions.324 Thus, it is important that delivery system reform efforts do not harm smaller practices that lack economies of scale to satisfy new rules and requirements accompanying delivery system reform more easily.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.
- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

Positively Realigning Incentives through Payment Reform

Patients with certain clinical needs can often seek care in one of a variety of settings. Medicare fee-for-service (FFS) reimbursement is often based predominately on the setting of care and not the patient's underlying medical need. This can create incentives for providers to refer patients selectively to more highly reimbursed care settings, unjustifiably increasing concentration and spending. Two examples of service types with multiple venue options are post-acute care (PAC) and certain physician services furnished in hospital outpatient departments (HOPD).

Post-Acute Care

Medicare post-acute care (PAC) providers are primarily used for recuperation and rehabilitation. These providers include home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). In 2016, Medicare spent approximately $60 billion on Medicare PAC services. Per statute, separate Medicare prospective payment systems (PPSs) were developed for each Medicare PAC setting. Base PPS payments for each of these settings differs considerably, even though the clinical characteristics of patients and the services delivered at any of the four PAC settings may be similar. The 2018 base PAC PPS payments (i.e., base payments prior to adjustments such as case mix) are about

$15,000 per discharge for IRF, about $400 per diem for SNF (up to 100 days in a covered spell of illness), about $3,000 per 60-day episode for an HHA, and about $41,000 per discharge for a standard LTCH stay or an inpatient hospital with comparable payment rate for patients who meet statutorily specified LTCH eligibility criteria. A unified or site-neutral PAC prospective payment system would base Medicare payment on the clinical characteristics of the patient instead of the provider setting.

Hospital Outpatient Departments

Many of the services delivered by hospital outpatient departments (HOPDs), such as evaluation and management visits, endoscopies, and imaging services, are also delivered in physician offices and ambulatory surgical centers (ASCs). Medicare FFS benefit payments are projected to be $50 billion in 2018 and $100 billion in 2027 for these services.325 Conceptually, physician reimbursement for ambulatory services has two components: the professional component, which covers the physician time, and the technical (also called facility) component, which covers the cost of the office, equipment, and auxiliary staff's time. The professional component is paid under the Medicare Physicians Fee Schedule (PFS) regardless of the place of service. However, the technical component is typically higher in the HOPD than in a physician's office or ambulatory surgical center.

Sec. 603 of the Bipartisan Budget Act of 2015 (BBA) modified how off campus outpatient services are paid. Prior to enactment of the BBA, hospitals were able to purchase freestanding clinics and bill for outpatient services under the Outpatient Prospective Payment System (OPPS) for the services furnished at these off-campus provider based departments. Sec. 603 changed the incentives so that after January 1, 2017, services furnished by certain off-campus provider based departments would no longer be payable under the OPPS (and would generally instead be paid lower rates under the Physician Fee Schedule), effectively decreasing payments for these services and eliminating an incentive for hospitals to purchase these freestanding clinics. Clinics purchased by the hospitals prior to November 2, 2015 or which were located less than 250 yards away from a remote location of the hospital were "grandfathered," and continue to have services rendered paid under OPPS. Elimination of this incentive to consolidate will hopefully serve to maintain market competition and slow increases in Medicare and private insurance sending.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In delivering these reforms, Congress should account for differing levels of patient acuity.

- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Quality Improvement and the Measurement and Reporting of Quality

One of the earliest experiences with quality reporting was the publication of “report cards” in New York and Pennsylvania, which started reporting physician and hospital coronary artery bypass graft (CABG) surgery mortality rates in the 1990s. These efforts led to some early successes, including a 41 percent decline in risk-adjusted mortality rates326 and 27 surgeons with low volume and high mortality rates ceasing performing CABG surgeries.327 Potential drawbacks are that report cards may have produced some “cherry picking” by providers, so that fewer severely ill patients received CABG and health outcomes for severely ill patients worsened.328 Several other studies have demonstrated positive results from measuring quality outcomes and publishing the results.329

While value is best determined by private sector interactions, the government can play a productive role in collecting and making available data that patients and insurance companies can use to make more informed decisions. In the past, the government has often failed to establish sensible metrics, creating significant reporting burdens for providers and metrics that are not informative for patients or industry and can easily be gamed when reimbursement is tied to them.

Quality Reporting History

Following the publication of the landmark reports, To Err is Human and Crossing the Quality Chasm by the Institute of Medicine in 1999 and 2001 respectively, numerous quality-reporting requirements have been imposed on providers. The premise of quality reporting is that it will motivate providers to improve the quality of healthcare they deliver and provide patients with the information they need to make informed choices about their care. Early quality public reporting initiatives centered around hospital mortality rates,330 and required many providers to abstract data manually from patient charts.

The Deficit Reduction Act of 2005 mandated that HHS develop a plan for value-based purchasing for Medicare hospitals starting in 2009, which led to Medicare’s first pay-for-reporting programs for hospitals and physicians.331 Medicare tested the first hospital pay- for-performance program through a partnership with Premier, an alliance of hospitals, in the Hospital Quality Incentive Demonstration,332 a six-year program that awarded top- performing hospitals with bonuses based on evidence-based quality

measures for five clinical conditions. This demonstration showed improvements in quality for participants and those who publicly reported quality.333 Refinements to Premier's methodology, rewarding both achievement and improvement as a means to address disparities,334 have led to implementation of similar features in Medicare's current value-based purchasing programs.

Since 2003, HHS has published a national report on quality and disparities through national databases in the Agency for Healthcare Research and Quality (AHRQ). The data show continued disparities among providers alongside overall improvements. The National Quality Forum is now looking at methodologies to display this data to providers to help improve care for disadvantaged populations (including poor, rural, and vulnerable populations) by reporting potentially preventable admissions that reflect the quality of primary care or higher rates of delayed care due to affordability.335

Medicare's Physician Value-Modifier (VM) program, a physician pay-for-performance program, sought to extend the goals of quality improvement in the ambulatory care setting and assess population outcomes such as preventable admissions, using Medicare claims data. In addition, the Quality Payment Program, enacted in 2015 through MACRA, has created another requirement for physicians to report on measures. Like the Value Modifier Program, the Quality Payment Program also assesses clinicians and group practices on population level outcomes including all-cause readmissions and avoidable ER visits.

Quality metrics have a greater effect on providers than on patients. Many of the patients did not consult the report cards, and of those who did, many reported that they did not affect their choice of hospitals or surgeons.336 However, the quality metrics certainly affect providers who do not wish to be publicly identified as potentially harming patients, and this seemingly drives many providers to improve. Although measuring quality has generally produced positive results, the proliferation of measures produces a burden that discourages providers and likely takes away from patient care. Moreover, many providers have learned to game certain measures or have become sophisticated in explaining away bad results as attributable to improper risk adjustment.

The shift to value-based payment, the large number of quality measures, and the potential lack of alignment in measures required by different payers (e.g., Medicare, state Medicaid agencies, and health insurers) further increases the burden of quality reporting on providers. Each year physicians and their staff in four common practice areas (cardiology, orthopedics, primary care, and multispecialty) spend 15.1 hours per week per physician on reporting quality measures—about 785 hours per physician per year—at an estimated average annual cost of $40,069 per physician or $15.4 billion per year for these specialties.337 This is clearly too much, especially given the problems intrinsic to many of the metrics being recorded. CMS estimated the total costs burden of MIPS in the first year to be $1.3 billion in 2017, decreasing to $694 million by 2018 due to fewer clinicians being eligible under revised volume requirements.

Half of physicians and 38 percent of nurse practitioners and physician assistants report that quality reporting requirements have a negative impact on the quality of care.338 This stands out as another example of well-intentioned government action having unintended consequences. To address this issue, the National Quality Forum (NQF) has endorsed a set of common quality reporting measures for use by public and private payers. Under current law, NQF endorsement is required to ensure standardization and stakeholder input in measures used for quality reporting and performance-based payment.

Another recent private-public effort, Core Quality Measures Collaborative,339 has worked to align measure specifications across payers including Medicare and Medicaid. In addition, CMS's Meaningful Measures Initiative removed 18 hospital reporting measures and is proposing removal of 36 measures from the MIPS program that have showed no variation and are topped-out (i.e. already showing high level of performance with minimal to no variation).

Impact of Quality Reporting on Competition

A recent report by the Government Accountability Office (GAO) predicts that many small practices will be unable to transition to MIPS due to lack of financial resources.340 The new requirements potentially disadvantage small, independent practices or solo practitioners who, unlike large health systems, are less likely to have the administrative infrastructure and staffing resources (e.g., a practice manager or other administrative staff) to report efficiently on quality and conduct regular quality improvement activities to improve performance. One potential concern is that practices that participate in these programs may harm patient care if they need to divert limited resources to reports and bureaucracy and away from actual quality improvement and patient care. The financial effects from penalties, diverted resources, and poor performance results could affect their ability to stay in business, force them to merge with larger systems, or lead to early retirement.

The GAO also suggests that small practices could work with partners to share in financial risk and help coordinate services, as well as work with non-partners in order to support quality reporting, patient surveys, and EHR requirements. Since many practices would like to remain independent and there is increasing evidence that small independent practices provide higher quality of care, such as fewer preventable hospital admissions, at lower cost,341 enabling them to achieve these benefits while remaining independent is important.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the

number of measures where the expected cost of collecting the measure exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.

- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that can increase the competitiveness of small practices through access to shared resources and help build capacity for care management.
- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Enabling Consumer-Driven Healthcare

Rising healthcare spending is partly attributable to consumers' insulation from the true market price of healthcare services through the presence of third-party payment. Historically, consumers have had little reason to seek out, or price shop for, lower-cost or higher-value providers and services due to the abundance of third-party payment. Instead, reimbursement rates are negotiated between third-party payers, generally the government or insurers, and providers. And consumers generally are provided with little information on the prices of healthcare products and services.

Perhaps not surprisingly, there is a wide variation in prices charged across providers, even within a geographic area.342 Substantial savings could be achieved if consumers actively shopped and selected lower-cost providers. For example, Table 2 demonstrates the potential savings for people who self-pay relative to the insurance rate. Unlike most industries, which typically offer relatively uniform prices to most consumers, the reimbursement of a specific service will vary significantly based on the third-party payer

with which a consumer is aligned. It is also worth noting that consumers may receive a lower price by paying cash for services.343 Yet it can be difficult for consumers to find price information.

The Cash Advantage

Patients who pay cash upfront for medical services can sometimes make out better than they would by using their insurance, especially if they have high- deductible plans and pay the insured rate in full. Some examples:

Patients who pay cash upfront for medical services can sometimes make out better than they would by using their insurance, especially if they have high- deductible plans and pay the insured rate in full. Some examples:

PROCEDURE	FACILITY | CITY	SELF-PAY RATE	INSURANCE RATE	INSURANCE COMPANY
MRI of the foot	**Regional Medical Imaging** | Flint, Mich.	**$379**	**$445**	Aetna
Tonsillectomy	**Banner Desert Medical Center** | Mesa, Ariz.	**$2,858***	**$5,442**	Arizona Blue Cross Blue Shield
MRI of the knee	**Boulder Community Hospital** | Boulder, Colo.	**$600**	**$1,100**	Arizona Blue Cross Blue Shield

Note: Insurers' rates may vary by plan. *Not including physicians' fees, typically $1,000 to

$1,400.

Sources: the providers; insurers' cost-estimator tools

In sum, the abundance of third-party payment creates a system in which consumers generally do not shop on price and providers lack incentives to compete on price and quality to attract and retain patients. Of note, while the third-party payers have knowledge of the reimbursement schedule, price transparency at this level is inefficient

for two reasons: (1) Insurers may lack incentives to obtain lower prices especially if profits are capped at a percentage of spending, and (2) Insurance introduces moral hazard and waste.

Despite the current foundational impediments to establishing a consumer-driven market, some examples provide insight into the results that might be achievable if consumers had greater incentives and ability to make informed decisions about their healthcare consumption.

Some government tax policies and payers' benefit design strategies have sought to encourage consumers to become more actively engaged in purchase decisions. As discussed earlier, consumer-directed models, such HDHP linked to HSAs, hold the promise of increasing consumer engagement in their healthcare decisions. So do initiatives that leverage the power of consumer shopping, like reference pricing. As of 2017, more than 20 million people were enrolled in an HSA-qualified plan, although only about 40 percent of these enrollees contributed to an HSA.344 One study found that HDHPs produce lower spending, primarily due to less utilization.345 Combining HDHPs with consumer-driven HSAs could create more effective incentive structures than existing third-party arrangements, incentivizing patients to shop for higher-value care without forgoing necessary treatments. However, patients cannot make fully informed decisions about where to receive care without information about the cost and quality of providers. Unfortunately, consumers often lack meaningful and understandable price information.

Payers Can Improve Incentives

Empowering consumers with price information and realigning financial incentives to give consumers a greater stake in their healthcare decisions has been shown to lower prices without affecting quality. One model for increasing consumer engagement is the

use of reference-based pricing. Reference pricing places an upper limit on the amount of reimbursement a payer will pay for a medical service. Generally, the reference price is set to a specific percentile of the distribution of provider reimbursements in a market, such as the median reimbursement. If an enrollee receives care from a provider that charges above the reference price, then the enrollee is responsible for the difference.

Reference pricing has been shown to reduce the variation in prices across providers, as providers increasingly compete on price. When the California Public Employees' Retirement System (CalPERS), which provides benefits to over 1.4 million enrollees, started using reference pricing, higher-cost providers soon responded by lowering their prices to attract these enrollees (Robinson 2017).346 CalPERS distributed lists of hospitals that exceeded a certain quality threshold and had different prices for its enrollees. Consumers increasingly used lower-cost providers with no negative impact on quality.347

The Centers of Excellence contracting approach is another method that many payers use to obtain value for employees. Under this approach, an employer or insurer contracts with specific high-value providers for particular services or procedures and offers its health plan enrollees lower cost sharing for using those providers. Often these arrangements rely on bundled payments, in which the payer reimburses the provider a set amount for a pre-defined episode of care.348 Centers of Excellence contracting is often used in non-emergency situations in which a consumer can travel to obtain care from a nationally recognized physician or hospital. For example, Walmart covers its health plan enrollees at zero-cost sharing if they travel to the Mayo Clinic, Cleveland Clinic, or another select high-quality provider for cardiac, spine, and transplant surgeries.349 In addition, Walmart covers travel and lodging costs for the patient and a caregiver.

Current State of Price-Transparency Efforts

Meaningful and timely consumer access to prices can supplement benefit designs to help consumers choose lower-cost, higher-value providers. In a competitive, functioning insurance market, insurers would have an incentive to use such approaches. To be effective, price transparency efforts must distinguish between the charges a provider bills and the rate negotiated between payers and each provider. Some health plans and self- insured employers have developed price transparency tools for their enrollees. CalPERS uses a price transparency platform that allows patients to see providers' prices along with out-of-pocket costs. Over 90 percent of enrollees in Aetna commercial health plans have access to Aetna's Member Payment Estimator which provides personalized out-of-pocket costs for more than 600 medical services—a helpful resource because it uses negotiated plan prices instead of relatively meaningless charges,350 and takes into account cost-sharing responsibilities such as any remaining deductible amount.

State governments purchase significant volumes of healthcare goods and services through Medicaid, departments of corrections, and public sector employees' pension and health benefit funds.351 In this capacity, states have an incentive to reduce their healthcare spending. Realigning incentives and promoting price transparency may help states do so. Most states have some laws related to price transparency; however, states may be able to do more.352

At the federal level, the ACA requires hospitals to report annually and make public a list of hospital charges for items and services. Starting in 2013, CMS publicly released average hospital-specific charges per patient and average Medicare payments for common diagnosis-related groups and ambulatory procedures. As part of the FY 2019 Inpatient Prospective Payment System Proposed Rule, CMS updated its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or

more often as appropriate, which may make it easier for consumers to find charges and for third parties to collect and analyze data when developing value and price transparency tools or reports. This data may show the very high rates that many hospitals charge for certain services and treatments. The agency also sought comment on how to make this information available in a consumer-friendly interface.

Boosting price transparency will likely have limited utility unless the dampening effect of third-party payment on consumer engagement is also addressed. One study classified 43 percent of healthcare spending as shoppable;353 however, third-party payment reduces the incentive to shop, resulting in low utilization of price transparency tools. Studies have found that only between 1 percent and 20 percent of patients use price transparency tools when they are available.354 The most promising results for price transparency tools have been for services that rely less on the established physician-patient relationship and are relatively fungible and shoppable, such as imaging and laboratory tests. Price shopping for imaging services is associated with savings of up to 19 percent.355 In addition, some

evidence suggests this shopping is associated with increased price competition among providers offering these services.356

Further development of a consumer market for healthcare, anchored around readily available healthcare prices will likely require reforms to the third-party payment system. Research suggests that without strong financial incentives and accessible data on value (like those present in the CalPERS reference pricing example) consumers are often unwilling to change providers, overly rely on current providers for referrals, and conflate high prices with perceived quality regardless of actual outcomes. Many patients also naturally lose interest in the cost of healthcare once they meet their insurance deductible.357

Importantly, price information may be less useful to consumers if price comparisons do not group, or bundle, services into common episodes of care. An episode of care can include multiple services and fees, which makes it difficult for consumers to obtain accurate price estimates. Consumers may be unaware, for example, of separate physician and facility fees, resulting in higher than expected prices and surprise medical bills. By developing a standardized set of services, such as those used in bundled payment approaches, price transparency efforts could better help consumers compare providers.

Not surprisingly, many insurers and providers do not wish to publicize price information, which inhibits price transparency efforts. Employers may lack access to healthcare pricing information if providers or insurers are unwilling to release their prices. In some instances, even self-insured employers lack access to pricing data that their administrator deems proprietary information,358 even though the employer is paying for much of their employees' healthcare. The Labor Department has finalized a rule that enhances small employers' and sole proprietors' options for banding together to form

Association Health Plans under Title I of the Employee Retirement Income Security Act.359 Small employers and sole proprietors that form these plans may be able to gain the market power necessary to leverage providers into these pricing arrangements.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.
- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by making it easier to pay for their healthcare directly. Actions might include:
    - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
    - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Empowering Patients:

Using Choice to Bring a Longer-Term View to Healthcare

Difficulty accessing price and use data is a barrier to choice and competition in healthcare. Without ready access to such data, consumers, even those with properly aligned incentives, struggle to shop for value. While a wealth of data exists in the healthcare sector, patients are often least able to benefit from it. By realigning

incentives and better leveraging health data, providers, payers and researchers can help consumers choose more effective treatment options, cut down on wasteful spending, and reduce the growth in their own spending on unnecessary services or treatments.

Claims data captures information on diagnoses, procedures and therapies administered, and retail and outpatient drug dispensing, as well as site of care (provider office, hospital, etc.). When available to payers, researchers and others, such data can fuel insightful comparisons of long-term patient outcomes using different treatment options.360 While any one data set (claims, clinical, etc.) may not contain all facets of a patient's experience, each can add value. For example, claims data have been increasingly recognized as central to studying long-term patient outcomes and some payers already use it to monitor the effectiveness of

patient management.361 Claims data can also be used to compare population-level

outcomes between different payment models and delivery systems, allowing the healthcare system to optimize patient care.362 The healthcare system has generated claims data over decades, providing a low-cost means to shed light on long-term cost, use and outcomes, across therapeutic options.363 Today's more advanced technology can now connect claims data across time and location in a secure manner.364

To better inform their healthcare decisions and allow patients and providers alike to take a holistic view of patient health, longitudinal studies will be important. These studies are more challenging if patients move across multiple payers over time, and making best use of such data would likely require cooperation among payers and providers. Of course, this data can and should be readily accessible for enrollees in Medicare and Medicaid.

Twenty-five states, in an attempt to support price transparency efforts and make information more accessible for consumers, employers, researchers and others, have established All-Payer Claims Databases (APCDs). Research on this data may generate useful findings, up-to-date price transparency tools, or other patient engagement applications, as well as allow self-insured employers to manage their own costs better. These efforts have had mixed results to date.

The eventual hope is that this data will allow payers, employers and researchers to better identify variations in pricing and quality across providers and payers. This in turn would help employers and others develop reference-pricing or center-of-excellence payment arrangements. In addition, states, academics and third parties could use these databases to develop price transparency tools, as well as research patient outcomes across providers, services and therapies. These tools may help patients find providers that offer services they value – supplementing often-outdated provider directories. They may also fill in gaps for consumers who lack access to a price transparency tool through

their provider, and give employers a tool to compare prices of services across insurers.365 Leveraging claims data may also help reduce the overuse of unnecessary or wasteful care, likely saving money for consumers, employers and taxpayers.366

Once claims data are accessible in a secure manner, any value-added analyses, presentations or tools built from it could be commercialized. This would leverage market forces to boost availability of insights about population health. Consumers could also access user-friendly information comparing price or value at potential sites of care.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.
- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

Healthcare Information Technology and Non-Competitive Healthcare Markets

Modern Computing and Non-Healthcare Markets

In the last two decades, we have seen transformations of many major markets, including airlines, autos, banking, brokerage, entertainment, lodging, music, printing, publishing, shipping, taxi and telephone industries driven, in part, through the availability of massive volumes of real-time price and service data. Information technology offers intriguing possibilities to transform healthcare markets as well by injecting information and competition into many points in the healthcare industry. With most American adults carrying smartphones, both the hardware and software required to assemble new combinations of real-time medical information—including data on care, nature of services, and provider prices—is widely available.

Current State of Healthcare Information Technology

Historically, healthcare IT systems have focused on revenue optimization, typically through support for large amounts of billing documentation required to maximize fee for service revenues from federal and private payers. In contrast to sectors of the economy

with competitive markets where there is great focus on automation, hospitals and providers employ almost no automation. It is worthwhile to examine which non-market incentives and disincentives have driven the apparent disinterest in automation. Similarly, consumers also have very limited software tools to understand, shop for, purchase or participate in their healthcare. The limited consumer access to healthcare information has been largely limited to federally mandated portals.

A common theme throughout healthcare is the limited state of interoperability. Patients have very limited ability to obtain or move their records. Providers similarly have significant barriers to get healthcare information from other providers, including systems that cannot communicate with each other. Payers have effectively no access to electronic clinical data about their patients.

Currently, health information technology (health IT) too often facilitates anti-competitive practices. These practices include blocking clinical information exchange between providers, as well as selectively providing minimal support for regional information sharing. Another practice common to the highest-priced delivery systems is using a single health IT vendor that systematically and preferentially shares clinical data with other high- priced providers to the exclusion of competitors.367 At least one health IT vendor has also engaged in policies where it effectively forced smaller hospitals to buy their software installs from larger local competitors368.

Importance of Interoperability

The ability to move the patient's clinical information from incumbent providers to competing providers is a key goal of interoperability and can promote competition and the growth of new and disruptive business models. Today this is the capability typically labeled as "interoperability." A broader model of interoperability that includes a network of patients and payers would also allow them to identify providers with best outcomes for specific procedures and treatments. It would also allow prescribers to see cost information about drugs prior to prescribing. Such interoperability would accelerate the development of consumer-facing apps that integrate medical healthcare, cost, and wellness data to help consumers make decisions about their care. Increasing interoperability may also empower consumers by lowering the switching costs that patients experience when moving from one provider to another. In its absence, providers can use the switching costs and barriers to entry associated with incompatible health information systems to impede patient mobility and competition between providers.

Barriers to Interoperability

Medical Complexity

The vast biologic complexity underlying human health is an intrinsic barrier to interoperability. This complexity means that a given diagnosis, treatment or procedure in

medical records can be recorded in many different ways. Sharing the underlying biological, microbial, genetic and protein data is even harder.

Lack of Business Drivers

Most of United States healthcare employs a fee-for-service model, where clinicians and health systems bill patients or their payers for each service (test or procedure) used rather than for the value of that service. Under this model, a hospital can generate more revenue by ordering its own imaging or lab tests rather than using results previously gathered by another provider. The fee-for-service model provides little incentive to connect with other clinicians or service providers and leads to significant disconnects across the care continuum, including among long-term and post-acute care facilities, outpatient services and support providers, behavioral health providers, free-standing imaging centers, and emergency medical services.

Not surprising, health IT installations interoperate more readily with other sites under the same ownership. Across the country, large health systems are acquiring small hospitals and provider practices, and limiting communications outside of their own network. This network effect can raise barriers to entry and provider competition. These acquisitions are designed to allow the systems to dictate prices to insurers and to craft narrow referral networks that also result in higher prices and difficult or disproportionately costly access for out-of-network services. In cases where there are less-expensive local competitors,

health systems have reportedly blocked use of those services by refusing to allow electronic orders for those services, such as imaging tests, to be sent outside of their system.

Lack of Accessible Application Programming Interfaces

The consumer app economy has blossomed in recent years, due in great part to data holders publishing application programming interfaces (APIs) that open their databases to third- party software developers. For example, ride-sharing apps rely on many different APIs to offer their service (i.e., mapping APIs for location, banking APIs for payments). In contrast, most medical data captured in electronic health records (EHRs) today is not readily accessible through APIs. Typically, EHR developers have either not published their APIs, charged prohibitively high fees, or set onerous contractual conditions to use their APIs. Lack of API access discourages new market entrants and new business models. Even if API access were opened, however, different classification ontologies would limit their utility. Accordingly, this would need to be addressed as well.

Lack of Network Exchange

Most systems do not or cannot communicate with one another. There are currently more than 100 regional and state health-information networks. Additionally, some EHR

developers have their own networks for their customers. Limited interoperability often affects patients who may be traveling and cannot retrieve their records from home. Therefore, it is often impracticable to query for information across networks for even one patient. Importantly there are also no standards-based APIs to allow payers to query provider EMR databases to get information about more than one of their patients at a time. Thus, payers have almost no computational way to get clinical data and have to rely on inference from claims data. Payers have a difficult time measuring and paying for care based on provider clinical performance and must rely on narrow quality measures or one- off data extracts to contract intelligently.

Overcoming Interoperability Barriers and the 21st Century Cures Act

Congress passed the 21st Century Cures Act in December 2016. Provisions in the act calling for usability and interoperability reflect the broad national consensus that the 2009 HITECH Act's $30 billion- plus EHR stimulus program did not materially address either usability or interoperability despite leading to widespread EHR purchases.

The 21st Century Cures Act provides powerful tools to increase the interoperability of health data and, by extension, market competition. Three pro-competitive provisions are worth noting specifically. First, the Cures Act defines information blocking broadly and outlaws it. In doing so, the Cures Act bans the practice of providers blocking access to an individual's health data. This will ease patients' ability to seek alternative providers or types of care. The legislation charged HHS with crafting a narrow set of exceptions to adequately address any concerns about privacy, security and appropriate patient care that might arise by enacting this provision.

A second major health IT provision of the Cures Act is the mandate to create a "Trusted Exchange Framework" and a "Common Agreement" to get the various health information networks to share data. ONC supervision here is needed to expand the "permitted purposes" of data sharing to facilitate data flow and more competitive markets.

The third key provision is the requirement that developers of certified electronic health records publish application programming interfaces and allow "health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces." This "open API" requirement is designed to foster plug-and-play capability with apps. The "without special effort" provision means the API must use modern industry software design and healthcare interoperability standards. Importantly, the availability of an open API should allow for population-level queries of batch data. Today there is no reasonable data standard for an insurer to get easily computable data across the population of patients a provider sees. Moreover, American healthcare providers have almost no computational accountability for the care they provide. The national discussions about "learning health systems," "big data," and machine learning are meaningless without computational access to clinical data sets. That is why many large American payers are working in

conjunction with ONC and the Health Level Seven International (HL7) FHIR standards group to build out these computational accountability standards.

CMS proposed requirements that promote interoperability of health data in their 2019 payment rules and is overhauling the EHR Incentive Program (formerly known as “Meaningful Use”) to an interoperability-focused program now renamed “Promoting Interoperability.” In the 2019 IPPS (Inpatient Prospective Payment System) rule, CMS has incentivized a number of interoperability measures including closing the referral loop through health information exchange and providing patients electronic access to view, download and transmit their data. The IPPS and other CMS payment rules in the public comment period also provide incentives to use the electronic health records certified to the 2015 standards (which support APIs). CMS’ Blue Button 2.0 initiative allows Medicare beneficiaries complete access to their Medicare claims data and will significantly improve beneficiary experience by providing this data in a universal and secure digital format that patients can share with the care provider of their choosing. Giving patients complete access to their claims data will break down barriers to interoperability by allowing patients to see a full picture of their care encounters and prescriptions on the device of their choosing as

they share it with their care team. CMS is also calling on all health insurers to release their claims data in a similar fashion to the Blue Button 2.0 initiative so that all patients have the same benefits as Medicare beneficiaries.

To promote data sharing and care coordination further, CMS is ensuring that patients have access to their healthcare data after a hospital discharge, and that their data are transferred with them to their next care setting. ONC and CMS are working on identifying the key provider burdens generated by using current electronic medical records and working on strategies to address these burdens.

Recommendations: Improve Health IT

- The administration should expeditiously implement provisions of 21st Century Cures Act to prevent information blocking, make it easier for patients anywhere to get their core health information, support “Open Application Programming Interfaces” to allow patients to get data on their smart phones, and encourage support of population-level data queries to allow payers electronic access to clinical data.
- CMS and ONC should continue work on documentation burden reduction to allow EHRs to provide informative medical records rather than boilerplate text for providers and patients.
- CMS should continue its emphasis on fostering interoperability across the healthcare sector.

- CMS should continue its efforts to make data available to patients through efforts such as “MyHealthEData” and Blue Button 2.0.
- ONC should continue making standards more comprehensive and robust.

Summary of Recommendations to Restore Choice and Competition to the Healthcare Sector

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.
- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.
- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of state licensure standards and approaches to telehealth.
- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.
- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted “residency waivers,” allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign-trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President’s Budget, the federal government should streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities.
- The administration should continue the work done by the HRSA’s National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
    - The administration’s workforce development programs.
    - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example

by ensuring that competitors of CON applicants cannot weigh in on these applications.

- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the

benefits and disadvantages of CON and COPA statutes and regimes.

- States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.

- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.

- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA- qualified non-group premiums, allowing Medicare beneficiaries in enrolled high- deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.
- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.
- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to

their employees, and to allow HRAs to be used in conjunction with non-group coverage.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.
- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In delivering these reforms, Congress should account for differing levels of patient acuity.
- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

- As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the number of measures where the expected cost of collecting the measure exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.
- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that

can increase the competitiveness of small practices through access to shared resources and help build capacity for care management.

- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.

- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by making it easier to pay for their healthcare directly. Actions might include:
    - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
    - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.
- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

Recommendations: Improve Health IT

- The administration should expeditiously implement provisions of 21st Century Cures Act to prevent information blocking, make it easier for patients anywhere to get their core health information, support “Open Application Programming Interfaces” to allow patients to get data on their smart phones, and encourage

support of population-level data queries to allow payers electronic access to clinical data.

- CMS and ONC should continue work on documentation burden reduction to allow EHRs to provide informative medical records rather than boilerplate text for providers and patients.
- CMS should continue its emphasis on fostering interoperability across the healthcare sector.
- CMS should continue its efforts to make data available to patients through efforts such as “MyHealthEData” and Blue Button 2.0.
- ONC should continue making standards more comprehensive and robust.

Footnotes to Trump Proposals, 2017

2 Assistant Secretary for Planning and Evaluation. Individual market premium changes: 2013-2017. May 23, 2017. https://aspe.hhs.gov/system/files/pdf/256751/IndividualMarketPremiumChanges.pdf. Accessed August 21, 2018. 3 Sawyer B, Cox C, Claxton G. An analysis of who is most at risk for high out-of-pocket health spending. Kaiser

Family Foundation. Washington DC. October 4, 2017. https://www.healthsystemtracker.org/brief/who-is-most-at-risk- for-high-out-of-pocket-health-spending/. Accessed September 27, 2018

4 Table 3. ASPE Research Brief. Health plan choice and premiums in the 2018 Federal Health Insurance Exchange. October 30, 2017. https://aspe.hhs.gov/system/files/pdf/258456/Landscape_Master2018_1.pdf. Accessed September

20, 2018.

5 Kaiser Family Foundation. 2018 Employer Health Benefits Survey, Summary of Findings. https://www.kff.org/report-section/2018-employer-health-benefits-survey-summary-of-findings/

6Centers for Medicare & Medicaid Services. National Health Expenditure Data-2016. . https://www.cms.gov/Research- Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf.

Accessed August 21, 2018.

10 Perry MJ. Chart of the day (century?): price changes 1997 to 2017. American Enterprise Institute. February 2, 2018. http://www.aei.org/publication/chart-of-the-day-century-price-changes-1997-to-2017/. Accessed August 21, 2018.

11 Cooper Z, Craig S, Gaynor M, Van Reenen J. The price ain't right? Hospital prices and health spending on the privately insured. National Bureau of Economic Research 21815. May 2018. This study estimates that the average prices at hospitals without local competitors are 12.5 percent higher than prices at hospitals with four or more competitors. For example, a 12.5 percent cost increase on an average admission would amount to almost $1,800. 12 Dafny L, Gruber J, Ody C, More insurers lower premiums: evidence from initial pricing in the health insurance marketplaces. *Am J Health Econ*. 2015; 1(1):53-81.

13 Van Parys J. ACA marketplace premiums grew more rapidly in areas with monopoly insurers than in areas with

more competition. *Health Aff*. 2018 Aug; 37(8):1243-1251. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.0054. Accessed September 20, 2018.

14 Dafny L, Duggan M, Ramanarayanan S. Paying a premium on your premium? Consolidation in the US health insurance industry. *Am Econ Rev*. 2012;102(2):1161-1185.

15 *Id*.

16 Guardado JR, Emmons DW, Kane CK. The price effects of a large merger of health insurers: a case study of UnitedHealth-Sierra. *Health Management, Policy and Innovation*. 2013;1(3):16-35.

17 For surveys of the research literature linking market-based competition among healthcare providers to positive results for consumers, such as reduced prices and improved quality of care, see, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation. The Synthesis Project. Policy Brief. No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018; Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 J *Econ Lit*. 2015;53(2):235. https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

Accessed August 21, 2018.

18 Kessler DP, McClellan MB. Is hospital competition socially wasteful? *Q J Econ*. 2000;115(2): 577-615.

19 Benjamin EJ, Blaha MJ, Chiuve SE, et al.; on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association [published online ahead of print January 25, 2017]. doi: 10.1161/CIR.0000000000000485. https://healthmetrics.heart.org/wp-

content/uploads/2017/06/Heart-Disease-and-Stroke-Statistics-2017- ucm_491265.pdf. Accessed August 21, 2018.

20 Herrick DM. The Market for Medical Care Should Work Like Cosmetic Surgery. National Center for Policy Analysis Policy report No. 349. Dallas, TX. May 2013. https://www.healthworkscollective.com/wp- content/uploads/2013/06/st349.pdf. Accessed September 28, 2018

21 *Id*.

22 Benjamin EJ, Blaha MJ, Chiuve SE, et al., on behalf of the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2017 update: a report from the American Heart Association [published online ahead of print January 25, 2017]. doi: 10.1161/CIR.0000000000000485. P. 5. https://healthmetrics.heart.org/wp-content/uploads/2017/06/Heart-Disease-and-Stroke-Statistics-2017- ucm_491265.pdf. Accessed August 21, 2018.

23 Haislmaier E. The 2017 health Insurance exchanges: major decrease in competition and choice. The Heritage Foundation. https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-exchanges-major-decrease- competition-and-choice. Accessed April 11, 2018.

24 Mendelson D. Experts predict sharp decline in competition across the ACA exchanges. Avalere. August 19, 2016. http://avalere.com/expertise/life-sciences/insights/experts-predict-sharp-decline-in-competition-across-the-aca-exchanges. Accessed August 21, 2018.

25 County by county analysis of plan year 2018 insurer participation in health insurance exchanges. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2017-10-20-Issuer- County-Map.pdf. Accessed August 21, 2018.

26 Lee MH, Schuur JD, Zink BK. Owning the cost of emergency medicine: beyond 2%. *Ann Emerg Med*. 2013;62(5):498-505.

27 Spending on shoppable services in healthcare. Healthcare Cost Institute. Issue Brief No. 11. March 2016. https://www.healthcostinstitute.org/images/easyblog_articles/110/Shoppable-Services-IB-3.2.16_0.pdf. Accessed August 21, 2018.

28 While a theoretical possibility, the empirical evidence for such economies of scale is weak. A recent health economics paper looking at the impact of hospital mergers on costs summarized the extant literature, stating, “On balance, the evidence thus far fails to support strong claims of systematic cost savings from mergers; while these articles typically find cost savings for at least some subset of studied mergers, overall the evidence is mixed.” Schmitt

M. Do hospital mergers reduce costs? *J Health Econ*. 2017;52:75.

29 In World War II, employers offered health insurance as a way to get around wage controls. The IRS then decided that those health insurance benefits would not be taxed as income, and Congress codified the practice in 1954.

30 Goldhill D. *Catastrophic Care: Why Everything We Think We Know about Health Care is Wrong*. New York: Vintage Books; 2013

31 Allen M. Why your health insurer doesn't care about your big bills. NPR. May 25, 2018. https://www.npr.org/sections/health-shots/2018/05/25/613685732/why-your-health-insurer-doesnt-care-about-your-big- bills. Accessed September 20, 2018.

32 Tullock G. The welfare costs of tariffs, monopolies, and theft. *West Econ J*. 1967;5(3):224–232; Murphy KM, Shleifer A, Vishny RW. Why is rent-seeking so costly to growth? *Am Econ Rev*. 1993;83(2):409–414.

33 See, for instance, the *Statement of the Federal Trade Commission in the Matter of Phoebe Putney Health Services, Inc., et al.*, Dkt. No. 9348 (Sept. 4, 2014), discussing entry restrictions imposed by Georgia's Certificate of Need

(CON) law: "Moreover, this case also illustrates how state CON laws, despite their original and laudable goal of reducing healthcare facility costs, often act as a barrier to entry to the detriment of competition and healthcare consumers." Available online at https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 21, 2018.

34 Pope C. How the ACA fuels healthcare market consolidation. The Heritage Foundation. August 1, 2014. https://www.heritage.org/health-care-reform/report/how-the-affordable-care-act-fuels-health-care-market- consolidation. Accessed August 21, 2018.

35 Council of Economic Advisers. 2018 Economic Report of the President. Washington DC. February 2018. https://www.whitehouse.gov/wp-content/uploads/2018/02/ERP_2018_Final-FINAL.pdf. Accessed September 28, 2018.

36 Baiker K, Taubman SL, Allen HL, Bernstein M, Gruber JH, Newhouse JP, et al. The Oregon experiment —effects of Medicaid on clinical outcomes. *N Engl J Med*. 2013 May 2; 368:1713-1722. https://www.nejm.org/doi/full/10.1056/NEJMsa1212321. Accessed September 20, 2018.

37 Finkelstein A, Hendren N, Luttmer EFP. The value of Medicaid: Interpreting results from the Oregon health insurance experiment. NBER Working Paper No. 21308. Cambridge, MA. June 2015. http://www.nber.org/papers/w21308. Accessed September 27, 2018.

38 Finkelstein A, Mahoney N, Notowidigdo MJ. What does (formal) health insurance do, and for whom? *Annu Rev Econom*. 2018;10:261-286

39 Murphy S, Xu J, Kochanek K, Arias E. Mortality in the United States, 2017. National Center for Health Statistics. November, 2018. https://www.cdc.gov/nchs/products/databriefs/db328.htm. Accessed November 30, 2018.

40 Dayaratna K. Studies Show: Medicaid Patients Have Worse Access and Outcomes than the Privately Insured. The Heritage Foundation. November 7, 2012. https://www.heritage.org/health-care-reform/report/studies-show-medicaid- patients-have-worse-access-and-outcomes-the. Accessed September 20, 2018.

41 Gawande A. Overkill. *The New Yorker*. May 11, 2015. https://www.newyorker.com/magazine/2015/05/11/overkill- atul-gawande. Accessed September 20, 2018.

45 Mathews AW. Behind your rising health-care bills: secret hospital deals that squelch competition. *Wall Street Journal*. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-

that-squelch-competition-1537281963. Accessed September 20, 2018.

46 Haas-Wilson D. *Managed Care and Monopoly Power: The Antitrust Challenge*. Cambridge: Harvard University Press; 2003; Dranove D, Lindrooth R. Hospital consolidation and costs: another look at the evidence. *J Health Econ*. 2003 Nov;22(6)983-997; Cuellar AW, Gertler PJ. Trends in hospital consolidation: the formation of local systems, *Health Aff*. 2003 Nov/Dec;22(6):77-87; Vogt WB, Town R. How has hospital consolidation affected the price and quality of hospital care? *Synth Proj Res Synth Rep.* 2006 Feb;(9):pii. https://www.ncbi.nlm.nih.gov/pubmed/22051574. Accessed August 21, 2018.

47 Chart 2.9: announced hospital mergers and acquisitions, 1998-2015. American Hospital Association. Trendwatch Chartbook 2016 Organizational Trends. 2016.

https://www.aha.org/system/files/research/reports/tw/chartbook/2016/chart2-9.pdf. Accessed August 21, 2018.

48 15 U.S.C. § 18. Section 7 of the Clayton Act prohibits mergers if “in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.”

49 See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town

RJ. Competition in healthcare markets. In *Handbook of Health Economics.* Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 J *Econ Lit*. 2015;53(2):235, 294, (2015). https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

50 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 1. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018, Studies cited include Haas-Wilson D, Garmon C. *Hospital mergers and competitive effects: two retrospective analyses*. *Int J Econ Bus*. 2011:17, 30 (post-merger review of Agency methods applied to two hospital mergers; data "strongly suggests" that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Dafny

L. Estimation and identification of merger effects: an application to hospital mergers. *J Law Econ*. 2009;52(3):523, 544 ("[H]ospitals increase price by roughly 40 percent following the merger of nearby rivals"); Capps C, Dranove D, Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 ("Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices."); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti- competitive price increases).

51 Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):382 (corroborating Michael G. Vita MG, Sacher S. The competitive effects of not-for-profit hospital mergers: a case study. *J Indus Econ*. 2001;49:63).

52 *Id*.

53 See, e.g., Ginsburg PB. Wide variation in hospital and physician payment rates evidence of provider market Power. Center for Studying Health System Change, Research Brief No. 16. November 2010. http://www.hschange.org/CONTENT/1162/. Accessed August 21, 2018.

54 Gaynor M. Competition policy in healthcare markets: navigating the enforcement and policy maze. *Health Aff*. 2014 Jun;33:1088.

55 Tenn S. The price effects of hospital mergers: a case study of the Sutter-Summit Transaction. *Int J Econ Bus*. 2011;18:65-82.

56 See, e.g., *In the Matter of Hospital Corp. of Am.*, 106 FTC 361 (1985), aff'd, 807 F.2d 1381 (7th Cir. 1986);

American Med. Int'l, Inc., 104 FTC 1 (1984), as modified by 104 FTC 617 (1984) and 107 FTC 310 (1986).

57 *Columbia/HCA Health Care Corp./Healthtrust, Inc.—The Hosp. Co.*, 120 FTC 743 (1995) (consent order); *Healthtrust, Inc.—The Hosp. Co./Holy Cross Health Servs. of Utah*, 118 FTC. 959 (1994) (consent order); *Columbia Health* Corp./HCA-Hosp. Corp. of Am., 118 FTC 8 (1994) (consent order).

58 *FTC v. Tenet Health Care Corp*., 186 F.3d 1045 (8th Cir. 1999); *FTC v. Freeman Hosp*., 911 F. Supp. 1213 (W.D.

Mo. June 9, 1995), aff'd, 69 F.3d 260 (8th Cir. 1995); *California v. Sutter Health Sys*., 84 F. Supp.2d 1057 (N.D. Cal.

2000), aff'd, 217 F.3d 846 (9th Cir. 2000), amended by 130 F. Supp. 2d 1109 (N.D. Cal. 2001); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, (E.D.N.Y. 1997); *FTC v. Butterworth Health Corp*., 946 F. Supp. 1285 (W.D. Mich. 2006), aff'd *per curiam*, 121 F.3d 708 (6th Cir. 1997); *United States v. Mercy Health Servs. & Finley Tri-States Health Group, Inc.*, 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3d 632 (8th Cir. 1997).

59 See Romano PS, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health . *Int J Econ Bus*. 2011;18:45; Haas-Wilson D, Garmon C. Two hospital mergers on Chicago's North Shore: a retrospective study. *Int J Econ Bus*. 2011;18:17; Thompson A. Effect of hospital mergers on inpatient prices: a case study of the New Hanover-Cape Fear transaction. *Int J Econ Bus*. 2011;18:91; Tenn

S. The price effects of hospital mergers: a case study of the Sutter-Summit transaction. *Int J Econ Bus*. 2011;18 :65. For an overview, see Ashenfelter O, Hosken D, Vita M, Weinberg M. Retrospective analysis of hospital mergers. *Int J Econ Bus*. 2011;18:5-16; Farrell J, Pautler PA, Vita MG. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Rev Indus Org*. 2009;35:375-383.

60 *In the Matter of Evanston Northwestern Health Corp*., FTC Dkt. No. 9315 (Opinion of the Commission, Aug. 6, 2007).

61 The agencies analyze hospital mergers using the same analytical framework they use for other mergers, following the 2010 Horizontal Merger Guidelines, which specify that "mergers should not be permitted to create, enhance, or entrench market power or to facilitate its exercise." U.S. Department of Justice and Federal Trade Commission.

Horizontal Merger Guidelines. § 1. August 19, 2010.
http://www.ftc.gov/os/2010/08/100819hmg.pdf. Accessed August 21, 2018.

62 P*roMedica Health System, Inc. v. FTC*, No. 12-3583 (6th Cir. Apr. 22, 2014).

63 *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *FTC v. Penn State Hershey Med. Center*, 838 F.3d 327 (3rd Cir. 2016).

64 *FTC and State of Ohio v. St. Luke's Health Sys., Ltd.*, Case No. 1:13-CV-00116-BLW (D. Idaho Jan. 24, 2014).

65 *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015). See also *FTC et al. v. Sanford Health,* No. 1-17-cv-133 (memorandum decision Dec. 15, 2017).

66 *Statement of the Commission, Phoebe Putney Health System, Inc.*, Dkt. No. 9348 (Mar. 31, 2015), https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 22, 2018.

67 As noted earlier, commonly used measures of concentration in the literature may be misleading and not as meaningful regarding the level of competition, compared to measures that take into account specific market attributes such as the set of competing suppliers in a particular local area or underlying market forces that may or may not be related to the competitiveness of a market.

68 U.S. Department of Justice and Federal Trade Commission. *Horizontal Merger Guidelines*. Section 1. August 19, 2010. http://www.ftc.gov/os/2010/08/100819hmg.pdf. Accessed August 21, 2018.

69 For example, consider 10 properly defined identical geographic markets, each served by a distinct monopolist hospital. Within the actual geographic markets, the HHIs would be 10,000. If all 10 of those hospitals were to merge into a hospital system, the post-merger HHI in each properly defined market would still be 10,000, so there would be no change. However, if the market was defined too broadly to include all of these true geographic markets, the pre- merger HHI would reflect 10 hospitals each having a 10 percent market share, or 10×102=1,000, and the post-merger HHI would be 10,000. Defining the market too broadly suggests that this merger increased concentration significantly even though it did not change the competitive landscape in any properly defined geographic market. Alternatively, suppose each of these identical geographic markets was served by two identical hospitals each, all of which are initially independent. The HHI in each geographic market would be 502+502=5,000. Suppose a hospital system forms by combining the two hospitals in one of these geographic markets. The HHI in that geographic market would now be 10,000. Now, suppose that the market was again defined overly broadly to include all 20 hospitals in 10 geographic markets. The pre-merger HHI would reflect 20 hospitals, each with a 5 percent share, or 20× 52=500, and the post- merger HHI would be 18×52+102=550. The very significant increase in concentration in the one geographic market impacted by the merger is muted by absence of change in the nine other geographic markets.

70 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

71 See Gaynor M, Ho K, Town RJ. The industrial organization of healthcare markets. *J Econ Lit* 2015;53(2):235-284. 72 In this and similar analyses, all hospitals in the same system are treated as part of the same "firm" for purposes of evaluating market concentration indices.

73 Gaynor, et al. used a population weighted average mean in computing their mean HHI. They also dropped any MSA for which the population exceeded 3 million. They did so because in it is likely that there were multiple relevant hospital markets in these MSAs. Hence, the MSA-level HHI is more likely to be uninformative in these MSAs. See Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284.

74 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

75 See Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff*. 2017;36(9):1530-1538.

76 Methodological differences between the two studies largely explain this difference in the mean HHI. Specifically, Fulton applied an unweighted mean HHI across MSAs, whereas, as noted above, Gaynor, et al. applied a population- weighted mean. Since lower-population MSAs are generally more concentrated than higher-population MSAs, weighting the mean HHI by MSA population will likely result in a significantly lower mean HHI. This methodological difference likely explains most the jump in the mean HHI in 2006 found by Gaynor, et al. and the mean HHI in 2010 found by Fulton. Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284 and Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff*. 2017;36(9):1530-1538.

77 Among specialist physicians, Fulton included cardiologists, hematologists/oncologists, radiologists, and orthopedists. To calculate the specialist-physician HHI at the MSA level, he calculated the HHI for each of the aforementioned specialties, and then calculated a weighted average of the HHI across specialties at the MSA level. Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff*. 2017;36(9):1530- 1538.

78 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-

your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

79 See Kleiner S, Lyons S, White WD. Provider concentration in markets for physician services for patients with traditional Medicare. *Health Management, Policy and Innovation* 2012;1(1):3–18.

80 See Baker L, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending." *Health Aff*. 2014;33(5):756-763.

81 See Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. Working Paper. 2017. Available at http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html.

82 MedPAC. Report to Congress: Medicare and the health care delivery system. Policy Brief. June 2013. http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html. Accessed August 22, 2018.

83 Kocher R, Sahni NR. Hospitals' race to employ physicians—the logic behind a money-losing proposition. *N Engl J Med*. 2011;364(19):1790-1793.

84 See, for example, the FTC's 2013 enforcement action challenging the acquisition of Saltzer Medical Group by St. Luke's Health System. While some people characterized the transaction as a vertical one, the FTC alleged, and the court found, that the combination of the hospital's employed physicians and Saltzer's 16 primary care physicians would lead to higher reimbursement rates for adult primary care services in Nampa, Idaho. *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015).

85 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 31-32. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

86 Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM. Occupational licensing. *J Econ. Persp* 2000;14:189,191.

87 See *Joint Hearing on Health Care and Competition Law and Policy Before the FTC and Department of Justice*, 33- 34 (Jun. 10, 2003), (statement of Dr. Morris Kleiner). http://www.ftc.gov/sites/default/files/documents/public_events/health-care-competition-law-policy- hearings/030610ftctrans.pdf. Accessed August 22, 2018.

88 Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix*. 2014;24:143,163; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic

Advisors, and the Department of Labor. July 2015, at 7 n.6, 31-34. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

89 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation 4-16. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018.
90 See, e.g., *Prepared Statement of the Federal Trade Commission on Competition and Occupational Licensure, Before the H. Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial, and Antitrust Law,* 115th Cong., 7-8 (Sept. 12, 2017).

https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_ 2017_vote.pdf. Accessed August 22, 2018; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives- competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

90 See, e.g., *Prepared Statement of the Federal Trade Commission on Competition and Occupational Licensure, Before the H. Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial, and Antitrust Law,* 115th Cong., 7-8 (Sept. 12, 2017).

https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_ 2017_vote.pdf. Accessed August 22, 2018; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives- competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

91 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-13; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation, at 3. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014, at 14-15. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

92 *Id. Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses, supra note 86, at 14.*; *Prepared Statement of the Federal Trade Commission on Competition and the Potential Costs and Benefits of Professional Licensure, Before the*

H. Comm. on Small Business, 113th Cong. (July 16, 2014), https://www.ftc.gov/system/files/documents/public_statements/568171/140716professionallicensurehouse.pdf. Accessed August 22, 2018. Correspondingly, the adoption of regulations that recognize new provider categories can sometimes lower the average regulatory burden placed on certain healthcare services, to the extent that these newly licensed workers may compete with professionals in established licensure categories.

93 Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM.

Occupational licensing. *J Econ. Persp*. 2000;14:13-14. By restricting the entry of competitors, licensure can restrict supply, which can increase the income of incumbents (at consumer expense) or decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience. See also Kleiner MM, Krueger AB. Analyzing the extent and influence of occupational licensing on the labor market. 31 *J Lab Econ*. 2013 Apr;31 S1, Part 2:73,75.

94 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 30. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix*. 2014;24:157.

95 *License to Compete: Occupational Licensing and the State Action Doctrine, Hearing Before the S. Comm. on the Judiciary, Subcomm. on Antitrust, Competition Pol'y and Consumer Rights*, 114th Cong., 1 (Feb. 2, 2016); *cf. N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015).

96 See, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:98-103,157- 161, annex 3-1; Eibner CE, Hussey PS, Ridgely MS, McGlynn EA. Controlling healthcare spending in Massachusetts: an analysis of options. RAND Health Report Submitted to the Commonwealth of Massachusetts. August 2009. http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf. Accessed August 22, 2018; National Governors Association (NGA). The role of nurse practitioners in meeting increasing demand for primary care. 2012:7-8 (study funded by U.S. Department of Health and Human Services, reviewing literature pertinent to nurse-practitioner (NP) safety and concluding: "None of the studies in the NGA's literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures.")

97 U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse- Midwives: A Policy Analysis*. Health Technology Case

Study 37. OTA-HCS-37. Washington, DC: U.S. Government Printing Office; December 1982:39. https://www.princeton.edu/~ota/disk2/1986/8615/8615.PDF. Accessed August 22, 2018. ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].")

98 Jorgenson D, Dalton D, Farrell B, Tsuyuki RT, Dolovish L. Guidelines for pharmacists integrating into primary care teams. *Can Pharm. J.* 2013 Nov;146(6):342-352; Durham MJ, Goad JA, Neinstein LS, Lou M. A comparison of pharmacist travel-health specialists' versus primary care providers' recommendations for travel-related medications, vaccinations, and patient compliance in a college health setting. *J Travel Med*. 2011 Jan-Feb;18(1):20-25; Hecox N. Tuberculin skin testing by pharmacists in a grocery store setting. *J Am Pharm Assoc*. 2008 Jan-Feb;48(1):86-91.

99 FTC, Bureau of Consumer Protection. *Staff Report on Advertising of Ophthalmic Goods and Servs and Proposed Trade Reg. Rule*, 16 CFR Part 456, 17-19 (1977).

For example, dental hygienists can provide preventive dental care, while dental therapists can provide limited restorative services as well as preventive services. Dentists can provide these services as well as the full range of more complex dental services. See, e.g., *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-ohio-state-senate-regarding- competitive-effects-sb-330-increasing-access-quality/v170003_ftc_staff_comment_to_ohio_state_senate_re_ohio_sb_330_re_dental_therapists_and_hygienists.pdf (accessed September 26, 2018); *FTC Staff Comment Before the Commission on Dental Accreditation Concerning Proposed Accreditation Standards for Dental Therapy Education Programs* (2013). https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-commission-dental- accreditation-concerning-proposed-accreditation-standards-dental/131204codacomment.pdf. Accessed September 20, 2018.

101 We use the term broadly, acknowledging that "[t]he allied health workforce includes hundreds of professionals employed in different professions with different job duties and different levels of preparation, but there is no single definition of "allied health" or list of allied health occupations. All formulations exclude physicians and dentists, and most exclude nurses. Others exclude pharmacists, physician assistants, and more." IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011.

102 Institute of Medicine, National Acad. of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:27; see also IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011:88 ("Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially

APRNs, in this area."). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. See, e.g., U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis*. Health Technology Case Study 37. OTA-HCS-37. Washington, D.C.: U.S. Government Printing Office; December 1986. ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].")

103 Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:4.

104 Improving efficiency in the healthcare system: removing anti-competitive barriers for advanced practice registered nurses and physician assistants. The Hamilton Project. Policy brief 2018-08. June 2018. http://www.hamiltonproject.org/assets/files/AM_PB_0608.pdf. Accessed August 22, 2018.

105 Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:5.

106 FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-

practice-nurses. Accessed August 22, 2018.

107 Dep't Veterans Affairs, Economic Impact Analysis for RIN 2900-AP44, Advanced Practice Registered Nurses, attachment 1, 5-7 (Nov. 9, 2016),

>https://www.va.gov/ORPM/docs/RegMgmt_ImpactAnalysis_AP44(F)_AdvancedPracticeRegisteredNurses.docx<.

108 *Id.* at 20.

109 *Id.* at 27.

110 See generally, e.g., FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation- advanced-practice-nurses. Accessed August 22, 2018, (regarding APRNs); *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/03/ftc-staff-comment-ohio-state-senate-regarding- competitive. Accessed August 22, 2018 (regarding dental therapy); *FTC Staff Comments to the Iowa Board of Physician Assistants on Proposed New Rules: 645—327.8: Definition of Physician*

Supervision of a Physician Assistant (2016). https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-professional-licensure- division-iowa-department-public-health-regarding-proposed/v170002_ftc_staff_comment_to_iowa_dept_of_public_health_12-21-16.pdf. Accessed August 22, 2018 (regarding physician assistants).

111 According to the American Association of Nurse Practitioners, 22 states plus the District of Columbia now grant full practice authority to APRNs. https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment. Accessed August 22, 2018. For examples of state restrictions on SOP besides supervision requirement see, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington, D.C.: National Academies Press; 2011:100-102, Box 3-1 Variation in State Licensure Requirements; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission.

March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018, at notes 35-37 and accompanying text.

112 Licensing rules are almost always state-based. See, e.g., *Dent v. West Virginia*, 129 U.S. 114 (1889) (upholding the authority of the State of West Virginia to license physicians); Health Resources and Services Administration, U.S. Department of Health and Human Services. Telehealth licensure report. Report 111-66. Special Report to the Senate Appropriations Committee (Requested by Senate). 2010. ("For over 100 years, health care in the United States has primarily been regulated by the states. Such regulation includes the establishment of licensure requirements and enforcement standards of practice for health providers, including physicians, nurses, pharmacists, mental health practitioners, etc.")

113 See, e.g., *Occupational Licensing: Regulation and Competition: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the House Comm. on the Judiciary,* 115th Cong. 1, 8-9 (2017) (statement of Maureen K. Ohlhausen, Acting Chairman, Federal Trade Commission). https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_

2017_vote.pdf. Accessed August 22, 2018; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-16. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

114 See, e.g., Health Resources & Services Administration, U.S. Department of Health & Human Services. *Special Report to the Senate Appropriations Committee, Telehealth*

Licensure Report, Requested by Senate Rep't 111-66 (2010), at 9, ("The basic standards for medical and nursing licensure have become largely uniform in all states.

Physicians and nurses must graduate from nationally approved educational programs and pass a national medical and nursing licensure examination.")

115 See, e.g., American Medical Association. Obtaining a medical license. http://www.ama- assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.page. Accessed August 22, 2018. ("The process of obtaining a medical license can be challenging and time consuming…. Physicians seeking initial licensure or applying for a medical license in another state should anticipate delays due to the investigation of credentials and past practice as well as the need to comply with licensing standards."); U.S. Department of the Treasury and U.S. Department of Defense, Supporting our military families: best practices for streamlining occupational licensing across state lines. February 2012:12-13. http://archive.defense.gov/home/pdf/Occupational_Licensing_and_Military_Spouses_Report_vFINAL.PDF. Accessed August 22, 2018. ("Nurses moving across state lines must apply for licensure by endorsement and pay any applicable fees.")

116 See, e.g., Nicholson S, Propper C. Medical workforce. In *Handbook of Health Economics*. Vol. 2. 1st ed. Waltham, MA: North Holland; 2012:885. (In medical labor markets, "[l]icensing is associated with restricted labor supply, an increased wage of the licensed occupation, rents, increased output prices, and no measurable effect on output quality.") 117 See, e.g., *Comment from FTC Staff to Department of Veterans Affairs*, 3 (Nov. 1, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-veterans-affairs- regarding-its-proposed-telehealth-rule/v180001vatelehealth.pdf. Accessed August 22, 2018. ("State laws and regulations that require licensure of telehealth providers licensed in another state inhibit VA employees from delivering telehealth services to beneficiaries in states in which they are not licensed.")

118 See, e.g., American Institute of Certified Public Accountants and National Association of State Boards of Accountancy. *Uniform Accountancy Act: Standards for Regulation*. 8th ed. Nashville, TN: American Institute of Certified Public Accountants; 2018. https://nasba.org/app/uploads/2018/02/Uniform-Accountancy-Act-%E2%80%93-Eighth-Edition-%E2%80%93-January-2018.pdf. Accessed August 22, 2018; Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-

_license_portability_transcript.pdf. Accessed August 22, 2018 (transcript of roundtable). (UAA mobility provisions adopted by 53 jurisdictions.) See also National Association of Boards of Pharmacy ("NABP"). *Comment to the FTC* (2017), at 1-2, https://www.ftc.gov/system/files/documents/public_comments/2017/07/00016-

141084.pdf. Accessed August 22, 2018. ("As required by the *NABP Constitution and Bylaws,* all NABP members participate in e-LTP and the NABP Clearinghouse.") The number of model laws with license portability provisions is unknown because they are not tracked by any organization.

119 U.S. Constitution Art. I, § 10, cl. 3.

120 See FTC Staff. Policy perspectives: options to enhance occupational license portability. Federal Trade Commission. September 24, 2018, at 9-10. https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-

license-portability/license_portability_policy_paper.pdf. Accessed September 26, 2018.

121 See, e.g., Interstate Medical Licensure Compact. http://www.imlcc.org/. Accessed August 22, 2018, (adopted by 22 states); Physical Therapy Licensure Compact. http://www.fsbpt.org/FreeResources/PhysicalTherapyLicensurecompact.aspx. Accessed August 22, 2018, (adopted by 16 states).

122 See 42 U.S.C. §254c-18; Office for the Advancement of Telehealth, U.S. Department of Health and Human Services. Funding Opportunity Announcement HRSA-16-014. 2016. https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm_rtc=16&dm_attid=2f 098e80-40a0-43ec-b4e7-2002033a031a. Accessed August 22, 2018.

123 See, e.g., Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 11-12, 16, 18-19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-_license_portability_transcript.pdf. Accessed August 22, 2018.

124 See, e.g., Rheuban KS. Welcome from IOM Planning Committee. *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary*. Washington, D.C.: The National Academies Press; 2012. http://www.nap.edu/catalog/13466/the-role-of-telehealth-in-an-evolving-health-care-environment. Accessed August 22, 2018. ("[T]elehealth programs have served as innovative tools for delivery of care, linking patients and providers separated by geographic and socioeconomic barriers, all the while mitigating specialty workforce shortages"); Committee on Geographic Adjustment Factors in Medicare Payment, Institute of Medicine. *Geographic Adjustment in Medicare Payment—Phase II, Implications for Access, Quality, and Efficiency*. Washington, D.C.: The National Academies Press; 2012:8. http://iom.nationalacademies.org/Reports/2012/Geographic-Adjustment-in-Medicare-Payment-Phase-II.aspx. Accessed August 22, 2018. (Telehealth is a "very promising and rapidly developing strategy to improve access and efficiency of care" and is being used by 50 medical subspecialties.)

125 See, e.g., Hilty DM, Ferrer DC, Parish MB, Johnson B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. *Telemed J E Health*. 2013 Jun;19(6):444, 449 (citing randomized controlled clinical trial of the use of telehealth services to treat depression and other mental conditions in adults). See also Gilman M, Stensland J. Telehealth and Medicare: payment policy, current use, and prospects for growth. *Medicare Medicaid Res Rev*. 2013;3(4):E1, E8. ("[O]f the 38,000 telehealth visits that Medicare beneficiaries had in 2009, most visits [62 percent] were for mental health services.")

126 See, e.g., Coates SJ, Kvedar J, Granstein RD. Teledermatology: from historical perspective to emerging techniques of the modern era. Part I: history, rationale, and current practice*. J Am Acad Derm*. 2015 Apr;72(4):563, 566-567; Coates SJ, Kvedar J, Granstein RD. From historical perspective to emerging techniques of the modern era. Part II: emerging technologies in teledermatology, limitations and future directions*. J Am Acad Derm*. 2015 Apr;72(4):577. 127 See, e.g., Fierson WM, Capone A. The American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, and the American Association of Certified Orthoptists. Telemedicine for evaluation of retinopathy of prematurity. *Pediatrics*. 2015 Jan;135(1):e238 (report providing guidance on the use of telemedicine- based retinal imaging techniques that "have the potential to allow diagnosis and monitoring of [retinopathy of prematurity] to occur in lieu of the necessity for some repeated on-site examinations in" neonatal intensive care units);

Silva PS, Aiello LP. Telemedicine and eye examinations for diabetic retinopathy: a time to maximize real-world outcomes. *JAMA Ophthalmol*. 2015 May;133(5):525 ("a telemedicine approach for diabetic retinopathy evaluation can effectively increase the rates of eye examinations, thereby potentially reducing the rates of blindness and vision loss in the diabetic population").

128 *See, e.g.,* Darkins A. U.S. Department of Veterans Affairs. In: Institute of Medicine of the National Academies. *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary.* Washington, DC: The National Academies Press; 2012: 99, 101. http://www.nap.edu/catalog/13466/the-role-of-telehealth-in-an-evolving-health-care- environment. Accessed August 22, 2018; Schwamm LH, Holloway RG, Amarenco P, Audebert HJ, Bakas T, Chumbler NR, et al. A review of the evidence for the use of telemedicine within stroke systems of care: a scientific statement from the American Heart Association/American Stroke Association. *Stroke.* 2009 Jul;40(7): 2630-2631 (recommending the use of telestroke, teleradiology, and other telehealth services for stroke care).

129 See, e.g., Mehrotra A. The convenience revolution for treatment of low-acuity conditions*. JAMA*. 2013;310:35, 36; Mehrotra A, Paone S, Martich GD, Albert SM, Shevchik GJ. A comparison of care at e-visits and physician office visits for sinusitis and urinary tract infections. *JAMA Int. Med*. 2013 Jan 14;173(1):72, 73.

130 See, e.g., *Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature* (March 25, 2016). https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/03/ftc-staff-comment-alaska-state-legislature- regarding. Accessed August 23, 2018. (Regarding telehealth provisions in Senate Bill 74, which would allow licensed Alaska physicians located out-of-state to provide telehealth services.) *See also* Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-

365. 2017. Highlights, at 21 ("[P]rovider and regional medical specialty shortages can be addressed through telehealth.") https://www.gao.gov/products/GAO-17-365#summary. Accessed August 23, 2018.

131 See generally Committee on Pediatric Workforce, Marcin JP, Rimsza ME, Moskowitz WB. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015 Jul;136(1):202, 203 ([U]rban as well as rural children "face significant disparities in access and time-distance barriers, which could be partly alleviated by the use of telehealth"); Bashshur RL, Shannon GW, Smith BR, Alverson DC, Antoniotti N, Barsan WG, et al. The empirical foundations of telemedicine interventions for chronic disease management. *Telemed J E Health*. 2014 Sep;20(9):769, 770 ("Differences in *access* to care reflect economic, geographic, and functional as well as social, cultural, and psychological factors….[M]any residents of the inner city have limited access to medical resources for economic reasons."); Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. *Ann Intern Med*. 2015 Nov 17;163(10):787 ("Limited access to care is not an issue specific to rural communities; underserved patients in urban areas have the same risks as rural patients if they lack primary or specialty care….")

132 See, e.g., Fish EM, Hickman SA, Chaudhry HJ. *SciTech Lawyer*. 2014;10:n.p. https://www.americanbar.org/content/dam/aba/publications/scitech_lawyer/2014/spring/state_licensure_regulations_evolve_to_meet_demands_modern_medical_practice.authcheckdam.pdf. Accessed August 23, 2018. ("Fifty-seven state medical and osteopathic boards and the District of Columbia Board of Medicine now require physicians engaging in telemedicine to be licensed in the state in which the patient is located."); Fleisher LD, Dechene JC. *Telemedicine and E-Health Law. N.p: Law Journal Press; 2014, 1.02[2] ("A large number of states require out-of-state telemedicine physicians to obtain a full, unrestricted medical license in order to 'see' patients in the state via telemedicine.")*

133 See, e.g., Thomas L, Capistrant, G. 50 state telemedicine gaps analysis: psychologist clinical practice standards & licensure. American Telemedicine Association. June 2016. https://higherlogicdownload.s3.amazonaws.com/AMERICANTELEMED/3c09839a-fffd-

46f7-916c-692c11d78933/UploadedImages/Policy/State%20Policy%20Resource%20Center/Psychol%20-%2050-state-telehealth- gaps-analysis-pysch-pgl_final.pdf. Accessed August 23, 2018. ("Across the care spectrum, inadequate licensure portability and arbitrary scope of practice standards challenge telehealth adoption and utilization….Mental and behavioral health providers are not spared from this fragmented policy landscape.")

134 See, e.g., Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. Ann Intern Med. 2015 Nov 17;163(10):App. ("One of the most significant challenges to wide-spread telemedicine adoption is reimbursement."); Burke BL, Hall WR, Section on Telehealth Care. Telemedicine: pediatric applications. Pediatrics. 2015 Jul;136(1):e294, e303 ("The most significant barriers are payment, licensing across state borders, and liability.")

135 See 42 U.S.C. § 1395m(m)(4)(C)(ii); 42 C.F.R. § 410.78(b)(3).

136 See 42 U.S.C. § 1395m(m)(4)(C)(i); 42 C.F.R. § 410.78(b)(4). See also Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-365. 2017. Highlights, at 8-9, 21-25. https://www.gao.gov/products/GAO-17-365#summary. Accessed August 23, 2018. (Medicare telehealth coverage restrictions that limit the geographic and practice settings in which beneficiaries may receive services are barriers to the use of telehealth). Legislators have been cautious about expanding coverage of telemedicine services in part because of concerns that its ease of use could lead to overutilization. In practice, however, Medicare telemedicine-related spending is very low. See ibid. at 14, 18 (in 2014, Medicare paid 175,000 telehealth claims for a total of about $14 million, less than 0.01 percent of the approximately $257 billion in total annual Medicare expenditures on Part B services); Neufeld JD, Doarn CR. Telemedicine spending by Medicare: a snapshot from 2012. Telemed J E Health. 2015 Aug;21(8):686-693. In addition, concerns about improper claims for reimbursement of telehealth services have been overblown. An Office of Inspector General (OIG) audit found that the Centers for Medicare and Medicaid Services (CMS) paid for some telehealth services that did not meet Medicare requirements, but most claims for telehealth services were appropriate. To reduce the number of unallowable claims, OIG recommended post-payment reviews to detect errors, and education and training of practitioners on Medicare telehealth requirements. See CMS paid practitioners for telehealth services that did not meet Medicare requirements. Department of Health and Human Services, Office of Inspector General. A-05-16-00058. April 2018. https://oig.hhs.gov/oas/reports/region5/51600058.pdf. Accessed August 23, 2018.

137 See, e.g., Comment from FTC Staff to the Delaware Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers 6 & nn.57, 59 (Nov. 29, 2016).

https://www.ftc.gov/system/files/documents/advocacy_documents/ftc- staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its- proposed-revisions-its/161130_ftc_dealers_final_.pdf. Accessed August 23, 2018. (Discussing initial in-person evaluation requirements before speech/language/pathology or audiology services may be provided by telehealth in Kentucky and Texas.) It is difficult to draw a bright line between services for which health and safety considerations warrant a prior in-person examination and those that do not, in part because rapid changes in technology and healthcare priorities may lead to changing views of the need for an in-person visit. See, e.g., Letter from Jonathan Linkous, chief executive officer, American Telemedicine Association, to Imelda L. Paredes, executive assistant, Drug Enforcement Administration, Department of Justice 8-11 (October 6, 2015). (Discussing changing views on telemedicine prescribing of controlled substances without a prior in-person examination). See also *FTC Staff Comment to Washington State Rep. Paul Graves, regarding S.S.B. 5411/H.B. 1473*, 4-5 (Feb. 9, 2018), https://www.ftc.gov/policy/advocacy/advocacy- filings/2018/02/ftc-staff-comment-washington-state-rep-paul-graves. Accessed August 23, 2018. This letter explains why allowing a practitioner to determine whether the use of telehealth care is appropriate is better than a rigid in-person examination requirement.

138 Centers for Medicare and Medicaid Services. National Health Expenditure Data. 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and- Reports/NationalHealthExpendData/downloads/highlights.pdf. Accessed September 21, 2018.

139 IMGs in the United States. Educational Commission for Foreign Medical Graduates. https://www.ecfmg.org/certification/imgs-united-states.html. Accessed September 21, 2018.

140 Baier E. Foreign-trained doctors could soon have easier path in MN. *MPR News*. February 27, 2015. https://www.mprnews.org/story/2015/02/27/foreign-trained-doctors. Accessed August 23, 2018.

141 Grisham S. Medscape physician compensation report 2017. Medscape. April 5, 2017.

https://www.medscape.com/slideshow/compensation-2017-overview-6008547. Accessed August 23, 2018.

142 The Complexities of Physician Supply and Demand: Projections from 2014 to 2025. Prepared for Association of American Medical Colleges. 2016 Apr 5: 5.

143 Carroll AE. Why America needs foreign medical graduates. *New York Times*. October 6, 2017. https://www.nytimes.com/2017/10/06/upshot/america-is-surprisingly-reliant-on-foreign-medical-graduates.html. Accessed August 23, 2018.

144 Conrad 30 J1 visa waiver requirements by state. U.S. Immigration Website. http://conrad30.com. Accessed August 23, 2018.

145 Patel D. Foreign doctors assist with Iowa's physician shortage. *Quad-City Times*. March 18, 2017. https://globegazette.com/business/foreign-doctors-assist-with-iowa-s-physician-shortage/article_d1549069-4d05-5f25- ad52-d804e4b0bee4.html. Accessed September 26, 2018.

146 Centers for Medicare and Medicaid Services. National Health Expenditure 2016 Highlights. 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf. Accessed September 21, 2018. One reason for lower foreign physician service prices, not discussed here, is the comparatively aggressive regulation of medical care delivery in other countries.

147 Squires D, Anderson C. U.S. healthcare from a global perspective: spending, use of services, prices, and health in 13 countries. The Commonwealth Fund. October 2015. http://johngarven.com/blog/wp- content/uploads/2017/07/Spending-Use-of-Services-Prices-and-Health-in-13-Countries-The-Commonwealth-Fund.pdf. Accessed September 21, 2018.

148 Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018. https://www.gao.gov/products/GAO- 18-240. Accessed August 23, 2018.

149 Association of American Medical Colleges, Liaison Committee on Medical Education (LCME), April 22, 2018. https://www.aamc.org/members/osr/committees/48814/reports_lcme.html

150 Table B-1.2: Total Enrollment at U.S. Medical School and Sex, 2013-2014 through 2017-2018. Association of American Medical Colleges. https://www.aamc.org/download/321526/data/factstableb1-2.pdf. Accessed August 23, 2018.

151 Table: Preliminary Enrollment Report Fall 2017. American Association of Colleges of Osteopathic Medicine. www.aacom.org/docs/default-source/data-and-trends/2017_fall_enrollment_report.pdf. Accessed August 23, 2018.

152 Heisler EJ, Panangala SV. The veterans health administration and medical education: in brief. Congressional Research Service. 7-5700. February 13, 2018. https://fas.org/sgp/crs/misc/R43587.pdf. Accessed August 23, 2018. 153 Roth AE, Peranson E. The redesign of the matching market for American physicians: some engineering aspects of economic design.” *Am Econ Rev*. 1999;89(4):748-780.

154 15 U.S.C. § 37b [Pension Funding Equity Act of 2004].

155 Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018. https://www.gao.gov/products/GAO- 18-240. Accessed August 23, 2018.

156 Eden J, Berwich D, Wilensky G., eds. *Graduate Medical Education That Meets the Nation's Health Needs*. Washington, D.C.: The National Academies Press; 2014:9.

157 Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018, at 10-12. https://www.gao.gov/products/GAO-18-240. Accessed August 23, 2018.

158 Physician workforce: HHS needs better information to comprehensively evaluate graduate medical education funding. U.S. Government Accountability Office. GAO-18-240. March 9, 2018, at 9. https://www.gao.gov/products/GAO-18-240. Accessed August 23, 2018.

159 Report to the Congress: aligning incentives in Medicare. Medicare Payment Advisory Commission (MedPAC). June 2010, at 109. http://www.medpac.gov/docs/default-source/congressional-testimony/20100623_EandC_Testimony_AligningIncentivesinMedicare.pdf?sfvrsn=0. Accessed August 23, 2018 ; see also Miller M. Graduate medical education payments. MedPAC. February 20, 2015. https://www.nhpf.org/uploads/Handouts/Miller-slides_02-20-15.pdf. . Accessed August 23, 2018; Wynn BO, Smalley R, Cordasco KM. Does It Cost More to Train Residents or to Replace Them? A Look at the Costs and Benefits of Operating Graduate Medical Education Programs. Santa Monica: Rand Corporation; 2013. https://www.rand.org/pubs/research_reports/RR324.html. Accessed August 23, 2018.

Report to the Congress: aligning incentives in Medicare. Medicare Payment Advisory Commission (MedPAC). June 2010, at 109.

http://www.medpac.gov/docs/default-source/congressional-testimony/20100623_EandC_Testimony_AligningIncentivesinMedicare.pdf?sfvrsn=0. Accessed August 23, 2018 ; see also Miller M.

Graduate medical education payments. MedPAC. February 20, 2015. https://www.nhpf.org/uploads/Handouts/Miller- slides_02-20-15.pdf. Accessed August 23, 2018; Wynn BO, Smalley R, Cordasco KM. Does It Cost More to Train Residents or to Replace Them? A Look at the Costs and Benefits of Operating Graduate Medical Education Programs. Santa Monica: Rand Corp.; 2013. https://www.rand.org/pubs/research_reports/RR324.html. Accessed August 23, 2018.

165 Federal Trade Commission and U.S. Department of Justice. Improving Health Care: A Dose of Competition. July 2004, ch. 8, at 1-6.

http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed August 23, 2018.

166 *See, e.g., Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of-Need (CON) Laws* and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust- division. Accessed August 23, 2018; *Joint Statement of the Federal Trade Commission and the Antitrust Division of the*

U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (2016). https://www.justice.gov/atr/file/812606/download. Accessed August 23, 2018. For selected FTC and Division comments regarding state CON laws from 2008 - 2016, see *Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would*

Repeal Alaska's CON Program (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement- federal-trade-commission-antitrust-division. Accessed August 23, 2018.

167 Pub. L. 93-641, 88 Stat. 2225 (1975) (codified at 42 U.S.C. §§ 300k-300n-5), *repealed*, Pub. L. 99-660, § 701, 100

Stat. 3799 (1986).

168 See Miles JJ. *Health Care and Antitrust Laws: Principles and Practice*. Vol. 2. N.p.:Thomson Reuters; 2003:

§16:1, at 16-2.

169 See Federal Trade Commission and U.S. Department of Justice. Improving Health Care: A Dose of Competition. July 2004, ch. 8, at 2. >http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf<. Accessed August 23, 2018; CHRISTINE L. WHITE ET AL., ANTITRUST AND HEALTHCARE: A COMPREHENSIVE GUIDE 527 (2013).

170 Regarding changes since 2011, see Koopman C, Philpot A. The state of certificate-of-need laws in 2016. Mercatus Center, George Mason Univ. September 27, 2016. https://www.mercatus.org/publications/state-certificate-need-laws- 2016. Accessed August 23, 2018; *cf.* CON – Certificate of Need State Laws. National Conference of State Legislatures, August 17, 2018, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx. Accessed September 26, 2018 (providing a table an interactive map representing some of the variation in state CON laws.).

171 Koopman C, Philpot A. The state of certificate-of-need laws in 2016. Mercatus Center, George Mason Univ. September 27, 2016.

https://www.mercatus.org/publications/state-certificate-need-laws-2016. Accessed August 23, 2018. New Hampshire is the state that most recently rescinded its CON requirements, with the enactment of NH SB481on June 6, 2016, effective July 1, 2016/ https://legiscan.com/NH/bill/SB481/2016. Accessed August 25, 2018. 172 Koopman C, Philpot A. The state of certificate-of-need laws in 2016. Mercatus Center, George Mason Univ.

September 27, 2016. https://www.mercatus.org/publications/state-certificate-need-laws-2016. Accessed August 23, 2018; Miles JJ. *Health Care and Antitrust Laws: Principles and Practice*. Vol. 2. N.p.:Thomson Reuters; 2003: §16:2, at 16-9.

173 Compare, e.g., OHIO ADMIN. CODE ANN. 3701-12-23, 23.2 (regarding certain activities by "long-term care" facilities

in Ohio) with OR. REV. STAT. § 442.315(1) (2017) (regarding "any new hospital or new skilled nursing or intermediate care service or facility" in Oregon, subject to certain exclusions).

174 For example, Connecticut generally requires a CON for establishment or acquisition of new healthcare facilities, Conn. Gen. Stat. § 19a-638(a), but exempts, e.g., residential care homes, nursing homes and rest homes, *ibid.* at § 19a- 638(b)(4), outpatient chronic dialysis services, *id.* at § 19a-638(b)(9), and transplant services, *ibid.* at § 19a-638(b)(10), among others. *See* Conn. Gen. Stat. § 19a-638(b)(1)-(22) (exemptions).

175 For example, Delaware requires a CON for a new facility, but only for capital expenditures by existing facilities in excess of $5.8 million (or a higher amount based on inflation). See 16 Del. C. § 9304.

176 For example, provisions of the Delaware Code requiring review, 16 Del. C. § 9304., are "[e]ffective until Dec. 31, 2020."

177 See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town RJ. Competition in healthcare markets. In *Handbook of Health Economics.* Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 J *Econ Lit*. 2015;53(2):235, 294, (201u5).
https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

Accessed August 21, 2018 (critical review of empirical and theoretical literature regarding markets in healthcare services and insurance).

178 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 1. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (citing, e.g., Haas-Wilson D, Garmon C. *Hospital mergers and competitive effects: two retrospective analyses*. *Int J Econ Bus*. 2011:17, 30 (post-merger review of agency methods applied to two hospital mergers; data "strongly suggests" that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Dafny L. Estimation and identification of merger effects: an application to hospital mergers. *J Law Econ*. 2009;52(3):523, 544 ("[H]ospitals increase price by roughly 40 percent following the merger of nearby rivals"); Capps C, Dranove D, Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 ("Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices."); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti- competitive price increases).

179 Sherman D. The effect of state certificate-of-need laws on hospital costs: an economic policy analysis. Federal Trade Commission. January 1988. https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs- economic-policy-analysis. Accessed August 23, 2018 (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data on 3,708 hospitals, that strong CON programs do not lead to lower costs but may actually increase costs); Noether M. Competition among hospitals. Federal Trade Commission. May 1987. https://www.ftc.gov/reports/competition-among-hospitals-0. Accessed August 23, 2018 (empirical study concluding that CON regulation led to higher prices and expenditures); Anderson KB, Kass DI. Certificate of need regulation of entry into home healthcare: a multi-product cost function analysis. Federal Trade Commission. January 1986.

180 *Health Care and Competition Law and Policy Hearings*. Federal Trade Commission. https://www.ftc.gov/news- events/events-calendar/2003/02/health-care-competition-law-policy-hearings. Accessed Dec. 2, 2015.

181 Federal Trade Commission and the U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 1-6. http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed August 23, 2018. 182 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*. October 26, 2015.

https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust- division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf.

Accessed August 23, 2018; Letter from Marina Lao, Director, Office of Policy Planning, Federal Trade Commission, et al., to The Honorable Marilyn W. Avila, N.C. House of Representatives. July 10, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-concurring-comment- commissioner-wright-regarding-north-carolina-house-bill-200/150113ncconadv.pdf. Accessed August 23, 2018; *Prepared Statement of the Federal Trade Commission Before the Florida State Senate*. April 2, 2008. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf. Accessed August 23, 2018; *Statement of the Antitrust Division*, *U.S. Department of Justice, Before the Florida Senate Committee on Health & Human Services*. March 25, 2008. http://www.justice.gov/atr/comments-competition-healthcare-and-certificates-need. Accessed August 23, 2018; *Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of- Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program* (2017) https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust- division. Accessed August 23, 2018; S*tatement of the Antitrust Division, U.S. Department of Justice, Before a Joint Session of the Health & Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia*. February 23, 2007. *http://www.justice.gov/atr/competition-healthcare-and-certificates-need.* Accessed August 23, 2018.

183 See, e.g., Bloom N, Propper C, Seiler S, Van Reenen JV. The impact of competition on management quality: evidence from public hospitals. *Rev Econ. Studies*. 2015 Apr 1;82(2):457, 457. ("We find that higher competition results in higher management quality.")

184 Vivian Ho & Meei-Hsiang Ku-Goto, State Deregulation and Medicare Costs for Acute Cardiac Care, 70 MED. CARE RES. & REV. 185, 202 (2012) (finding an association between the lifting of CON laws and a reduction in mean patient costs for coronary artery bypass graft surgery, and finding that these cost savings slightly exceed the fixed costs of new entrants); Patrick A. Rivers et al., The Effects of Certificate of Need Regulation on Hospital Costs, 36 J. HEALTH CARE FIN. 1, 11 (2010) (finding a positive relationship between the stringency of CON laws and healthcare costs per adjusted admission and concluding that the "results, as well as those of several previous studies, indicate that [CON] programs do not only fail to contain [hospital costs], but may actually increase costs as well" (emphasis in original)). While other studies evaluate the impact of repealing CON laws (with varying results), many of these

studies are less persuasive because they do not account for preexisting cost differences between the states. Compare Michael

D. Rosko & Ryan L. Mutter, The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation, 71 MED. CARE RES. & REV. 1, 15 (2014) (finding "a plausible association between CON regulation and greater hospital cost-efficiency"), with Gerald Granderson, The Impacts of Hospital Alliance Membership, Alliance Size, and Repealing Certificate of Need Regulation on Cost Efficiency of Non-profit Hospitals, 32 MANAGE. DECIS. ECON. 159, 167-68 (2011) ("[R]epealing state CON programs contributed to an improvement in hospital cost efficiency.").

185 Some papers find that CON laws are associated with lower utilization of hospital beds. These studies, however, do not address the critical question of whether the lower bed utilization in states with CON laws is a result of preventing over-investment or restricting beneficial investment. See, e.g., Delamater PL, Messina JP, Grady SC, WinklerPrins V, Shortridge AM. Do more hospital beds lead to higher hospitalization rates? A spatial examination of Roemer's Law. *PLOS ONE.* 2013;8:13-14 (finding "a positive, significant association between hospital bed availability and hospital utilization rates"); Hellinger FJ. The effect of certificate-of-need laws on hospitals beds and healthcare expenditures: an empirical analysis. *Am J Man Car*e. 2009;15:737 (finding that CON laws "have reduced the number of hospital beds by about 10%").

186 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250* (2016), at text accompanying notes 14-25 (detailing lengthy application, hearing, and appeal process in South Carolina). https://www.justice.gov/atr/file/812606/download. Accessed August 23, 2018.

187 See Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodological critique of the literature. *Ann Intern Med*. 2002 Sep 17;137(6):511, 514. ("We found the most consistent and striking differences in mortality rates between high- and low-volume providers for several high-risk procedures and conditions, including pancreatic cancer, esophageal cancer, abdominal aortic aneurysms, pediatric cardiac problems, and treatment of AIDS. The magnitude of volume-outcome relationships for more common procedures, such as [coronary artery bypass graft surgery], coronary angioplasty, and carotid endarterectomy, for which selective referral and regionalization policies have been proposed, was much more modest.")

188 *See* Gaynor M, Seider H, Vogt WB. The volume-outcome effect, scale economies, and learning-by-doing. *Am Econ Rev*. 2005;95(2):243, 244.

189 See, e.g., Ho V, Ku-Goto M, Jollis JG. Certificate of need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res*. 2009 Apr;44(2 Pt 1):483, 483 (2009) ("States that dropped CON experienced lower [coronary artery bypass graft

surgery] mortality rates relative to states that kept CON, although the differential is not permanent.")

190 See Li S, Dor A. How do hospitals respond to market entry? Evidence from a deregulated market for cardiac revascularization. *Health Econ*. 2015;24:990, 1006 (finding that repeal of Pennsylvania's CON program improved "the match between underlying medical risk and treatment intensity"); Ho V, Ku-Goto M. State deregulation and Medicare costs for acute cardiac care. *Med Care Res Rev*. 2012;70:199 (finding association between lifting of CON laws and shorter lengths of stay and fewer strokes during admission for coronary artery bypass patients, finding no significant association between lifting CON laws and three other complications during admission for coronary artery bypass graft patients, and finding no significant associations between lifting of CON laws and length of stay or need for coronary artery bypass graft surgery for percutaneous coronary intervention patients); Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):51, 52 (finding that new entry after repeal of Pennsylvania's CON program "had a salutary effect on the market for cardiac surgery by directing more volume to better doctors and increasing access to treatment").

191 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 3. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018; *see also* Romano P, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health care. *Int J Econ Bus*. 2011;18:45, 64 (2011).

192 Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):63 (finding that, following repeal of Pennsylvania's CON program, incumbent hospitals "were not put in a precarious position by the elimination of CON"); The Lewin Group. An evaluation of Illinois' Certificate of Need Program: prepared for the State of Illinois Commission on Government Forecasting and Accountability. 2007 Feb 15;ii:27-28. http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf. Accessed August 23, 2018. ("Through our research and analysis we could find no evidence that safety-net hospitals are financially stronger in CON states than other states.")

193 Garmon C. Hospital competition and charity care. *Forum Health Econ Policy*. 2009;12:1, 13.

194 See Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 4. http://www.ftc.gov/reports/healthcare/040723health carerpt.pdf. Accessed August 23, 2018 (discussing examples of how CON programs limited access to new cancer treatments and shielded incumbents from competition from innovative newcomers).

195 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Div. of the U.S. Department of Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program*, 6-7 (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-

antitrust-division. Accessed August 23, 2018.

196 *United States v. Charleston Area Med. Ctr., Inc.*, No. 2:06-0091 (S.D. W.Va. 2006). In a separate but similar case, informal suggestions by state CON officials led closely competing West Virginia hospitals to agree that one hospital would seek a CON for open heart surgery and the other for cancer treatment. *United States v. Bluefield Reg'l Med. Ctr., Inc*., No. 1:05-0234 (S.D. W.Va. 2005). While the Division secured consent decrees prohibiting these agreements between competitors to allocate services and territories, such conduct indicates that CON laws can provide the opportunity for anti-competitive agreements. See, e.g., U.S. Department of Justice, Department of Justice Statement on the Closing of the Vermont Home Health Investigation. Press Release. November 23, 2005. http://www.justice.gov/archive/opa/pr/2005/November/05_at_629.html. Accessed August 23, 2018.

197 See generally *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348 (March 31, 2015). https://www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney- memorial. Accessed August 23, 2018.

198 FTC v. Phoebe Putney Health Sys., 793 F. Supp. 2d 1356, 1361-1362 (M.D. Ga. 2011).

199 *FTC v. Phoebe Putney Health Sys.*, 663 F.3d 1369 (11th Cir. 2011).

200 *FTC v. Phoebe Putney Health Sys.*, 133 S. Ct. 1003, 1007 (2013).

201 The Eleventh Circuit had dissolved the stay that had prevented the parties from consummating the merger. With the stay dissolved, the parties had consummated their merger before the Supreme Court resolved the state-action question. *FTC v. Phoebe Putney Health Sys. Inc.*, 133 S. Ct. at 1011.

202 *Statement of the Federal Trade Commission*, at 1, *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348, (March 31, 2015):1.

https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 23, 2018.

203 Several states have passed COPA statutes since the 1990s, and there appears to be a recent resurgence in the implementation of COPA regulations. The following hospital mergers have been permitted to proceed pursuant to COPA oversight:

HealthSpan Hospital System (Minnesota, 1994); Mission Health System (North Carolina, 1995); Benefis Health System (Montana, 1996); Palmetto Health System (South Carolina, 1998); Cabell Huntington Hospital/St. Mary's Medical Center (West Virginia, 2016); and Mountain States Health Alliance/Wellmont Health System (Tennessee and Virginia, 2017). In addition, the Staten Island Performing Provider System in New York recently received a COPA for certain collaborative activities (2016). See COPA Application #COPA-SIPPS Staten Island PPS. New York Department of Health, Public Health and Health Planning Council. https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2016-11-17/docs/copa- sipps_staten_island_pps.pdf. Accessed August 23, 2018.

204 To obtain antitrust immunity for conduct that might otherwise violate the federal antitrust laws, the state action doctrine requires both a clear articulation of the state's intent to displace competition in favor of regulation and that the state provide active supervision over the regulatory scheme or body. *See N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015); *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1013 (2013).

205 Benefits typically considered by the states include cost efficiencies, quality improvements, population health improvements, preservation of hospital facilities and resources, and increased patient access to healthcare services. Disadvantages typically considered by the states include price increases, an inability of health plans to negotiate reasonable contract terms with providers, and reduced quality and access for healthcare services attributable to a reduction in competition.

206 For example, the Federal Trade Commission recently dismissed an administrative complaint filed in the matter of Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center, after the West Virginia state legislature passed a COPA statute intended to shield the transaction from an antitrust challenge, and the West Virginia Health Care Authority approved the hospitals' COPA application. See Statement of the Federal Trade Commission In the Matter of Cabell Huntington Hospital, Inc., Dkt. No. 9366 (Jul. 6, 2016). https://www.ftc.gov/system/files/documents/public_statements/969783/160706cabellcommstmt.pdf. Accessed September 26, 2018.

207 In 2015, the North Carolina legislature repealed the state's COPA statute, leaving no effective constraint on Mission Health System, which had operated under a COPA since 1995. See S.B. 698, Gen. Assemb., 2015-16 Session, Session Law 2015-288 (N.C. 2015), http://www.ncleg.net/Sessions/2015/Bills/Senate/PDF/S698v5.pdf. Accessed August 23, 2018 (ratified by General Assembly Sept. 29, 2015; signed into law by Governor Oct. 29, 2015, repealing Article 9A of Chapter 131E of the NC General Statutes, relating to Certificate of Public Advantage, effective Jan. 1, 2018); H.B.

1030, Gen. Assemb., 2015-2016 Session, Session Law 2016-94, at 93 (N.C. 2016), http://www.ncga.state.nc.us/Sessions/2015/Bills/House/PDF/H1030v8.pdf. Accessed

August 23, 2018. (revising the effective date of repeal from January 1, 2018 to September 30, 2016). In 2007, the Montana state legislature revised the state's COPA statute to limit the duration of COPAs to ten years, effectively terminating the COPA that Benefis Health System had operated under since 1996. See Mont. Code Ann. § 50-4-603(5) (amended 2007). http://leg.mt.gov/bills/mca/50/4/50-4-603.htm. Accessed August 23, 2018 (limiting the duration of a COPA to no more than 10 years from the date of issuance).

208 See, e.g., FTC staff submissions regarding the proposed merger and COPA applications of Mountain States Health Alliance and Wellmont Health System. https://www.ftc.gov/enforcement/cases-proceedings/151-0115/wellmont-healthmountain-states-health. Accessed August 23, 2018; Submission of Amerigroup Tennessee Inc. to the Tennessee Department of Health on the review of the application for a Certificate of Public Advantage from Wellmont Health System and Mountain States Health Alliance (Nov. 18, 2016). November 18, 2016. https://www.tn.gov/content/dam/tn/health/documents/COPA_AmeriGroup_Submission_to_Tennessee_DOH_with_Exhibits_11.18.16.pdf. Accessed August 23, 2018; Written Comments of America's Health Insurance plans submitted to the Tennessee Department of Health – COPA Index Advisory Group. April19, 2016. https://www.tn.gov/content/dam/tn/health/documents/AHIP_COPA_Comments_041819.pdf. Accessed August 23, 2018; Letter submitted by professors and academic economists to the Tennessee Department of Health. November 21, 2016. https://www.tn.gov/content/dam/tn/health/documents/Comment_on_Wellmont-MSHA_COPA_Application_by_Professors_and_Academic_Eco.pdf. Accessed August 23, 2018; Public comments submitted to the Virginia Department of Health regarding the cooperative agreement application of Mountain States Health Alliance and Wellmont Health System. http://www.vdh.virginia.gov/licensure-and-certification/cooperative-agreement/public-comment/. Accessed August 23, 2018.

209 See FTC staff notice of COPA assessment: request for empirical research and public comments. November 1, 2017. https://www.ftc.gov/system/files/attachments/press-releases/ftc-staff-seeks-empirical-research-public-comments- regarding-impact-certificates-public-advantage/p181200_copa_assessment_comment_notice_11-1-17.pdf. Accessed August 23, 2018.

210 See, e.g., *FTC Staff Comment to New York State Department of Health, Concerning Certificate of Public Advantage Applications, Intended to Exempt Performing Provider Systems from the Antitrust Laws* (April 22, 2015), at 3. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy- resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf. Accessed August 23, 2018. ("The antitrust laws already recognize, and, indeed, have long stood for the proposition that competitor collaborations can be procompetitive. As explained in numerous sources of guidance

issued by the federal antitrust agencies, this position extends to collaborations among competing healthcare providers.")

211 15 U.S.C. § 45(a)(2).

212 15 U.S.C. § 44.

213 For example, the Commission generally cannot challenge anti-competitive conduct, such as collusive behavior, by nonprofit hospitals. In three past enforcement actions, the Commission alleged that groups of physicians and hospitals had participated in unlawful price-fixing arrangements but was able to sue only the physicians and a for-profit hospital. See Piedmont Health Alliance.138 F.T.C. 675 (2004) (consent order), https://www.ftc.gov/enforcement/cases- proceedings/0210119i/piedmont-health-alliance-inc-et-al-matter. Accessed August 24, 2018; Tenet Healthcare Corp./Frye Regional Medical Center. 137 F.T.C. 219 (2004) (consent order). https://www.ftc.gov/enforcement/cases- proceedings/0210119h/tenet-healthcare-corporation-frye-regional-medical-center-inc. Accessed August 24, 2018; Maine Health Alliance, 136 F.T.C. 616 (2003) (consent order). https://www.ftc.gov/enforcement/cases-proceedings/0210017/maine-health-alliance-william-r-diggins-matter. Accessed August 24, 2018.

214 Philipson TJ, Posner RA. Antitrust in the not-for-profit sector. *J Law Econ*. 2009 Feb;52(1): 1-18.

215 15 U.S.C. § 18.

216 See, e.g., *Fed. Trade Comm'n v. Sanford Health*, No. 1:17 CV-133 (N.D. 2017); *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *Fed. Trade Comm'n v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014), cert. denied, 135 S. Ct. 2049 (2015); *St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys.*, 778 F.3d 775 (9th Cir. 2015).

217 See, e.g., *Fed. Trade Comm'n v. OSF Health Care Sys.*, 852 F. Supp. 2d 1069, 1081 (N.D. Ill. 2012) ("[T]he evidence in this case reflects that nonprofit hospitals do seek to maximize the reimbursement rates they receive."); *Fed. Trade Comm'n v. ProMedica*, No. 3:11 CV 47, 2011 WL 1219281, at *22 (N.D. Ohio Mar. 29, 2011) (finding that a nonprofit hospital entity "exercises its bargaining leverage to obtain the most favorable reimbursement rates possible from commercial health plans."); *United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1284-87 (7th Cir. 1990) (rejecting the contention that nonprofit hospitals would not seek to maximize profits by exercising their market power); *Fed. Trade Comm'n v. Univ. Health, Inc.*, 938 F.2d 1206, 1213-14 (11th Cir. 1991) ("[T]he district court's assumption that University Health, as a nonprofit entity, would not act anticompetitively was improper."); *Hospital Corp. of*

America v. Fed. Trade Comm'n, 807 F.2d 1381, 1390-91 (7th Cir. 1986) (rejecting the contention that nonprofit hospitals would not engage in anticompetitive behavior).

218 15 U.S.C. § 4. See *United States v. Charleston Area Med. Ctr. et al*., No. 2-16-cv-03664 (stipulated final judgment Oct. 21, 2016), which describes a Herman Act case involving an illegal agreement between two nonprofit hospitals to allocate marketing territories.

219 Minda G. The common law, labor and antitrust. *Berk J Employ Labor Law*. 1989 Dec;11(4):461-539. https://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1189 &context=bjell. Accessed August 24, 2018.

220 Gilson RJ. The legal infrastructure of high technology industrial districts: Silicon Valley, Route 128, and covenants not to compete. *NY Univ Law R*. 1999 Jun:74(3):575-629. https://law.stanford.edu/index.php?webauth-document=publication/256234/doc/slspublic/NYULawReview-74-3-Gilson.pdf. Accessed August 24, 2018.

221 Goold SD. Report of the Council on Ethical and Judicial Affairs. CEJA Report 3-A-14. https://www.ama- assn.org/sites/default/files/media-browser/public/about-ama/councils/Council Reports/council-on-ethics-and-judicial- affairs/ceja-3a14.pdf. Accessed August 24, 2018.

222 Lavetti K, Simon C, and White WD. The Impacts of Restricting Mobility of Skilled Service

Workers: Evidence from Physicians. Forthcoming *Journal of Human Resources*. http://kurtlavetti.com/UIPNC_vf.pdf. Accessed November 27, 2018.

223 *Ibid* at 41.

224 *Murfreesboro Medical Clinic, P.A., v. David Udom*, S.C.T. M2003-00313-SC-CV (June 29, 2005). https://caselaw.findlaw.com/tn-supreme-court/1058188.html. Accessed August 24, 2018.

225 *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).

https://www.leagle.com/decision/19851183138illapp3d104511046. Accessed August 24, 2018.

226 Horton RW. Restrictive covenants in physician employment relationships. American Health Lawyers Association— Member Briefing. April 2013. http://www.bassberry.com/~/media/Files/Publications/2013/05/AHLA_Article_Horton_and_Padgett_April_2013.pdf. Accessed August 24, 2018.

227 Garmaise JM. Ties that truly bind: noncompetition agreements, executive compensation, and firm investment. *J Law Econ Org*. 2011 Aug;27(2):376-425.

https://academic.oup.com/jleo/article-abstract/27/2/376/2194339. Accessed August 24, 2018.

228 See, e.g., Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. Ch. 6. July 2004: 29-30. http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed August 23, 2018; Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing- provider" regulations. *J Health Econ*. 2011;20:955, 956; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:192, 196-197.

229 *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).

https://www.leagle.com/decision/19851183138illapp3d104511046. Accessed August 24, 2018.

230 State AWP (and FOC) laws vary substantially in scope – e.g., applying to some types of plans but not others, or some types of providers but not others. They also vary in stringency and may impose greater or lesser restraints, via varied enforcement mechanisms, on plan contracting and benefits design. Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of 'any-willing-provider' regulations. *J Health Econ*. 2011;20:959; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*.

2015;17:198-200. For example, some states have adopted AWP laws for pharmacy services. See, e.g., Carroll A, Ambrose JM. Any-willing-provider laws: their financial effect on HMOs. *J Health Polit Policy Law*. 2002;27:928. Depending on these variables, AWP and FOC laws may have greater or lesser economic impact. See, e.g., Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*. 2011;20:959.

231 See generally, e.g., Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*. 2010;29(11):2009; Robinson JC. Hospital tiers in health insurance: balancing consumer choice with financial incentives*, Health Aff*. 2003 Jan-Jun Suppl Web Exclusives:W3-135; Yegian JM. Tiered hospital networks. *Health Aff.* 2003;147:W3. Coverage for the non-preferred tier is therefore lower – in some limiting cases, zero.

232 See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*. 2010;29(11):2010.

233 Often—not always—drug benefits are designed to encourage substitution of lower-cost generic versions of branded products. See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*.

2010;29(11):2011.

234 Beneficiaries or subscribers might generally prefer more choice rather than less, all other things being equal. Providers might also have more self-interested reasons for favoring AWP or FOC laws to the extent that they suffer financially when excluded from preferred tiers of provider networks and/or to the extent that competitive bidding can otherwise diminish profits, say, in significantly concentrated provider markets. See, e.g., Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*.

2011;20:956.

235 42 USCS § 1395w-104(b)(1). See, e.g., CMS. Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. 79 *Fed Reg* 1918, 1978-1982 (Jan. 10, 2014) (discussing proposed "any-willing-pharmacy" rules).

236 See Medicare Program. Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 *Fed Reg*. 16440, 16440-16757 (Apr. 16, 2018).

237 The limited literature on this issue tends to look at the effect of any-willing-provider laws on total spending, instead of prices. Because the quantity of healthcare is generally measured to have a negative, though small, relationship with healthcare prices, these studies likely understate the effect of AWP laws on prices. See, e.g., *Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs.*, 8, n.15 (March 2014).
https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers- medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf. Accessed August 24, 2018.

238 Klick J, Wright JD. The effect of any-willing-provider and freedom-of-choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:204-05. Klick & Wright find smaller, and not statistically significant effects associated with FOC laws. That may be due, they suggest, to the commonly weaker restraints provided by FOC laws that, in effect, permit beneficiaries to leave the bounds of a network by forgoing the savings gleaned by selective contracting on an *ad hoc* basis, doing less general damage to selective contracting. *Ibid.,* at 194.

239 Durrance CP. The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures.

Atlantic Econ J. 2009;37:409.

240 Vita M. Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*. 2001;20:955, 960-66. Panel data

show, e.g., that states with highly restrictive AWP/FOC laws spent approximately 2 percent more on healthcare than states without such policies.

241 Gaynor M, Mostashari F, Ginsburg PB. Making healthcare markets work: competition policy for healthcare. Brookings. April 13, 2017. >https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report-v11.pdf< at 24, n.34. Accessed September 26, 2018.

242 See Maryland Health Care Commission and Maryland Insurance Administration. Mail order purchase of maintenance drugs: impact on consumers, payers, and retail pharmacies. (Dec. 23, 2005).

243 Gruber J, McKnight R. Controlling healthcare costs through limited network insurance plans: evidence from Massachusetts state employees. *Am Econ J: Econ Policy*. 2016;8(2):219, 221.

244 Wu VY. Managed care's price bargaining with hospitals. *J Health Econ*. 2009(28):350.

245 Sorensen AT. Insurer-hospital bargaining: negotiated discounts in post-deregulation Connecticut. *J. Indus Econ*. 2003;51:469 (building a simple theoretical model describing the dynamics of the bargaining effects and testing it with data on negotiated Connecticut hospital discounts).

246 Part D Claims Analysis: Negotiated Pricing Between Preferred and Non-Preferred Pharmacy Networks. April 30, 2013. http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/PharmacyNetwork.pdf. Accessed August 24, 2018; Part D Claims Analysis: Negotiated Pricing Between General Mail Order and Retail Pharmacies. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/Negotiated- Pricing-Between-General-Mail-Order-and-Retail-PharmaciesDec92013.pdf. Accessed August 24, 2018.

247 See, e.g., Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs., (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers- medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf at 4-5 for a discussion of the CMS studies and their potential limitations. Accessed August 24, 2018.

248 See, e.g., *Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs.*, (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers- medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf at 10, n.34 (also noting that FTC staff had undertaken a literature review in conjunction with their comments to CMS and had not found any countervailing evidence suggesting increased costs). Accessed August 24, 2018.

249 2017 Employer Health Benefits Survey. Menlo Park, California: Kaiser Family Foundation and Health Research and Education Trust. September 19, 2017. https://www.kff.org/health-costs/report/2017-employer-health-benefits- survey/. Accessed August 24, 2018.

250 Employer Health Benefits 2016 Annual Survey. Menlo Park, CA: Kaiser Family Foundation and Health Research and Education Trust; 2016. https://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/. Accessed August 24, 2018.

251 Polsky D, Zhang Y, Yasaitis L, Weinger J. Trends in physician networks in the marketplace in 2016. UPenn Leonard Davis Institute of Health Economics. December 6, 2016. https://ldi.upenn.edu/brief/trends-physician- networks-marketplace-2016. Accessed August 24, 2018.

252 Polsky D, Cidav Z, Swanson A. Plans with narrow physician networks feature lower monthly premiums than plans with larger networks. *Health Aff*. 2016;35(10):1841-1848.

253 Finkelstein A, Hendren N, Shepard M. Subsidizing health insurance for low-income adults: evidence from Massachusetts. NBER Working Paper No. 23668. Cambridge, MA. August 2017. http://www.nber.org/papers/w23668. Accessed August 24, 2018.

254 Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017. https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf. Accessed August 24, 2018.

255 Ahn S, Corlette S, Lucia K. Can telemedicine help address concerns with network adequacy? Opportunities and challenges in six states. Urban Institute. April 6, 2016. https://www.urban.org/research/publication/can-telemedicine- help-address-concerns-network-adequacy-opportunities-and-challenges-six-states. Accessed August 24, 2018.

256 Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017. https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf. Accessed August 24, 2018.

257 Howard DH. Adverse effects of prohibiting narrow provider networks. *New Engl J Med* 2014;371:591-592.

257 Howard DH. Adverse effects of prohibiting narrow provider networks. *New Engl J Med* 2014;371:591-592.

258 The burden of medical debt: results from the Kaiser Family Foundation/New York Times Medical Bills Survey. January 5, 2016. https://www.kff.org/health-costs/report/the-burden-of-medical-debt-results-from-the-kaiser-family-

foundationnew-york-times-medical-bills-survey/. Accessed August 24, 2018.

259 CMS. Online provider directory review report. 2018. https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/Provider_Directory_Review_Industry_Report_Final_01-13-17.pdf. Accessed August 24, 2018.

260 Hall MA, Ginsburg PB. A better approach to regulating provider network adequacy. USC Schaeffer Center for Health Policy and Economics and Brookings Center for Health Policy. September 2017. https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf. Accessed August 24, 2018.

261 *Id.*

262 *Id.*

263 2017 Employer Health Benefits Survey. Menlo Park, CA: Kaiser Family Foundation and Health Research and Education Trust. September 19, 2017. https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey./

Accessed August 24, 2018.

264 The 10 required categories are: 1) ambulatory patient services, 2) emergency services, 3) hospitalization, 4) maternity and newborn care, 5) mental health and substance use disorder services, 6) prescription drugs, 7) rehabilitative and habilitative services and devices, 8) laboratory services, 9) preventive and wellness services and chronic disease management, and 10) pediatric services.

265 Koskinen J. Letter updating members of Congress regarding 2016 tax filings related to ACA provisions. January 9, 2017, https://www.irs.gov/pub/newsroom/commissionerletteracafilingseason.pdf. Accessed August 24, 2018.

266 This requirement is distinct from proposals discussed elsewhere in this report concerning the ability of high- deductible health plans (HDHPs) that enable individuals to contribute to health savings accounts (HSAs) to cover preventive services before the patient pays the full deductible if it is cost efficient for them to do so.

267 The USPSTF is an independent, volunteer panel comprised of experts from the fields of preventive medicine and primary care. The Task Force does not consider the costs of a preventive service when determining what policies to recommend. USPSTF determines the services under Public Health Service Act (PHS Act) §2713(a)(1), while the CDC determines services under PHS Act §2713(a)(2), and HRSA determines services under PHS Act §2713(a)(3) and (4). 268 Cohen JT, Neumann PJ, Weinstein MC. Does preventive care save money? Health economics and the presidential

candidates. *N England J Med*. 2018 Feb 13:358:661-663. http://www.nejm.org/doi/full/10.1056/NEJMp0708558.

Accessed August 24, 2018.

269 Russell LB. Preventing chronic disease: an important investment, but do not count on cost savings. *Health Aff.* 2009 Jan-Feb;28(1):42-45. https://www.healthaffairs.org/doi/full/10.1377/hlthaff.28.1.42. Accessed August 24, 2018.

270 Gawande A. Overkill. *The New Yorker*. May 11, 2015. https://www.newyorker.com/magazine/2015/05/11/overkill- atul-gawande. Accessed September 20, 2018.

271 The large-group market minimum MLR requirement is 85 percent. MLR requirements do not apply to insurers with fewer than 1,000 enrollees per state.

272 Medical Loss Ratio (MLR). Healthcare.gov. https://www.healthcare.gov/glossary/medical-loss-ratio-mlr/. Accessed August 24, 2018.

273 Book R. How the medical loss ratio requirement could increase health insurance premiums and insurer profits at taxpayer expense. American Action Forum. April 2013. https://www.americanactionforum.org/wp-content/uploads/files/research/MLR_Paper_Final.pdf. Accessed August 24, 2018.

Roy, A. Obamacare's MLR 'Bomb' Will Create Private Insurance Monopolies and Drive Premiums Skyward. Hallelujah! Forbes. December 6, 2011.

275 Haislmaier E, Senger A. The 2017 health insurance exchanges: major decrease in competition and choice. The Heritage Foundation. January 30, 2018. https://www.heritage.org/health-care-reform/report/the-2017-health-insurance-

exchanges-major-decrease-competition-and-choice. Accessed August 24, 2018.

276 *Id*.

277 Health plan choice and premiums in the 2018 federal health insurance exchange. ASPE. October 30. 2017. https://aspe.hhs.gov/system/files/pdf/258456/Landscape_Master2018_1.pdf. Accessed August 24, 2018.

278 Turner G. ACA rules allow people to game the system, contributing to premium spikes. Galen Institute. June 11. 2016. http://galen.org/2016/aca-rules-allow-people-to-game-the-system-contributing-to-premium-spikes/. Accessed

August 24, 2018.

279 Centers for Medicare & Medicaid Services, HHS. Patient Protection and Affordable Care Act; market stabilization: final rule. *Fed Regist.* 2017;82(73):18346-18382.

280 Employee Benefits Security Administration, Department of Labor. Definition of "employer" under section 3(5) of ERISA-association health plans: final rule. *Fed Regist.* 2018;83(120):28912-28964.

281 Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services. Short-term, limited- duration insurance: final rule. *Fed Regist.* 2018;83(150):38212-38243.

282 Congressional Budget Office. Federal subsidies for health insurance coverage for people under age 65: 2018 to 2028. May 23, 2018. https://www.cbo.gov/publication/53826. Accessed September 27, 2018.

283 Bluey RB. Obamacare has a poison pill for doctor owned hospitals. The Heritage Foundation. May 4. 2010. https://www.heritage.org/health-care-reform/commentary/obamacare-has-poison-pill-doctor-owned-hospitals. Accessed August 24, 2018.

284 Leonard K. Obamacare wounds doctor-owned hospitals. *Washington Examiner*. July 10. 2017. http://www.washingtonexaminer.com/obamacare-wounds-doctor-owned-hospitals/article/2627880. Accessed August 24, 2018.

285 Dickson V. Lifting restrictions on physician-owned hospitals could be key to widening access to care. *Modern Health Care.* June 27, 2017. http://www.modernhealthcare.com/article/20170627/NEWS/170629899. Accessed August 24, 2018.

286 Ramirez AG, Tracci MC, Stukenborg GJ, Turrentine FE, Kozower BD, Jones RS. Physician-owned surgical hospitals outperform other hospitals in Medicare value-based purchasing program. *J Am Coll Surg.* 2016 Oct;223(4):559-567. https://www.sciencedirect.com/science/article/pii/S1072751516307207?via%3Dihub. Accessed August 24, 2018.

287 Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6. 2015. https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531. Accessed August 24, 2018.

288 Note CMS released an updated star rating approach in 2017 that expanded the number of hospitals that qualify for top 5-star ratings.

289 Turner G. Lift the ban on physician-owned hospitals. *Forbes*. November 6. 2015. https://www.forbes.com/sites/gracemarieturner/2015/11/06/lift-the-ban-on-physician-owned-hospitals/#5311bcd11531. Accessed August 24, 2018.

290 Translated resources for covered entities. U.S Department of Health & Human Services. September 7, 2016. https://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html. Accessed August 24, 2018.

291 *Id*.

292 U.S. Department of Health & Human Services. Nondiscrimination in health programs and activities. *Federal Reg* 2015 Sep 8;80(173):54172-55221. https://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-22043.pdf. Accessed August 24, 2018. See also Barlas S. Formulary policies a battleground in HHS proposal on nondiscrimination. *P T*. 2016 Mar;41(3):173-175, 193. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4771086/. Accessed August 24, 2018.

293 Haviland AM, Eisenberg MD, Mehrotra A, Huckfeldt PJ, Sood N. Do "consumer-directed" health plans bend the cost curve over time? NBER Working Paper No. 21021. Issued March 2015, revised July 2015. http://www.nber.org/papers/w21031. Accessed September 21, 2018.

294 See 26 CFR 601.602: Tax forms and instructions. Also Part 1, §§ 1, 223. Rev. Proc. 2017-37. https://www.irs.gov/pub/irs-drop/rp-17-37.pdf. Accessed August 24, 2018; Also: Part I, § 223. Rev. Proc.2018-27. https://www.irs.gov/pub/irs-drop/rp-18-27.pdf. Accessed August 24, 2018.

295 Note that short-term, limited-duration insurance plans that provide significant benefits and that meet these requirements may constitute an HSA-qualified plan.

296 Notice 2004-23, 2004-15 IRB 725, Notice 2004-50, 2004-33 IRB 196, and Notice 2013-57 2013-40 IRB 293.

297 Withdrawals prior to age 65 not spent on qualified medical expenses are subject to income taxes plus a 20 percent penalty. Withdrawals after age 65 not spent on qualified medical expenses are subject to income taxes but are not subject to a penalty, resulting in tax-free return on investment, similar to the tax treatment of 401(k) retirement plans. Withdrawals for medical care are not subject to income taxes or the penalty. Therefore, HSA funds used for future medical care receive both tax-free return on investment and the exclusion of the contribution from income (and payroll taxes if contributed through an employer plan). This is like adding the tax preference for 401(k)'s to the tax exclusion for employer sponsored health benefits.

298 Cohen RA, Martinez ME, Zammitti EP. Health insurance coverage: early release of estimates from the National Health Interview Survey. January-March 2017. National Center for Health Statistics. https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201708.pdf. Accessed August 24, 2018

299 The actuarial value measures the fraction of covered benefits paid by the plan for a standard population. Hence, it

measures the expected generosity of the plan.

300 Internal Revenue Code §§ 223(f)(1), (2) and (4).

301 It is unclear whether, under current rules, consumer-provider fixed-fee arrangements, such as direct primary-care arrangements, should be considered health plans and thus be prohibited from being coupled with HSA-qualified plans. 302 The direct immediate budgetary cost of deeming 70 percent AV plans as HSA-qualified plans could be relatively small. This is because among individuals in employer-sponsored plans much of the cost of tax-preferred HSA spending would be offset by reduced tax-preferred premiums.

303 IRS Notice 2002-45, 2002-02 CB 93; Revenue Ruling 2002-41, 2002-2 CB 75.

304 83 FR 54420. *Federal Register*. A Proposed Rule by the Internal Revenue Service, the Employee Benefits Security Administration, and the Health and Human Services Department on October 29, 2018. https://www.federalregister.gov/documents/2018/10/29/2018-23183/health-reimbursement-arrangements-and-other- account-based-group-health-plans

305 Dafny, L., Ho, K., and Varela, M. Let Them Have Choice: Gains from Shifting Away from Employer-Sponsored Health Insurance and Toward an Individual Exchange. *American Economic Journal: Economic Policy*. 2013 February; 5(1): 32-58. https://www.jstor.org/stable/23358336?seq=1#metadata_info_tab_contents

306 Herzlinger, Regina and Klein, Joel. The IRS can save American health care. *Wall Street Journal*. July 1, 2018. https://www.wsj.com/articles/the-irs-can-save-american-health-care-1530477705 See also: https://www.researchgate.net/profile/Barak_Richman/publication/316282783_Changing_the_Tax_Code_to_Create_Co nsumer-Driven_Health_Insurance_Competition/links/594aa2b7458515225a830ab4/Changing-the-Tax-Code-to-Create- Consumer-Driven-Health-Insurance-Competition.pdf

307 Azar AM. Remarks to the Heritage Foundation. U.S. Department of Health & Human Services. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-the-heritage-foundation.html. Accessed September 21, 2018.

308 Medicare shared savings program fast facts. Centers for Medicare and Medicaid Services (CMS). January 2018. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast- Facts.pdf. Accessed August 24, 2018.

309 Shared savings and losses are determined against a benchmark based on baseline and national and regional trends. 310 A patient-centered medical home is a model of care coordination in which care is comprehensive and coordinated across multiple resources within the healthcare system as well as the broader community. More information can be found at Defining the PCMH. U.S. Department of Health & Human Services AHRQ. https://pcmh.ahrq.gov/page/defining-pcmh. Accessed August 25, 2018.

311 Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Aff (Millwood)*. 2014 May;33(5):756-763.

312 Robinson JC, Miller K. Total expenditures per patient in hospital-owned and physician-owned physician organizations in California. *JAMA.* 2014;312(16):1663–1669.

313 Bishop TF, Shortell SM, Ramsay PP, Copeland KR, Casalino LP. Trends in hospital ownership of physician practices and the effect on processes to improve quality. *Am J Manag Care*. 2016 Mar;22(3):172-176; Rodriguez HP, McClellan SR, Bibi S, Casalino LP, Ramsay PP, Shortell SM. Increased use of care management processes and expanded health information technology functions by practice ownership and Medicaid revenue. *Med Care Res Rev*. 2016 Jun;73(3):308-328.

314 Pesko MF, Ryan AM, Shortell SM, et al. Spending per Medicare beneficiary is higher in hospital-owned small- and medium-sized physician practices. *Health Serv Res*. 2017 Sep 21. doi: 10.1111/1475-6773.12765.

315 Neprash HT, Chernew ME, Hicks AL, Gibson T, McWilliams JM. Association of financial integration between physicians and hospitals with commercial health care prices. *JAMA Intern Med*. 2015 Dec;175(12):1932-1939.

316 Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. *Health Aff (Millwood)*. 2014 May;33(5):756-763.

317 Federal Trade Commission and Department of Justice. Statement of antitrust enforcement policy regarding accountable care organizations participating in the Medicare Shared Savings Program. *Fed Register*. 2011 Oct 28;76(209):67026-67032. https://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf. Accessed August 24,

2018.

318Accountable care organizations. FTC. https://www.ftc.gov/tips-advice/competition-guidance/industry- guidance/health-care/accountable-care-organizations. Accessed August 24, 2018; Federal Trade Commission and Department of Justice. Statement of antitrust enforcement policy regarding accountable care organizations participating in the Medicare Shared Savings Program. *Fed Register*. 2011 Oct 28;76(209):67026-67032. https://www.gpo.gov/fdsys/pkg/FR-2011-10-28/pdf/2011-27944.pdf. Accessed August 24, 2018.

319 Richards MR, Smith CT, Graves AJ, Buntin MB, Resnick MJ. Physician competition in the era of accountable care organizations. *Health Serv Res*. 2018 Apr;53(2):1272-1285.

320 Neprash HT, Chernew ME, McWilliams JM. Little evidence exists to support the expectation that providers would consolidate to enter new payment models. *Health Aff (Millwood).* 2017 Feb 1;36(2):346-354.

321 West J, Johnson G, Jha AK. Trends in acquisitions of physician practices and subsequent clinical integration: a mixed methods study. *J Eval Clin Pract*. 2017 Dec;23(6):1444-1450.

322 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project, Policy Brief No. 9, June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018.

323 McWilliams JM, Chernew ME, Zaslavsky AM, Hamed P, Landon BE. Delivery system integration and health care spending and quality for Medicare beneficiaries. *JAMA Intern Med*. 2013 Aug 12;173(15):1447-1456.

324 Casalino LP, Pesko MF, Ryan AM, et al. Small primary care physician practices have low rates of preventable hospital admissions. *Health Aff (Millwood)*. 2014 Sep;33(9):1680-1688.

325 CBO Baseline, 2017. These figures include some services that are not paid under OPPS. Some of these HOPD payments are copayments and some are paid via Part B premium. Also, these figures pertain to FFS enrollees only. Any change in payment rates will yield savings on the Medicare Advantage side.

326 Hannan EL, Kilburn H, Racz M, Shields E, Chassin MR. Improving the outcomes of coronary artery bypass surgery in New York State. *JAMA*. 1994;271(10):761-766.

327 Chassin MR, Hannan EL, DeBuono, BA. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996;334(6):394-398.

328 Dranov D, Kessler D, McClellan M, Satterthwaite M. Is more information better? The effects of 'Report Cards' on health care providers. *J Polit Econ*. 2003;111(3):555-588.

329 In 1997, for example, the Cleveland Health Quality Choice project began a regional initiative to profile hospital performance and found improved outcomes in risk-adjusted mortality for six medical and two surgical procedures. **(**Rosenthal GE, Quinn L, Harper DL. Declines in hospital mortality associated with a regional initiative to measure hospital performance. *Am J Med Qual*. 1997 Summer;12(2):103-112. PMID: 9161057). In addition, a 2008 Pennsylvania study showed significantly lower odds of in-hospital mortality associated with intensive public reporting (OR=0.59-0.79, p<0.01). (Hollenbeak CS, Gorton CP, Tabak YP, et al. Reductions in mortality associated with intensive public reporting of hospital outcomes. *Am J Med Qual*. 2008;23:279–286). The CABG Outcomes Public Reporting Program (CCORP), mandated by the California

legislature in 2003, also generates annual report cards, including risk-adjusted operative mortality rates, for all nonfederal hospitals and surgeons who perform the procedure. The program reported observed mortality decreased statewide (2.90% to 2.22%, p<0.01) and no evidence that high-risk patients denied CABG because of public reporting. (Li Z, Carlisle DM, Marcin JP, et al. Impact of public reporting on access to coronary artery bypass surgery: the California Outcomes Reporting Program. *Ann Thorac Surg*. 2010 Apr;89(4):1131-1138. PMID: 20338320). In addition, in 2016 a systematic review and meta-analysis of impact of public reporting on clinical outcomes, showed positive impact of public reporting on overall mortality (RR=0.85 [95% CI, 0.79-0.92]). (Campanella P, Vukovic V, Parente P, et al. The impact of public reporting on clinical outcomes: a systematic review and meta-analysis. *BMC Health Serv Res*. 2016 Jul 22;16:296.) Finally, an evaluation of state- mandated health-care-associated infection reporting laws on central-line associated bloodstream infection rates at the hospital/ICU level found that states with such laws had lower CLABSI rates beginning approximately six months prior to the law's effective date (IRR = 0.66; p < .001). This effect has persisted for > 6.5 years. (Liu H, Herzig CTA, Dick AW, et al. Impact of state reporting laws on central line-associated bloodstream infection rates in U.S. adult intensive care units. *Health Serv Res*. 2017 Jun;52(3):1079-1098). See also Hannan EL, Kumar D, Racz M, et al. New York State's Cardiac Surgery Reporting System: four years later. *Ann Thorac Surg*. 1994 Dec;58(6):1852-1857. PMID: 7979781; Chassin MR, Hannan EL, DeBuono BA. Benefits and hazards of reporting medical outcomes publicly. *N Engl J Med*. 1996 Feb 8;334(6):394-398. PMID: 8538714; Dehmer GJ, Drozda JP Jr, Brindis RG, et al. Public reporting of clinical quality data: an update for cardiovascular specialists. *J Am Coll Cardiol*. 2014 Apr 8;63(13):1239- 1245. Review. PMID: 24509280.

330 These early quality measures relied on manual abstraction from medical records. The below support the claim this was a burden: General Accounting Office. Report cards: a useful concept but significant issues need to be addressed. Washington, D.C.: Government Printing Office, 1994.

See also: Epstein A. Performance reports on quality--prototypes, problems, and prospects. N Engl J Med. 1995 Jul 6;333(1):57-61.

331 Damberg CL, Sorbero M, Mehrotra A, Teleki S, Lovejoy S, Bradley L. An environmental scan of pay for performance in the hospital setting: final report. Working paper prepared by RAND. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. November 2007. https://aspe.hhs.gov/system/files/pdf/75266/PayPerform07.pdf. Accessed August 25, 2018.

332 Premier Hospital Quality Incentive Demonstration. https://www.cms.gov/Medicare/Quality-Initiatives-Patient- Assessment-

Instruments/HospitalQualityInits/Downloads/HospitalPremierPressRelease-FactSheet.pdf. Accessed August 25, 2018.

333 Centers for Medicare and Medicaid Services, Evaluation of the Premier Hospital Quality Incentive Demonstration. Executive Summary. March 3, 2009. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-

and-Reports/Reports/downloads/Premier_ExecSum_2010.pdf. Accessed August 25, 2018.

334 Ryan AM, Blustein J, Doran T, Michelow MD, Casalino LP. The effect of Phase 2 of the Premier Hospital Quality Incentive Demonstration on incentive payments to hospitals caring for disadvantaged patients. *Health Serv Res*.

2012;47(4):1418-1436.

335 Compendium of U.S. Health Systems, 2016. U.S. Department of Health and Human Services, AHRQ. https://www.ahrq.gov/chsp/compendium/index.html. Accessed August 25, 2018.

336 Marshall MN, Shekelle PG, Leatherman S, Brook RH. The public release of performance data: what can we expect to gain. A review of the evidence. *JAMA*. 2000;2831866-1874; Schneider EC, Epstein AM. Use of public performance reports: a survey of patients undergoing cardiac surgery. *JAMA*. 1998;2791638-1642.

337 Casalino LP, Gans D, Weber R, et al. US physician practices spend more than $15.4 billion annually to report quality measures. *Health Aff (Millwood)*. 2016 Mar;35(3):401-406.

338 Ryan J, Doty MM, Hamel L, Norton M, Abrams MK, Brodie M. Primary care providers' views of recent trends in healthcare delivery and payment: findings from the Commonwealth/Kaiser Family Foundation 2015 National Survey of Primary Care Providers. Commonwealth Fund/Kaiser Family Foundation. Issue Brief. August 5, 2015. https://www.commonwealthfund.org/publications/issue-briefs/2015/aug/primary-care-providers-views-recent-trends- health-care-delivery. Accessed August 25, 2018.

339 Core measures. CMS. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment- Instruments/QualityMeasures/Core-Measures.html. Accessed August 25, 2018.

340 Medicare value-based payment models: participation challenges and available assistance for small and rural practices. U.S. Government Accountability Office (GAO). Report to Congressional Committees. December 2016. https://www.gao.gov/assets/690/681541.pdf. Accessed August 25, 2018.

341 Casalino LP, Pesko MF, Ryan AM, et al. Small primary care physician practices have low rates of preventable hospital admissions. *Health Aff (Millwood)*. 2014 Sep;33(9):1680-1688.

342 Newman D, Parente S, Barrette E, Kennedy K. DATAWATCH: Prices for common medical services vary substantially among the commercially insured. *Health Aff*. 2016;35:5923-5927. doi:10.1377/hlthaff.2015.1379. 343 Beck M. How to cut your health-care bill: pay cash. *Wall Street Journal*. February 15, 2016. https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277. Accessed August 25, 2018.

344 Fronstin, P. Has enrollment in HSA-eligible plans stalled? Washington, D.C. Employee Benefit Research Institute. February 16, 2018 [cited 2018 May 7]. https://www.ebri.org/pdf/briefspdf/EBRI_IB_441.pdf. Accessed August 25,

2018.

345Brot-Goldberg ZC, Chandra A, Handel BR, Kolstad JT. What does a deductible do? The impact of cost sharing on healthcare prices, quantities, and spending dynamics The Quarterly Journal of Economics. 2017;132(3):1261-1318.

346 Robinson CR, Brown TT, Whaley C. Reference pricing changes “choice architecture” of healthcare for consumers.

Health Aff. 2017;3:524-530. doi: 10.1377/hlthaff.2016.1256.

347 *Id*.

348 Delbanco SF, Murray R, Berenson RA, Upadhyay, DK. Centers of Excellence. Payment methods and benefit designs: how they work and how they work together to improve healthcare. Urban Institute. April 2016. https://www.urban.org/sites/default/files/06_centers_of_excellence.pdf. Accessed September 21, 2018.

349 Welborn S. The right care at the right time: expanding our Centers of Excellence network. Walmart. https://news.walmart.com/2016/10/10/the-right-care-at-the-right-time-expanding-our-centers-of-excellence-network. Accessed August 25, 2018.

350 Charges are defined as the prices of a service, diagnostic test, medical procedure, and other items for which a hospital bills a patient or insurer before any discount is applied. For the most part, charges do not reflect the actual price a consumer pays, as charges do not take into account any discount received through insurance or discount the hospital applies for paying in cash.

351 Sinaiko AD, Chien AT, Rosenthal MB. The role of states in improving price transparency. *JAMA Int Med*. 2015. 175(6):886-887.

352 Delbanco S, de Brantes F. States must step up to help consumers gain access to health care prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain- access-to-health-care-prices/. Accessed June 2013.

354Mehrotra MD, Brannen T, Sinaiko, AD. Use patterns of a state healthcare price transparency web site: what do patients shop for? Inquiry. 201; 51:1-3. and Desai S, Hatfield LA, Hicks AL, Sinaiko AD, Chernew ME, Cowling D, et al. Offering a price transparency tool did not reduce overall spending among California public employees and retirees. Health Aff (Millwood). 2017;36(7):1401–07 among others.

355 Whaley C, Schneider Chafen J, Pinkard S, Kellerman G, Bravata D,

Kocher R, et al. Association between availability of health service prices and payments for these services. JAMA. 2014;312(16):1670–6 and Wu S, Sylwestrzak G, Shah C, DeVries A. Price transparency for MRIs increased use of less costly providers and triggered provider competition. Health Affairs. 2014. 33(8):1391-8.

356 Wu S, Sylwestrzak G, Shah C, DeVries A. Price transparency for MRIs increased use of less costly providers and triggered provider competition. Health Affairs. 2014. 33(8):1391-8.

357 (Semigran HL, Gourevitch R, Sinaiko AD, et al. Patients' Views on Price Shopping and Price Transparency. *AM J Manag Care*. 2017;23(6);e186-92,, Sinaiko AD, Rosenthal MB. Examining a healthcare price transparency tool: who uses it, and how they shop for care. Health Aff (Millwood). 2016;35(4):662–70, and Volpp, KG. Price transparency: Not a panacea for healthcare costs. JAMA 2016;315(17): 1842-3.

358 Delbanco S, de Brantes F. States must step up to help consumers gain access to healthcare prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain- access-to-health-care-prices/. Accessed June 2013.

359 Definition of "employer" under section 3(5) of ERISA-association health plans. *Federal Register*. A final rule by the Employee Benefits Security Administration on June 21, 2018. https://www.federalregister.gov/documents/2018/06/21/2018-12992/definition-of-employer-under-section-35-of-erisa- association-health-plans. Accessed October 5, 2018.

360 Hilton RP, Serban N, Zheng RY. Uncovering longitudinal healthcare utilization from patient-level medical claims data. March 4, 2016. https://arxiv.org/pdf/1603.00896.pdf. Accessed August 25, 2018.

361 Research Action for Health Network (REACHnet): an overview and implications for clinical research. REACHnet. October 19, 2016. Page 8. https://pcornetcommons.org/wp-content/uploads/2017/02/REACHnet-Technical-Paper.pdf.

Accessed August 25, 2018.

362 Hilton RP, Serban N, Zheng RY. Uncovering longitudinal healthcare utilization from patient-level medical claims data. March 4, 2016. https://arxiv.org/pdf/1603.00896.pdf. Accessed August 25, 2018.

363 Porter J. State innovations in the use of APCD data. APCD Council. https://nashp.org/wp- content/uploads/2015/01/j.porter.24.drilling.claims.data_.pdf. Accessed August 25, 2018

364 Hammill BG, Hernandez AF, Peterson ED, Fonarow GC, Schulman KA, Curtis LH. Linking inpatient clinical registry data to Medicare claims data using indirect identifiers. *Am Heart J*. 2009 Jun;157(6):995-1000. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2732025/. Accessed August 25, 2018.

365 These tools should use paid claims amounts (rather than charges) to develop more accurate measures of cost. See Delbanco S, de Brantes F. States must step up to help consumers gain access to health care prices. *The Health Care Blog*. March 18, 2013. www.thehealthcareblog.com/blog/2013/03/18/states-must-step-up-to-help-consumers-gain- access-to-health-care-prices/. Accessed June 2013.

366 Sinaiko AD, Chien AT, Rosenthal MB. The role of states in improving price transparency. *JAMA Int Med*. 2015. 175(6):886-887.

367 Mandl KD, Mandel JC, Kohane IS. Driving innovation in health systems through an apps-based information economy. *Cell Sys*. 2015 July 29;1(1):8-13. https://www.sciencedirect.com/science/article/pii/S2405471215000046. Accessed August 25, 2018.

368 Epic helps convert its large hospital customers into Epic hosting sites/consultants. *Lab Soft News*. http://labsoftnews.typepad.com/lab_soft_news/2011/03/thepic-converts-its-academic-health-system-customer-into- franchisees.html. Accessed September 21, 2018.

369 HIPAA refers to the Health Insurance Portability and Accountability Act.

370 Samal L, Dykes PC, Greenberg JO, et al. Care coordination gaps due to lack of interoperability in the United States: a qualitative study and literature review. *BMC Health Serv Res.* 2016 April 22;16:143. https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1373-y. Accessed August 25, 2018.

Issue 9: Extending the Medicare Modernization Act - Expansion of Health Reimbursement Accounts and ICHRAs

Since HSAs are the property of the individual, increasing consumers' ability to use HSAs is likely the best way to encourage first-party payment. Expanding HRAs could also encourage more efficiency through greater consumer control over their healthcare and somewhat reduced third-party payment.

Originally described in IRS guidance in 2002, HRAs allow employers to reimburse their employees' medical expenses. An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical expenses incurred by the employee or his or her family up to a maximum dollar amount for a period. Historically, HRAs have often been used by employers that did not choose to offer group insurance to their workers, as well as to supplement group coverage.

As a result of the interpretation of some ACA provisions, HRAs can currently only be offered if employers also offer ACA-compliant group health insurance plans. In implementing the ACA, the Obama administration determined that standalone HRAs violated the ACA prohibition on annual dollar limits and the requirement that group health plans provide certain preventive care without cost sharing. Although the Obama administration issued regulations allowing HRAs to be offered as long as the employee had other group health insurance coverage, the Obama administration restricted individuals' ability to use an HRA to purchase individual market insurance of their own choosing, even if the insurance did not have annual and lifetime dollar limits and covered preventive care without cost sharing.

The following two expansions of HRAs, both proposed in a notice of proposed rule-making issue on October 23, 2018, would increase their usability and provide employers, and their employees, with a greater set of alternatives for financing health coverage. First, reversing the Obama administration restriction on HRAs for individuals with individual market insurance would encourage more employers to offer HRAs, increase consumer choice, and provide equal tax treatment for employee-selected coverage in the individual market as for

traditional employer-selected group coverage.304 In essence, allowing HRAs to be

integrated with non-group coverage that does not have annual dollar limits and that covers the necessary preventive care without cost sharing would allow employers to provide a tax- advantaged, defined contribution arrangement for each employee to select the health insurance that best works for his or her circumstances. In addition to the benefit for workers, the proposed rule would better enable businesses to focus on what they do best— serve their customers—and not on navigating and managing complex health benefit designs.

This proposed rule is increasingly important as fewer employees at small and mid-sized firms are enrolled in employer coverage and most employers that do offer a plan only provide their workers a single option. For firms that employ 3-24 workers, the percentage of workers covered by employer health benefits has fallen from 44% in 2010 to 30% in 2018. For firms that employ 25-49 workers, the percentage of workers covered by employer health benefits has fallen from 59 percent in 2010 to 44 percent in 2018. 81 percent of small to midsized employers (fewer than 200 employees), and even 42 percent of larger employers (at least 200 employees), offering health benefits only provide a single coverage option for their employees. Economists have found that increasing plans available to employees is extremely valuable, providing the median consumer equivalent benefit as a 13 percent premium reduction.305

An additional way to expand the use of HRAs is to allow a limited "excepted benefit" HRA that, as with all excepted benefits, would not be subject to the ACA's market rules (such as the prohibition on annual dollar limits and the requirement to cover preventive care without cost sharing) or certain other requirements for group health plans under the Code and the Employee Retirement Income Security Act of 1974 (ERISA). Providing an excepted benefit HRA would reduce the bias toward comprehensive ESI and allow employees another tax-advantaged arrangement to finance limited healthcare expenses. The proposed regulation would permit employers that offer traditional group coverage to provide an HRA of up to $1,800 per year (indexed to inflation) to reimburse an employee for certain qualified medical expenses, including standalone dental benefits and premiums for a short-term health insurance plan.

According to preliminary estimates from the Treasury Department, once fully phased in, roughly 800,000 employers are expected to provide HRAs to pay for individual health insurance coverage to over 10 million employees. Some experts, such as Harvard Business School professor Regina Herzlinger, suggest the effect could be larger since expanded HRAs will create a more efficient healthcare system as consumerism will be unleashed.306 This phenomenon could lead to increased workforce investment and higher wages as less is spent on health insurance and could spur innovation among providers and insurers as they directly compete for consumer dollars.

Individual Coverage Health Reimbursement Accounts (ICHRAs)

This Question and Answer section comes from New Health Coverage Options for Employers and Employees Individual Coverage and Excepted Benefit Health Reimbursement Arrangements, June 2019 jointly published by the US Departments of the Treasury and Labor.

https://www.irs.gov/pub/irs-utl/health_reimbursement_arrangements_faqs.pdf

Q1. What are the benefits of offering an Individual Coverage HRA to employees?

Individual Coverage HRAs can help enable businesses to focus on what they do best—serve their customers—and not on navigating and managing complex health benefit

designs. Individual Coverage HRAs provide tax advantages because the reimbursements provided to employees do not count toward the employees' taxable wages. In effect, Individual Coverage HRAs extend the tax advantage for traditional group health plans (exclusion of premiums, and benefits received, from federal income and payroll taxes) to HRA reimbursements of individual health insurance premiums. Employers may also allow employees to pay for off-Exchange health insurance on a tax-favored basis, using a salary reduction arrangement under a cafeteria plan, to make up any portion of the individual health insurance premium not covered by the employee's Individual Coverage HRA.

In most cases, the Individual Coverage HRA rule will increase worker options for health insurance coverage, allowing workers to shop for plans in the individual market and select coverage that best meets their needs. It will also result in coverage being more portable for many workers. 81% of small to midsized employers (fewer than 200 employees) and 42% of larger employers (at least 200 employees) offering health benefits in 2018 provided only one type of health plan to their employees.

Q2. How does an Individual Coverage HRA work?

An Individual Coverage HRA reimburses employees for their medical care expenses (and sometimes their family members' medical care expenses), up to a maximum dollar amount that the employer makes available each year. The employer can allow unused amounts in any year to roll over from year to year. Employees must enroll in individual health insurance (or Medicare) for each month the employee (or the employee's family member) is covered by the Individual Coverage HRA. This can be individual health insurance offered on or off an Exchange. However, it cannot be short-term, limitedduration insurance (STLDI) or coverage consisting solely of dental, vision, or similar "excepted benefits." There are other important requirements too. An employer that wants to offer an Individual Coverage HRA should review the HRA rule for more information on the conditions the HRA must meet.

Q3. Why is the HRA rule important for small businesses and their workers?

The HRA rule will provide hundreds of thousands of businesses a better way to offer health insurance coverage and millions of workers and their families a better way to obtain coverage. The HRA rule will especially help small employers, who face larger administrative costs from offering a traditional group health plan, compete for talent. Many small employers struggle to offer coverage to their employees, and a significant number of small employers have stopped offering coverage since 2010. Between 2010 and 2018, the percentage of firms offering coverage declined from 59% to 47% at firms with 3-9 workers, from 76% to 64% at firms with 10-24 workers, from 92% to 71% at firms with 25-49 workers, and from 95% to 91% at firms with 50-199 workers.

Q4. What are the expectations for take-up of the Individual Coverage HRA?

The Departments estimate that once employers fully adjust to the new rules, roughly 800,000 employers will offer Individual Coverage HRAs to pay for insurance for more than 11 million employees and family members, providing these Americans with more options for selecting health insurance coverage that better meets their needs. The Departments estimate that, once fully phased in, about 800,000 people who were uninsured will gain coverage.

The HRA rule, combined with the Administration's rules to expand Association Health Plans (AHPs) and STLDI has been projected to increase private insurance coverage by nearly 2 million people. (Source: The HRA rule regulatory impact analysis combined with the Congressional Budget Office January 2019 estimates of the AHP and STLDI rule).

Q5. I am an employer. To whom can I offer an Individual Coverage HRA?

If you offer an Individual Coverage HRA, you must offer it on the same terms to all individuals within a class of employees, except that the amounts offered may be increased for older workers and for workers with more dependents. You cannot offer an Individual Coverage HRA to any employee to whom you offer a traditional group health plan. However, you can decide to offer an individual coverage HRA to certain classes of employees and a traditional group health plan (or no coverage) to other classes of employees.

Employers may make distinctions, using classes based on the following status:

> • Full-time employees, • Part-time employees, • Employees working in the same geographic location (generally, the same insurance rating area, state, or multi-state region), • Seasonal employees, • Employees in a unit of employees covered by a particular collective bargaining agreement, • Employees who have not satisfied a waiting period, • Non-resident aliens with no U.S.-based income, • Salaried workers, • Non-salaried workers (such as hourly workers), • Temporary employees of staffing firms, or • Any group of employees formed by combining two or more of these classes.

To prevent adverse selection in the individual market, a minimum class size rule applies if you offer a traditional group health plan to some employees and an Individual Coverage HRA to other employees based on: full-time versus part-time status; salaried versus non-salaried status; or geographic location, if the location is smaller than a state. Generally, the minimum class size rule also applies if you combine any of these classes with other classes. The minimum class size is:

• Ten employees, for an employer with fewer than 100 employees,

• Ten percent of the total number of employees, for an employer with 100 to 200 employees, and

• Twenty employees, for an employer with more than 200 employees.

Also, through a new hire rule, employers can offer new employees an Individual Coverage HRA, while grandfathering existing employees in a traditional group health plan.

Q6. How do my employer contributions work?

Employers can contribute as little or as much as they want to an Individual Coverage HRA. However, an employer must offer the HRA on the same terms to all employees in a class of employees, except that employers can increase the amount available under an Individual Coverage HRA based on the employee's age or number of dependents. Also, see Q7 for employers subject to the employer mandate.

Q7. Can an employer offer an Individual Coverage HRA to satisfy the employer mandate?

First, only certain employers – in general, those with at least 50 full-time employees, including full-time equivalent employees, in the prior year – are applicable large employers subject to the employer mandate.

An offer of an Individual Coverage HRA counts as an offer of coverage under the employer mandate. In general, whether an applicable large employer that offers an Individual Coverage HRA to its full-time employees (and their dependents) owes a payment under the employer mandate will depend on whether the HRA is affordable. This is determined under the premium tax credit rule being issued as part of the HRA rule and is based, in part, on the amount the employer makes available under the HRA. Therefore, if you are an applicable large employer and want to avoid an employer mandate payment by offering an Individual Coverage HRA, in general, you will need to contribute a sufficient amount for the offer of the Individual Coverage HRA to be considered affordable.

The Internal Revenue Service will provide more information on how the employer mandate applies to Individual Coverage HRAs soon. For more information on the employer mandate, see https://www.irs.gov/affordable-care-act/employers/employershared-responsibility-provisions.

Q8. What other responsibilities do I, the employer, have?

Individual Coverage HRAs must provide a notice to eligible participants regarding the Individual Coverage HRA and its interaction with the premium tax credit. The HRA must also have reasonable procedures to substantiate that participating employees and their families are enrolled in individual health insurance or Medicare, while covered by the HRA. The Appendix to this document includes a model notice and a model substantiation form that you can use. Employees must also be permitted to opt out of an Individual Coverage HRA at least annually so they may claim the premium tax credit if they are otherwise eligible and if the HRA is considered unaffordable.

You generally will not have any responsibility with respect to the individual health insurance itself that is purchased by the employee, because it will not be considered part of your employer-sponsored plan, provided:

> • An employee's purchase of any individual health insurance is completely voluntary. • You do not select or endorse any particular insurance carrier or insurance coverage. • You don't receive any cash, gifts, or other consideration in connection with an employee's selection or renewal of any individual health insurance. • Each employee is notified annually that the individual health insurance is not subject to the Employee Retirement Income Security Act (ERISA), which is the federal law governing employer-provided health coverage.

Q9. May an employer allow employees to pay any portion of the premium for their individual health insurance that is not covered by the Individual Coverage HRA on a tax-preferred basis by using a salary reduction arrangement under a cafeteria plan?

It depends on whether the employee buys the individual health insurance on an Exchange or off an Exchange. The Internal Revenue Code provides that an employer may not permit employees to make salary reduction contributions to a cafeteria plan to purchase coverage offered through an Exchange. However, that restriction does not apply to coverage that is purchased off an Exchange. Therefore, if an employee buys individual health insurance outside an Exchange and the HRA doesn't cover the full premium, the employer could permit the employee to pay the balance of the premium for the coverage on a pre-tax basis through its cafeteria plan, subject to other applicable regulations.

Q10. Can large employers offer Individual Coverage HRAs too?

Yes. Although the Departments expect that the rule will especially benefit small and mid-sized employers, employers of all sizes may offer an Individual Coverage HRA, subject to the conditions in the HRA rule.

Q11. What are the benefits of offering an Excepted Benefit HRA?

There may be scenarios in which you wish to offer an HRA in addition to a traditional group health plan, for example to help cover the cost of copays, deductibles, or noncovered expenses. Excepted Benefit HRAs generally allow for higher levels of employer contributions than health flexible spending arrangements (FSAs) and can permit rollover of unused amounts from year to year.

Beginning in 2020, HRAs can be offered as "excepted benefits" which are exempt from many federal health care requirements that don't work well for account-based plans. Employees may use these Excepted Benefits HRAs even if they do not enroll in the traditional group health plan (or in any other coverage), which distinguishes the Excepted Benefit HRA from other HRAs.

To qualify as excepted benefits:

• The annual HRA contribution must be limited to $1,800 per year (indexed for inflation beginning in 2021).

• The HRA must be offered in conjunction with a traditional group health plan, although the employee is not required to enroll in the traditional plan.

• The HRA cannot be used to reimburse individual health insurance premiums, group health plan premiums (other than COBRA), or Medicare premiums, although it can reimburse premiums for excepted benefits, such as dental and vision coverage, as well as for STLDI.

• The HRA must be uniformly available to all similarly situated individuals (as defined under the Health Insurance Portability and Accountability Act, which generally permits bona fide employment-based distinctions unrelated to health status).

In particular, the Excepted Benefit HRA will benefit some of the growing number of employees who have been opting out of their employer's traditional group health plan because the employee's share of premiums is too expensive. In 1999, 17 percent of workers eligible for employer coverage at small and midsized firms (those with 3 to 199 workers) turned down the offer of employer coverage. By 2011, this share had climbed to 22 percent, and in 2018 it was 27 percent.

Note that Excepted Benefit HRAs, which can reimburse medical care expenses other than excepted benefits, are different from an HRA that reimburses only excepted benefits. Employers can continue to offer HRAs that reimburse only excepted benefits, and those HRAs need not meet the requirements for Excepted Benefit HRAs.

Issue 10: Extending the Medicare Modernization Act - Association Health Plans

This section comes from the CBO Paper: INCREASING SMALL-FIRM HEALTH INSURANCE COVERAGE THROUGH ASSOCIATION HEALTH PLANS AND HEALTHMARTS, January 2000. https://www.cbo.gov/publication/12066

Numbers in the text and tables of this paper may not add up to totals because of rounding.

All dollar values are expressed as 1999 dollars. All footnotes are at the end of this section.

SUMMARY AND INTRODUCTION

The rising number of people who lack health insurance continues to be a major concern to policymakers. According to the Census Bureau's Current Population Survey, about 43 million people under age 65 were uninsured in 1997. That estimate represents about 18 percent of the nonelderly population, compared with less than 15 percent who were uninsured a decade earlier.1

Given that the primary source of private health insurance coverage in the United States is employment, one might reasonably assume that people who lack insurance also lack jobs. Yet most uninsured people are members of families with at least one full-time worker. Uninsured workers are usually employees of small firms (those with fewer than 50 employees), and small firms typically face higher costs for health insurance than do larger firms, which may make small firms less likely to offer it. In 1996, 42 percent of small-firm establishments offered health insurance to their employees (see Table 1). (An establishment is a single geographic location of a firm.)2 By contrast, more than 95 percent of establishments in firms with 100 or more employees offered insurance. Another reason for lower rates of health insurance coverage for workers in small firms is lower take-up rates when insurance is offered. In 1996, about 81 percent of employees in small firms accepted insurance coverage when it was offered by their employers, compared with 87 percent of employees in firms with at least 100 employees.3

Concerns about low rates of coverage for employees of small firms have led to a number of initiatives at both the state and federal levels as well as in the private sector. One example is the formation of group purchasing cooperatives, some private and some sponsored by state or local governments, in which firms join together to purchase insurance in larger volumes at more affordable prices. By one estimate, almost a third of small firms purchase their health insurance through some form of cooperative purchasing arrangement.4 Even so, concerns persist about the affordability of insurance coverage and the lack of sufficient alternatives for reducing its cost. Recently, the House passed H.R. 2990, the Quality Care for the Uninsured Act of 1999, which among other things calls for establishing association health plans (AHPs) and

HealthMarts, two new vehicles for offering health insurance coverage to small employers. (The House passed similar legislation—H.R. 4250—in the 105th Congress, but the bill was never considered by the Senate.) Several other proposals for AHPs and HealthMarts have also been introduced in the House.5

This paper considers how the introduction of AHPs and HealthMarts would affect premiums and coverage in the small-group health insurance market.6 (Although entities known as association health plans already exist, all of the legislative proposals would create federally certified AHPs operating under a different set of rules.) The new entities would be exempt from some state insurance regulations that apply to insurance plans offered in the small-group market. Such regulations tend to increase premiums for those traditional plans.

Currently, about 48 million people either work for a small firm or are a dependent of someone who does. Under the most likely scenario for AHPs and HealthMarts, the Congressional Budget Office (CBO) estimates that approximately 4.6 million of those people might obtain their coverage through the proposed new insurance arrangements. But overall enrollment in employer-sponsored health insurance would increase by only about 330,000 people, because most firms purchasing coverage through an AHP or HealthMart would be switching from traditional insurance coverage—that is, insurance plans subject to the full array of state insurance regulations.7 On average, premiums paid by small firms that purchased health insurance through an AHP or HealthMart would be about 13 percent lower than the premiums they would otherwise pay under current law. With AHPs and HealthMarts in place, the firms that continued to purchase traditional coverage would face an average increase in premiums of about 2 percent.

THE HEALTH INSURANCE MARKET FOR SMALL GROUPS

As noted earlier, small firms are less likely than large employers to offer health insurance coverage to their employees, and small-firm employees are less likely to take up coverage when it is offered. Factors contributing to those lower rates of coverage include the characteristics of workers in small firms, firms' costs for providing insurance benefits, and state insurance regulations.

The earnings of employees in small firms are one of the chief reasons for lower rates of health insurance coverage among small employers. Compared with employees in large firms, those in small firms tend to be paid lower wages and have lower family income, although some employees are members of households with higher-paid workers. Given their lower income, employees of small firms may be unwilling to accept the even lower wages that would result if their employer sponsored a health benefits plan. Furthermore, because lower-income workers probably have fewer assets to protect in the event of a large medical expense, they may place less value on having insurance. Their lower wages also mean that smallfirm employees have less of a tax incentive to purchase insurance than do higher-paid workers. (Because employees are not taxed

on their employer's contribution for health insurance, workers in higher tax brackets gain a larger subsidy for health insurance than do workers in lower tax brackets.)8

The cost of health insurance for small firms may be another factor in their lower rates of coverage. Health insurance premiums for equivalent benefit packages are higher for small firms than for large ones. The premiums themselves do not differ consistently on the basis of firm size, but the benefit packages that large firms offer their employees are more generous than those offered by small firms.9 In addition, the administrative costs included in the premium are higher for small firms because they have fewer employees among whom to spread the fixed costs of a health benefits plan, including costs for marketing and enrollment. Premiums are also likely to be higher for small firms because they do not have as much purchasing power as large firms, which limits their ability to bargain for lower rates from providers and insurers.

State insurance regulations may also contribute to higher premiums for small firms. For example, premium compression regulations, although reducing premiums for some firms, have raised premiums for others. Because of their size, small firms may experience much greater variation than large firms in their expenses for health benefits. One employee's serious illness can dramatically boost a small firm's health expenses, and in the absence of regulatory intervention, the firm's health insurance premiums could also rise substantially (since, in general, premiums are set to reflect those expenses).10 Such significant rate variation, and even cancellation of policies, characterized the small-group market during the late 1980s.11 In response, many states imposed new regulations that guaranteed availability and renewability of insurance and limited the degree to which premiums could vary among small firms.12 In California, for example, the highest premium that an insurer may charge for a particular policy can be no more than 20 percent above its lowest premium for that policy. To comply with that kind of regulation, known as premium (or rate) compression, the insurer must increase the premiums it charges its lowest-cost, or healthiest, firms and reduce the premiums it charges its highest-cost firms. The result is cross-subsidization—the increased premiums paid by the healthiest firms are used to help pay for the expenses of less healthy firms, whose premiums are no longer high enough to cover their expected costs.

Another way in which state regulations may have boosted premiums for small firms is by mandating the inclusion of certain benefits in all health insurance plans. (In a number of states, those mandates cover treatment for alcoholism, drug abuse, and mental illness as well as chiropractic care and bone marrow transplants.) If such regulations force insurers in the small-group market to provide benefits that firms would not otherwise purchase, the mandates will, in effect, push up premiums by more than the additional coverage's value to employees. Mandates may also discourage some small employers from offering coverage, particularly firms with employees who are relatively

healthy and who—given the choice—would probably forgo at least some of the mandated benefits to obtain lower premiums. Another way in which state regulations may increase premiums is through premium taxes, which are paid by insurers. In 1996, such taxes ranged from less than 1 percent to as much as 4 percent of premiums.13

Although, in principle, mandates and premium taxes affect the premiums of any firm (regardless of size) that purchases insurance from a licensed insurer, they frequently have a greater impact on small firms. The reason is that larger firms can avoid such regulations by self-insuring—that is, by bearing the financial risks of their employees' health care costs themselves rather than purchasing coverage from a health insurer or health plan. The federal Employee Retirement Income Security Act (ERISA) exempts firms' self-insured health plans from most state insurance regulations. However, small firms are less likely than large firms to self-insure because they have fewer potential enrollees (employees and their dependents) among whom to spread expenditures and as a result are vulnerable to greater financial risk (see Table 1 on page 2). Small firms that offer coverage are much more likely to purchase it from a health insurer and must therefore bear the full cost of state insurance regulation.14

ASSOCIATION HEALTH PLANS AND HEALTHMARTS

AHPs and HealthMarts are intended to reduce the cost of health insurance for small employers. Like group purchasing cooperatives, they could enhance the purchasing power of their members, and they might reduce some administrative costs. But AHPs and HealthMarts would have two additional advantages compared with cooperatives: they would be exempt from most state benefit mandates, and they could avoid the full effect of state regulation of insurance premiums.

Association Health Plans

AHPs would operate subject to several important requirements. Trade, industry, or professional associations that had been in existence for at least three years could sponsor an AHP, which would have to offer its insurance products to all member firms. Those products could constitute a full range of health plans, including a selfinsured plan, under certain conditions: generally, the AHP would have to offer at least one fully insured plan (purchased from a licensed health insurer), and the sponsoring association would have to meet other qualifying criteria designed to limit favorable selection (attracting enrollees that are healthier than average) and the risk of financial insolvency. Both the AHP's self-insured and fully insured plans would be exempt from state benefit mandates, but they would not be exempt from state premium taxes.15

Because of their structure, AHPs would be subject in only a limited way to state laws that regulate premiums in the small-group health insurance market. In general, AHPs would have to abide by the premium-setting regulations of each state for their enrollees who resided in that state. Some states require insurers that offer small-group policies to community-rate their premiums (a practice in which the price for a given health policy

must be the same for all purchasers despite variations in those purchasers' expected costs per enrollee). Other states limit the degree to which premiums for a particular policy can vary among firms. AHPs would have to follow the state's rating rules, but the premiums they offered would be based on the average expected costs per enrollee of only the association's member firms—not on the costs of the broader (and potentially more expensive) groups that insurers offering traditional coverage serve. As a result, AHP premiums are likely to be lower than they would be if they reflected the availability rules applying to traditional (fully regulated) plans.

HealthMarts

In many respects, HealthMarts would be similar to AHPs, but certain features—in particular, eligibility based on geographic location rather than association membership—would set them apart. HealthMarts would be nonprofit organizations that offered health insurance products to all small firms within their geographic service area, which would have to cover at least one county or an area of equivalent size. All of the health benefits plans that a HealthMart offered would be available to any small employer within its service area. Employers who chose to participate would have to agree to purchase health insurance only from the HealthMart. (That is, participating employers could not offer their employees plans from the traditional market in addition to HealthMart plans.)

Like AHPs, health plans offered through HealthMarts would be exempt from most state benefit mandates but would have to pay state premium taxes. HealthMarts would also be subject to state premium regulations that applied within their service area.16 Unlike AHPs, however, HealthMarts could offer only fully insured plans from insurance issuers licensed in the state; self-insurance would not be an option.

HOW AHPs AND HEALTHMARTS WOULD AFFECT PREMIUMS AND COVERAGE

The effects of AHPs and HealthMarts on the premiums of and number of people enrolled in traditional plans would depend on the response of small firms to health insurance policies comprising fewer benefits coupled with lower premiums. Coverage might increase if AHPs and HealthMarts could offer plans with premiums that were lower than those for traditional coverage. Firms that do not currently offer insurance to their employees might choose to do so if the price was lower, even if the benefits were not as comprehensive as in some plans. Yet that response is only part of the coverage picture. Firms that already purchase traditional coverage might instead seek lower-cost coverage through an AHP or HealthMart. If the firms that dropped traditional coverage had healthier-than-average employees, and thus lower costs for insurance, fewer of those so-called low-cost firms would remain to subsidize the premiums of higher-cost firms. As a result, premiums for at least some firms purchasing traditional plans would have to rise, which could lead those firms to drop coverage.

Premiums in the AHP/HealthMart Market

AHPs and HealthMarts could offer premiums that were lower than those for traditional coverage to the extent that they were exempt from state benefit mandates and could avoid some of the effects of state premium-setting regulations. Group purchasing of health insurance through AHPs and HealthMarts could also lower the cost of health insurance for small firms if it reduced administrative costs or increased firms' purchasing power. AHP premiums might undergo further paring depending on whether a particular AHP could achieve savings through self-insurance.

Avoiding State Regulation. According to their advocates, reducing the cost of state regulation is one of the principal attractions of AHPs and HealthMarts. Unlike the purchasing cooperatives that can now be found in many states, AHPs and HealthMarts would not be subject to state benefit mandates and might also avoid some restrictions on premiums. (Box 1 briefly discusses several kinds of purchasing cooperatives.) For example, small firms could obtain lower premiums if AHPs and HealthMarts dropped some of the benefits that states required insurers to cover and offered less generous benefit packages than were available in traditional plans. The extent of such savings and their effect on premiums would depend on whether employees of small firms still desired some of those mandated benefits. Firms take into account the preferences of their employees in designing their benefit packages and will not necessarily sponsor policies that omit all mandated benefits. (One study of self-insured employers found that many of those firms offered mandated benefits despite their exemption from state regulations under ERISA.)17

Exempting AHPs and HealthMarts from offering mandated benefits might substantially affect selection. With the exemption, AHPs and HealthMarts could design benefit packages that had fewer benefits and were relatively unattractive to firms whose employees had costly health care needs. Those firms would want more extensive benefit packages and would probably maintain their enrollment in traditional (fully regulated) plans. As a result, their high health care costs would not affect the premiums offered by AHPs and HealthMarts, which might allow those plans to lower their costs by more than the savings from the mandates exemption alone. Lower-priced plans with leaner benefit packages would appeal more to healthy firms (with lower-than-average expected health care costs)—both those that offered no coverage at all to their employees and those that already offered insurance. Some firms with higher-than-average expected health costs might also be attracted by the lower premiums, but they would be less likely to participate because of the leaner benefits.

Health insurance purchase cooperatives

Health insurance purchasing cooperatives are relatively popular among small firms. A recent study estimated that 33 percent of establishments in firms with fewer than 10 employees and 28 percent of establishments in firms with 10 to 49 employees purchase health insurance through some type of group purchasing cooperative.1 Such group purchasing arrangements can be divided into three broad categories: state-sponsored

health insurance purchasing alliances, multiple-employer welfare arrangements (MEWAs), and multiemployer union-sponsored plans (also known as Taft-Hartley plans).

To encourage small firms to purchase health insurance, a handful of states sponsored health insurance purchasing alliances beginning in the early 1990s.2 (An example is California's Health Insurance Purchasing Cooperative.) Typically, state alliances offer a variety of plans, including one or more managed care options, to any qualifying employer who wishes to purchase insurance through the alliance, and employees then enroll in the plan of their choice. The health plans that alliances offer are subject to normal state insurance regulations, including premium-setting rules and benefit mandates, although a few states exempt alliance plans from some of those requirements.

MEWAs can take many different forms including privately sponsored alliances, which function like the state-sponsored type, and association health plans, which can offer coverage only to members of their sponsoring association. (Those existing association health plans should not be confused with the proposed association health plans that are the focus of this paper.) The association-sponsored plans are employee benefit plans as defined by the Employee Retirement Income Security Act, or ERISA. They are more likely than purchasing alliances to offer a limited selection of health insurance options, and they can self-insure if they choose. In general, both fully insured and self-insured MEWAs are subject to state insurance regulations, including benefit mandates and premium-setting rules.

Union-sponsored plans are the only type of purchasing cooperative that does not have to adhere to state insurance regulations. Even though Taft-Hartley plans may involve many employers, ERISA classifies them separately from MEWAs and exempts them from state regulations such as benefit mandates and premium-setting rules.

There is little direct evidence about the effect of cooperatives on premiums. According to a study of a major purchasing alliance in California, the premiums that participating insurers offered to qualifying small employers were not as low as those offered to large firms.3 Long and Marquis’s analysis of a national survey of small firms found that premiums for cooperatives were roughly the same as those offered by traditional plans. The advantages of alliances appear to be primarily choice and information. For about the same premium, firms purchasing their coverage through a cooperative are more likely than other small firms to offer a choice of health plans to their employees. They also have better access to information about those plans, such as the benefits offered and the quality of care provided.

In the long run, one would expect the most successful AHPs to be sponsored by associations whose members had lower-than-average health care costs. Similarly, the most successful HealthMarts would probably be located in lower-cost areas of the country or areas where the costs of regulation and mandates were high.

Group Purchasing.

To a limited extent, the advantages offered by group purchasing might enable AHPs and HealthMarts to offer premiums that were lower than those for traditional coverage. Like other group purchasing arrangements, AHPs and HealthMarts would probably have more negotiating power with health insurers than would small employers negotiating on their own. The larger the number of potential enrollees, the more willing health insurers and provider networks would be to discount their rates to attract business. Another advantage of group purchasing that might be reflected in lower premiums would be lower administrative costs—with group purchasing, some fixed costs would be shared among a larger number of enrollees.

Savings from group purchasing, however, are unlikely to induce many small firms to add coverage, because the group purchasing option, with its associated advantages, is already available to them through purchasing cooperatives. One exception may be AHPs and HealthMarts in states that have not been particularly supportive of cooperative purchasing arrangements.

Self-Insuring Through AHPs.

Although AHPs would be able to offer self-insured plans, several factors would limit the attractiveness of that option. For example, all plans offered by AHPs, whether self-insured or fully insured, would be exempt from benefit mandates and would have to pay premium taxes. As a result, selfinsured AHP plans would offer no advantage in those areas over fully insured AHP plans.18 Other advantages of self-insuring might also go unrealized. For example, firms that self-insure can retain and earn interest on the money that they would ordinarily pay in premiums to a health insurer until the money is needed to pay medical claims.19 But small firms enrolling in an AHP's self-insured plan would still have to pay premiums to a third party—the AHP. Moreover, to curb favorableselection practices, some of the proposals being considered would restrict the selfinsurance option to AHPs sponsored by associations whose member firms had higher-than-average health expenditures or represented a broad cross-section of industries (such as a chamber of commerce).

The option to self-insure jointly with other firms is not new. ERISA already allows small firms to self-insure by joining together with other firms in so-called multiple-employer welfare arrangements (MEWAs). However, MEWAs might not be as attractive a vehicle for self-insuring as AHPs would be. Unlike AHPs, MEWAs must comply with some state regulations, including benefit mandates. In addition, some small firms may consider participation in a MEWA to be too risky. Overlapping state and federal laws have made regulating MEWAs a complicated and difficult task. According to the General Accounting Office, "MEWAs have proven to be a source of regulatory confusion, enforcement problems, and, in some instances, fraud."20 As of December 1998, the Department of Labor had initiated 358 civil and 70 criminal investigations of

MEWAs that affected over 1.2 million enrollees and involved monetary violations of more than $83.6 million.21

To bypass such problems, all of the AHP proposals include requirements to facilitate effective regulation of small firms that self-insure collectively. AHPs that offered self-insured plans would be subject to federal solvency standards, including requirements to set aside adequate reserves and to purchase stop-loss and indemnification insurance. Stop-loss insurance, which insures against the risk of unusually high claims, would apply to claims for a specific enrollee as well as aggregate claims for the plan as a whole. Indemnification insurance would pay outstanding claims if the plan was unable to meet its obligations. Thus, although self-insured AHP plans might not offer many advantages over their fully insured counterparts, they might still be more attractive to small firms than self-insuring through a MEWA.

Premiums for Traditional Insurance Plans

If firms with healthier-than-average employees switched from traditional insurance to AHPs and HealthMarts, premiums for some firms' traditional policies would rise. Moreover, that selection effect could be exacerbated by recently enacted federal requirements regarding the portability of insurance coverage. The Health Insurance Portability and Accountability Act of 1996 limits exclusions for preexisting conditions when purchasers of insurance switch from one policy to another. That provision could lead to the sorting of "healthy" and "sick" firms into AHP/HealthMart and traditional plans, respectively. For example, a firm with healthy employees (and thus relatively low expected health costs) might purchase a relatively inexpensive policy (covering few mandated benefits) in the AHP/HealthMart market. If one or more of its employees subsequently developed a serious illness, the firm could switch back to a traditional plan to obtain a more comprehensive policy, and its employees would face no exclusion (or only a limited exclusion) for preexisting conditions.22

To discourage favorable-selection practices, the proposals covering AHPs and HealthMarts generally include requirements that would limit their ability to attract healthier-than-average groups. For example, AHPs would have to offer their plans to any small firm that qualified for membership in the sponsoring association. Similarly, HealthMarts would have to make their plans available to any small firm located in their designated geographic area. A further factor tempering favorableselection efforts may be that increasingly aggressive attempts by AHPs and HealthMarts to attract low-cost firms would add to administrative costs. Moreover, premium-setting regulations would still apply.

Even if AHPs and HealthMarts were successful in attracting primarily low-cost firms, the resulting premium increases for traditional plans would be relatively small. High-cost firms would be a small minority of those firms retaining traditional coverage, even

though some lower-cost firms would switch to less costly AHP or HealthMart options. The low-cost firms that continued to purchase traditional health insurance would cross-subsidize the higher-cost firms, just as they do now.

Coverage

How AHPs and HealthMarts affected coverage would depend on how small firms responded to changes in premiums and benefits and, more specifically, on the differential responses by low-cost and high-cost firms. The effect on coverage of reforms in the small-group market that were enacted by many states in the early 1990s—reforms that AHPs and HealthMarts would weaken—may provide some insight into the potential impact of the proposed new insurance vehicles. Although the reforms may have stabilized premiums and made health insurance more available in the small-group market, they may also have led to reduced coverage: between 1987 and 1996, enrollment of small-firm employees in employer sponsored health insurance declined by about 3 to 4 percentage points. 23

New insurance laws—including benefit mandates and premium compression requirements—that raised premiums for low-cost firms in the small-group market probably contributed to that loss of coverage. Benefit mandates may have caused firms to pay for benefits that their employees did not value highly. When those mandates resulted in higher-priced insurance policies, some losses in coverage probably occurred. Premium compression requirements, which lead to low-cost firms cross-subsidizing the coverage of higher-cost firms, raise the cost of insurance for firms with healthier employees and lower it for firms with less healthy employees.24 Some empirical studies suggest that because low-cost firms and their employees have less immediate need for health insurance, they may be more sensitive to price changes than high-cost firms and their employees (see the appendix). Consequently, the studies show that the number of employees in lowcost firms who dropped coverage when their premiums rose was greater than the number of employees in high-cost firms who gained coverage when their premiums fell.

The differential responses to changes in premiums by firms with different expected health care costs is key to understanding the net effect of AHPs and HealthMarts on coverage. AHPs and HealthMarts would weaken some of the effects of state premium reforms; as a result, some low-cost firms would gain access to lower premiums, but some high-cost firms would see their premiums rise.25 If, indeed, high-cost firms respond less to price changes than do low-cost firms, the resulting net coverage loss among high-cost firms would probably be less than the net coverage gain among low-cost firms, so overall coverage levels would probably increase. In addition, the mandates exemption of the AHPs and HealthMarts would allow them to offer plans with fewer benefits and at a lower price than the traditional plans can offer. The new plans are likely to be particularly attractive to low-cost firms, which would encourage some firms and workers to add coverage.

ESTIMATING THE EFFECTS OF AHPs AND HEALTHMARTS ON PREMIUMS AND COVERAGE

CBO constructed an analytical model to project how small firms and their employees would respond to the introduction of AHPs and HealthMarts. Two measures of the potential impact of those proposed new insurance arrangements are the net increase in the number of people covered by insurance and the increase in total premiums paid to insurers. The latter measure reflects both the additional people covered by insurance and the net overall changes in the value of benefits offered to people with coverage. Changes in coverage might accompany either an increase or decrease in the total premiums paid. The estimates reported here indicate the long-term changes in premiums and coverage that would occur after the market had fully adjusted to the introduction of AHPs and HealthMarts.

Main Findings

The model's main findings rely on assumptions that were developed from the results of empirical studies about how firms and employees respond to changes in premiums and insurance regulations (see the appendix for details). Under those assumptions, the introduction of AHPs and HealthMarts would increase net coverage through small firms by about 1.3 percent, or 330,000 people, including employees and their dependents (see Table 2). The increase in the overall number of people with insurance, however, would be slightly lower, because some of those who gained employer-sponsored coverage through AHPs and HealthMarts would have otherwise obtained coverage through the individual market. The 330,000 figure represents a net increase of about 340,000 enrollees among low-cost firms that would be slightly offset by a net drop of 10,000 people among higher-cost firms. (For these estimates, low-cost firms are those with expected claims costs per enrollee in the lower 90 percent of the distribution for all small firms.) Altogether, CBO estimates that about 4.6 million people would be insured through AHPs and HealthMarts, with most of those people switching from the fully regulated market to the new plans.

Once AHPs and HealthMarts were in full operation, total premiums paid annually by small firms and their employees would be approximately $150 million more than they otherwise would be, which represents about a 0.3 percent increase in total spending for health insurance in the small-group market (see Table 3). Firms that continued to purchase traditional health insurance plans would pay an additional $800 million in premiums. That increase would be more than offset by the $1.2 billion in net premium savings that would result because firms faced lower premiums in AHP and HealthMart plans. In addition, the net increase in coverage among low-cost firms would add $600 million in premiums; among higher-cost firms, the increase in the price of traditional plans would lead to a cut of about $50 million worth of coverage.

The price of a policy would be lower for some firms as a result of introducing AHPs and HealthMarts. On average, premiums paid by firms that participated in AHPs and

HealthMarts would be about 13 percent lower than the premiums they would pay in the small-group market under current law (see Table 4). Five percentage points of that reduction come from the benefit mandate exemption and savings from group purchasing (see the appendix). The other 8 percentage points stem from the expected health costs of firms in the AHP and HealthMart market that are generally lower than average and that allow participating firms to avoid some of the premium-boosting effects of rate compression laws.

Once AHPs and HealthMarts became available, firms that continued to purchase traditional plans would, on average, see some increases in their premiums arising from the shift of some low-cost firms to the new insurance vehicles. CBO's projections indicate a net transfer of approximately 4.3 million enrollees in low-cost firms from fully regulated plans to an AHP or HealthMart plan. Those transfers would cause premiums offered to firms with traditional coverage to rise, on average, by 2 percent. The increase is relatively small because low-cost firms would continue to be a substantial part of the market for traditional plans.

Findings Under Alternative Assumptions

To determine a plausible range of possible outcomes once AHPs and HealthMarts were introduced, CBO varied its assumptions about the behavioral responses of firms and employees (see the appendix). At one extreme, the model estimated that coverage through small firms would increase by only 10,000 enrollees. That figure is associated with a negligible increase in premiums for small firms purchasing traditional insurance and a 9 percent reduction in premiums for participants in AHPs and HealthMarts. At the upper end of the range, the model estimated that coverage could increase by as many as 2 million people. The accompanying changes in premiums would be an increase of 2 percent for firms retaining traditional coverage and a reduction of 25 percent for firms participating in AHPs and HealthMarts. Under those alternative scenarios, the total number of enrollees in AHPs and HealthMarts ranges from less than 1 million to 5.7 million.

CONCLUSIONS

CBO projects that the introduction of AHPs and HealthMarts would have only slight effects on insurance coverage nationwide, increasing the number of people insured through small firms by about 330,000. Although about 4.6 million people would enroll in the new plans, the net boost in the number of people insured through small firms would be far smaller because many enrollees in the new plans would otherwise have been insured through traditional plans and because the increase in enrollees from some firms (those that gained coverage through AHPs and HealthMarts) would be offset by the decrease in enrollees from others (those that dropped their traditional coverage). Although coverage among small firms would grow by about 1.3 percent, total spending for health insurance would actually rise by only 0.3 percent, for two reasons: some coverage would be less comprehensive—because AHPs and HealthMarts are exempt

from most statemandated benefit requirements—and the mix of low-cost and high-cost firms with coverage would change.

If low-cost firms moved to AHPs and HealthMarts, some firms with traditional coverage would see their premiums rise because fewer low-cost firms would remain to cross-subsidize the high-cost firms. In response, some firms and workers covered under traditional plans would drop coverage, but most would continue to be covered and pay slightly higher premiums. After summing the changes in enrollment in both AHP/HealthMart and traditional plans, CBO estimates that, on balance, high-cost firms would drop coverage and low-cost firms would add coverage. Consequently, among firms that have coverage, the proportion of low-cost firms would increase, and the share of high-cost firms would decrease.

Among the states, the impact of AHPs and HealthMarts would probably be uneven because states differ in the extent and intensity of their regulations. States that have imposed relatively strict premium compression rules would be likely to attract more of the new plans than states that allow insurers to charge a wider range of premiums. The reason is that in states with more tightly compressed premiums—where the most cross-subsidization occurs—low-cost firms would face the greatest potential difference in price between traditional and AHP/HealthMart plans. Similarly, states with benefit mandates that are more costly or that cover benefits perceived as having little value to the average employee would be riper markets for AHPs and HealthMarts, as would areas with greater concentrations of small firms. In addition to considering who would gain and who would lose under these proposed new insurance arrangements, policymakers must address issues of regulatory authority and solvency standards. Much uncertainty attends the overlapping of federal and state jurisdiction over AHPs and HealthMarts. States, for example, would exercise considerable regulatory authority over HealthMart plans—which could only be fully insured products offered by state-licensed insurers. But the Department of Health and Human Services would also be given regulatory authority over HealthMarts. States would have some authority over AHPs but might rely on the Department of Labor to oversee those plans—especially since self-insured AHPs would have to comply with federal solvency standards. How great a role the federal government or the states played in regulating the new entities would depend, in part, on the resources that the two designated federal oversight agencies devoted to that function.

Notes

1. Paul Fronstin, Sources of Health Insurance and Characteristics of the Uninsured: Analysis of the March 1998 Current Population Survey, Issue Brief 204 (Washington, D.C.: Employee Benefits Research Institute, 1998), pp. 1 and 4.

2. A firm may have many establishments; however, most small firms have only one.

3. This paper considers only private-sector for-profit and not-for-profit firms.

4. Stephen H. Long and M. Susan Marquis, "Pooled Purchasing: Who Are the Players?" Health Affairs, vol. 18, no. 4 (July/August 1999), pp. 105-111.

5. See H.R. 448, H.R. 1136, H.R. 1496, H.R. 1687, and H.R. 2926.

6. At least one of the bills would create individual membership associations, or IMAs, that would face some regulatory rules similar to those for AHPs and HealthMarts. Unlike those proposed insurance arrangements, however, IMAs would not be sold as part of an employee benefit plan. This paper focuses on the market for employer-sponsored health insurance available through small firms and does not consider IMAs.

7. Of nonelderly people in families headed by someone working for a small firm, CBO estimates that almost 26 million are currently insured through a small employer, a further 13 million are uninsured, about 3.5 million purchase coverage in the individual market, and the remainder obtain coverage from other sources.

8. For an extended discussion of this issue, see Congressional Budget Office, The Tax Treatment of Employment-Based Health Insurance (March 1994). The average employee in a small firm has a relatively low income and therefore receives little benefit from the tax subsidy. However, the tax advantage is significant for employees in those small firms, such as law firms or other professional groups, that usually pay higher salaries.

9. See Len Nichols and others, Small Employers: Their Diversity and Health Insurance (Washington, D.C.: Urban Institute, June 1997).

10. That issue is discussed in Rick Curtis and others, "Health Insurance Reform in the Small-Group Market," Health Affairs, vol. 18, no. 3 (May/June 1999), p. 1.

11. Elliot K. Wicks and Jack A. Meyer, "Small Employer Health Insurance Purchasing Arrangements: Can They Expand Coverage?" New Directions for Policy, National Coalition on Health Care (May 1999) (available at http://www.americashealth.org/releases/stevesedit.html).

12. Federal law—specifically, the Health Insurance Portability and Accountability Act of 1996—also incorporates guaranteed availability and renewability of health insurance.

13. General Accounting Office, Health Insurance Regulation: Varying State Requirements Affect Cost of Insurance, GAO/HEHS-96-161 (August 1996), pp. 26-27.

14. Some small firms have chosen to partially self-insure by combining a self-insured plan with stop-loss insurance (an insurance policy that covers catastrophic health care expenditures). Partially self-insuring limits a firm's exposure to the risk of excessive health care expenditures—a critical consideration for a small firm—yet allows the firm to benefit from the advantages of self-insuring. Depending on the regulations of their state, firms that partially self-insure may avoid providing mandated benefits and paying

premium taxes. However, states may limit the attractiveness of this option by effectively restricting the amount of stop-loss coverage that firms may purchase.

15. Under some proposals, including H.R. 2990, states could charge premium taxes on self-insured AHP plans commencing operations after enactment of the legislation.

16. Depending on the specific proposal, a HealthMart might be required to charge the same premium to every participating employer.

17. Jonathan Gruber, “State-Mandated Benefits and Employer-Provided Health Insurance,” Journal of Public Economics, vol. 55 (1994), pp. 433-464.

18. Some association-sponsored plans in existence on the date of enactment of an AHP/HealthMart proposal might be able to claim an exemption from premium taxes.

19. See Martha Patterson and Derek Liston, Analysis of the Number of Workers Covered by Self-Insured Health Plans Under the Employee Retirement Income Security Act of 1974: 1993 and 1995 (Menlo Park, Calif.: Henry J. Kaiser Family Foundation, August 1996).

20. General Accounting Office, Employee Benefits: States Need Labor’s Help Regulating Multiple Employer Welfare Arrangements, GAO/HRD-92-40 (March 1992), p. 2.

21. Department of Labor, Pension and Welfare Benefits Administration, Office of Public Affairs, “Fact Sheet on MEWA Enforcement” (December 1998).

22. For a limited set of categories, federal portability regulations allow plans to impose limitations on coverage of preexisting conditions if a person’s previous plan did not cover those conditions. The coverage categories are mental health, substance abuse treatment, prescription drugs, dental care, and vision care.

23. See Philip Cooper and Barbara Schone, "More Offers, Fewer Takers for Employment-Based Health Insurance: 1987 and 1996," Health Affairs, vol. 16, no. 6 (November/December 1997), p. 14.

24. Because premium compression requirements also effectively impose an upper limit on the price of policies sold to higher-cost groups, insurers may have responded by not aggressively marketing their plans to as many firms with relatively less healthy employees as they would have if they had been allowed to charge higher rates.

25. That statement would be true only in general. A number of low-cost firms might remain enrolled in traditional plans, even though some of them would face increased premiums as other low-cost firms switched to AHPs and HealthMarts. In addition, some high-cost firms might obtain access to an AHP or HealthMart with predominantly healthy firms, enabling the high-cost firms to pay lower premiums than they would have paid if they had purchased traditional cover

Issue 11: The Affordable Care Act

Patient Protection and Affordable Care Act - Title I: Quality, Affordable Health Care for All Americans - Subtitle A: Immediate Improvements in Health Care Coverage for All Americans - (Sec. 1001, as modified by Sec. 10101) Amends the Public Health Service Act to prohibit a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from establishing lifetime limits or annual limits on the dollar value of benefits for any participant or beneficiary after January 1, 2014. Permits a restricted annual limit for plan years beginning prior to January 1, 2014. Declares that a health plan shall not be prevented from placing annual or lifetime per-beneficiary limits on covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted.

Prohibits a health plan from rescinding coverage of an enrollee except in the case of fraud or intentional misrepresentation of material fact.

Requires health plans to provide coverage for, and to not impose any cost sharing requirements for: (1) specified preventive items or services; (2) recommended immunizations; and (3) recommended preventive care and screenings for women and children.

Requires a health plan that provides dependent coverage of children to make such coverage available for an unmarried, adult child until the child turns 26 years of age.

Requires the Secretary of Health and Human Services (HHS) to develop standards for health plans (including grandfathered health plans) to provide an accurate summary of benefits and coverage explanation. Directs each such health plan, prior to any enrollment restriction, to provide such a summary of benefits and coverage explanation to: (1) the applicant at the time of application; (2) an enrollee prior to the time of enrollment or re-enrollment; and (3) a policy or certificate holder at the time of issuance of the policy or delivery of the certificate.

Requires group health plans to comply with requirements relating to the prohibition against discrimination in favor of highly compensated individuals.

Requires the Secretary to develop reporting requirements for health plans on benefits or reimbursement structures that: (1) improve health outcomes; (2) prevent hospital readmissions; (3) improve patient safety and reduce medical errors; and (4) promote wellness and health.

Prohibits: (1) a wellness and health promotion activity implemented by a health plan or any data collection activity authorized under this Act from requiring the disclosure or collection of any information relating to the lawful use, possession, or storage of a firearm or ammunition by an individual; (2) any authority provided to the Secretary under this Act from being construed to authorize the collection of such information or the maintenance of records of individual ownership or possession of a firearm or

ammunition; or (3) any health insurance premium increase, denial of coverage, or reduction of any reward for participation in a wellness program on the basis of the lawful use, possession, or storage of a firearm or ammunition.

Requires a health plan (including a grandfathered health plan) to: (1) submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums; and (2) provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees and activities that improve health care quality to the total amount of premium revenue for the plan year is less than a 85% for large group markets or 80% for small group or individual markets.

Requires each U.S. hospital to establish and make public a list of its standard charges for items and services.

Requires a health plan to implement an effective process for appeals of coverage determinations and claims.

Sets forth requirements for health plans related to: (1) designation of a primary care provider; (2) coverage of emergency services; and (3) elimination of referral requirements for obstetrical or gynecological care.

(Sec. 1002) Requires the Secretary to award grants to states for offices of health insurance consumer assistance or health insurance ombudsman programs.

(Sec. 1003, as modified by Sec. 10101) Requires the Secretary to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.

(Sec. 1004) Makes this subtitle effective for plan years beginning six months after enactment of this Act, with certain exceptions.

Subtitle B: Immediate Actions to Preserve and Expand Coverage - (Sec. 1101) Requires the Secretary to establish a temporary high risk health insurance pool program to provide health insurance coverage to eligible individuals with a preexisting condition. Terminates such coverage on January 1, 2014, and provides for a transition to an American Health Benefit Exchange (Exchange).

(Sec. 1102, as modified by Sec. 10102) Requires the Secretary to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees before January 1, 2014.

(Sec. 1103, as modified by Sec. 10102) Requires the Secretary to establish a mechanism, including an Internet website, through which a resident of, or small

business in, any state may identify affordable health insurance coverage options in that state.

(Sec. 1104) Sets forth provisions governing electronic health care transactions. Establishes penalties for health plans failing to comply with requirements.

(Sec. 1105) Makes this subtitle effective on the date of enactment of this Act.

Subtitle C: Quality Health Insurance Coverage for All Americans - Part I: Health Insurance Market Reforms - (Sec. 1201, as modified by Sec. 10103) Prohibits a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from: (1) imposing any preexisting condition exclusion; or (2) discriminating on the basis of any health status-related factor. Allows premium rates to vary only by individual or family coverage, rating area, age, or tobacco use.

Requires health plans in a state to: (1) accept every employer and individual in the state that applies for coverage; and (2) renew or continue coverage at the option of the plan sponsor or the individual, as applicable.

Prohibits a health plan from establishing individual eligibility rules based on health status-related factors, including medical condition, claims experience, receipt of health care, medical history, genetic information, and evidence of insurability.

Sets forth provisions governing wellness programs under the health plan, including allowing cost variances for coverage for participation in such a program.

Prohibits a health plan from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable state law.

Requires health plans that offer health insurance coverage in the individual or small group market to ensure that such coverage includes the essential health benefits package. Requires a group health plan to ensure that any annual cost-sharing imposed under the plan does not exceed specified limitations.

Prohibits a health plan from: (1) applying any waiting period for coverage that exceeds 90 days; or (2) discriminating against individual participation in clinical trials with respect to treatment of cancer or any other life-threatening disease or condition.

Part II: Other Provisions - (Sec. 1251, as modified by Sec. 10103) Provides that nothing in this Act shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled on the date of enactment of this Act. Allows family members of individuals currently enrolled in a plan to enroll in such plan or coverage if such enrollment was permitted under the terms of the plan. Allows new employees and their families to enroll in a group health plan that provides coverage on the date of enactment of this Act.

Defines a "grandfathered health plan" as a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act.

States that this subtitle and subtitle A shall not apply to: (1) a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act, regardless of whether the individual renews such coverage after such date of enactment; (2) an existing group health plan that enrolls new employees under this section; and (3) health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act until the date on which the last of the collective bargaining agreements relating to the coverage terminates.

Applies provisions related to uniform coverage documents and medical loss ratios to grandfathered health plans for plan years beginning after enactment of this Act.

(Sec. 1252) Requires uniform application of standards or requirements adopted by states to all health plans in each applicable insurance market.

(Sec. 1253, as added by Sec. 10103) Directs the Secretary of Labor to prepare an annual report on self-insured group health plans and self-insured employers.

(Sec. 1254, as added by Sec. 10103) Requires the HHS Secretary to conduct a study of the fully-insured and self-insured group health plan markets related to financial solvency and the effect of insurance market reforms.

(Sec. 1255, as modified by Sec. 10103) Sets forth effective dates for specified provisions of this subtitle.

Subtitle D: Available Coverage Choices for All Americans - Part I: Establishment of Qualified Health Plans - (Sec. 1301, as modified by Sec. 10104) Defines "qualified health plan" to require that such a plan provides essential health benefits and offers at least one plan in the silver level at one plan in the gold level in each Exchange through which such plan is offered.

(Sec. 1302, as modified by Sec. 10104) Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.

Sets forth levels of coverage for health plans defined by a certain percentage of the costs paid by the plan. Allows health plans in the individual market to offer catastrophic coverage for individuals under age 30, with certain limitations.

(Sec. 1303, as modified by Sec. 10104) Sets forth special rules for abortion coverage, including: (1) permitting states to elect to prohibit abortion coverage in qualified health plans offered through an Exchange in the state; (2) prohibiting federal funds from being used for abortion services; and (3) requiring separate accounts for payments for such services. Prohibits any qualified health plan offered through an Exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(Sec. 1304, as modified by Sec. 10104) Sets forth definitions for terms used in this title.

Part II: Consumer Choices and Insurance Competition Through Health Benefit Exchanges - (Sec. 1311, as modified by Sec. 10104) Requires states to establish an American Health Benefit Exchange that: (1) facilitates the purchase of qualified health plans; and (2) provides for the establishment of a Small Business Health Options Program (SHOP Exchange) that is designed to assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the state.

Requires the Secretary to establish criteria for the certification of health plans as qualified health plans, including requirements for: (1) meeting market requirements; and (2) ensuring a sufficient choice of providers.

Sets forth the requirements for an Exchange, including that an Exchange: (1) must be a governmental agency or nonprofit entity that is established by a state; (2) may not make available any health plan that is not a qualified health plan; (3) must implement procedures for certification of health plans as qualified health plans; and (4) must require health plans seeking certification to submit a justification of any premium increase prior to implementation of such increase.

Permits states to require qualified health plans to offer additional benefits. Requires states to pay for the cost of such additional benefits.

Allows a state to establish one or more subsidiary Exchanges for geographically distinct areas of a certain size.

Applies mental health parity provisions to qualified health plans.

(Sec. 1312, as modified by Sec. 10104) Allows an employer to select a level of coverage to be made available to employees through an Exchange. Allows employees to choose to enroll in any qualified health plan that offers that level of coverage.

Restricts the health plans that the federal government may make available to Members of Congress and congressional staff after the effective date of this subtitle to only those health plans that are created under this Act or offered through an Exchange.

Permits states to allow large employers to join an Exchange after 2017.

(Sec. 1313, as modified by Sec. 10104) Requires an Exchange to keep an accurate accounting of all activities, receipts, and expenditures and to submit to the Secretary, annually, a report concerning such accountings. Requires the Secretary to take certain action to reduce fraud and abuse in the administration of this title. Requires the Comptroller General to conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges.

Part III: State Flexibility Relating to Exchanges - (Sec. 1321) Requires the Secretary to issue regulations setting standards related to: (1) the establishment and operation of Exchanges; (2) the offering of qualified health plans through Exchanges; and (3) the establishment of the reinsurance and risk adjustment programs under part V.

Requires the Secretary to: (1) establish and operate an Exchange within a state if the state does not have one operational by January 1, 2014; and (2) presume that an Exchange operating in a state before January 1, 2010, that insures a specified percentage of its population meets the standards under this section.

(Sec. 1322, as modified by Sec. 10104) Requires the Secretary to establish the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets. Requires the Secretary to provide for loans and grants to persons applying to become qualified nonprofit health insurance issuers. Sets forth provisions governing the establishment and operation of CO-OP program plans.

(Sec. 1323, deleted by Sec. 10104)

(Sec. 1324, as modified by Sec. 10104) Declares that health insurance coverage offered by a private health insurance issuer shall not be subject to federal or state laws if a qualified health plan offered under the CO-OP program is not subject to such law.

Part IV: State Flexibility to Establish Alternative Programs - (Sec. 1331, as modified by Sec. 10104) Requires the Secretary to establish a basic health program under which a state may enter into contracts to offer one or more standard health plans providing at least the essential health benefits to eligible individuals in lieu of offering such individuals coverage through an Exchange. Sets forth requirements for such a plan. Transfers funds that would have gone to the Exchange for such individuals to the state.

(Sec. 1332) Authorizes a state to apply to the Secretary for the waiver of specified requirements under this Act with respect to health insurance coverage within that state for plan years beginning on or after January 1, 2017. Directs the Secretary to provide for an alternative means by which the aggregate amounts of credits or reductions that

would have been paid on behalf of participants in the Exchange will be paid to the state for purposes of implementing the state plan.

(Sec. 1333, as modified by Sec. 10104) Requires the Secretary to issue regulations for the creation of health care choice compacts under which two or more states may enter into an agreement that: (1) qualified health plans could be offered in the individual markets in all such states only subject to the laws and regulations of the state in which the plan was written or issued; and (2) the issuer of any qualified health plan to which the compact applies would continue to be subject to certain laws of the state in which the purchaser resides, would be required to be licensed in each state, and must clearly notify consumers that the policy may not be subject to all the laws and regulations of the state in which the purchaser resides. Sets forth provisions regarding the Secretary's approval of such compacts.

(Sec. 1334, as added by Sec. 10104) Requires the Director of the Office of Personnel Management (OPM) to: (1) enter into contracts with health insurance issuers to offer at least two multistate qualified health plans through each Exchange in each state to provide individual or group coverage; and (2) implement this subsection in a manner similar to the manner in which the Director implements the Federal Employees Health Benefits Program. Sets forth requirements for a multistate qualified health plan.

Part V: Reinsurance and Risk Adjustment - (Sec. 1341, as modified by Sec. 10104) Directs each state, not later than January 1, 2014, to establish one or more reinsurance entities to carry out the reinsurance program under this section. Requires the Secretary to establish standards to enable states to establish and maintain a reinsurance program under which: (1) health insurance issuers and third party administrators on behalf of group health plans are required to make payments to an applicable reinsurance entity for specified plan years; and (2) the applicable reinsurance entity uses amounts collected to make reinsurance payments to health insurance issuers that cover high risk individuals in the individual market. Directs the state to eliminate or modify any state high-risk pool to the extent necessary to carry out the reinsurance program established under this section.

(Sec. 1342) Requires the Secretary to establish and administer a program of risk corridors for calendar years 2014 through 2016 under which a qualified health plan offered in the individual or small group market shall participate in a payment adjusted system based on the ratio of the allowable costs of the plan to the plan's aggregate premiums. Directs the Secretary to make payments when a plan's allowable costs exceed the target amount by a certain percentage and directs a plan to make payments to the Secretary when its allowable costs are less than target amount by a certain percentage.

(Sec. 1343) Requires each state to assess a charge on health plans and health insurance issuers if the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in the

state for the year. Requires each state to provide a payment to health plans and health insurance issuers if the actuarial risk of the enrollees of such plan or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in the state for the year. Excludes self-insured group health plans from this section.

Subtitle E: Affordable Coverage Choices for All Americans - Part I: Premium Tax Credits and Cost-sharing Reductions - Subpart A: Premium Tax Credits and Cost-sharing Reductions - (Sec. 1401, as modified by section 10105) Amends the Internal Revenue Code to allow individual taxpayers whose household income equals or exceeds 100%, but does not exceed 400%, of the federal poverty line (as determined in the Social Security Act [SSA]) a refundable tax credit for a percentage of the cost of premiums for coverage under a qualified health plan. Sets forth formulae and rules for the calculation of credit amounts based upon taxpayer household income as a percentage of the poverty line.

Directs the Comptroller General, not later than five years after enactment of this Act, to conduct a study and report to specified congressional committees on the affordability of health insurance coverage.

(Sec. 1402) Requires reductions in the maximum limits for out-of-pocket expenses for individuals enrolled in qualified health plans whose incomes are between 100% and 400% of the poverty line.

Subpart B: Eligibility Determinations - (Sec. 1411) - Requires the Secretary to establish a program for verifying the eligibility of applicants for participation in a qualified health plan offered through an Exchange or for a tax credit for premium assistance based upon their income or their citizenship or immigration status. Requires an Exchange to submit information received from an applicant to the Secretary for verification of applicant eligibility. Provides for confidentiality of applicant information and for an appeals and redetermination process for denials of eligibility. Imposes civil penalties on applicants for providing false or fraudulent information relating to eligibility.

Requires the Secretary to study and report to Congress by January 1, 2013, on procedures necessary to ensure the protection of privacy and due process rights in making eligibility and other determinations under this Act.

(Sec. 1412) Requires the Secretary to establish a program for advance payments of the tax credit for premium assistance and for reductions of cost-sharing. Prohibits any federal payments, tax credit, or cost-sharing reductions for individuals who are not lawfully present in the United States.

(Sec. 1413) Requires the Secretary to establish a system to enroll state residents who apply to an Exchange in state health subsidy programs, including Medicaid or the Children's Health Insurance Program (CHIP, formerly known as SCHIP), if such residents are found to be eligible for such programs after screening.

(Sec. 1414) Requires the Secretary of the Treasury to disclose to HHS personnel certain taxpayer information to determine eligibility for programs under this Act or certain other social security programs.

(Sec. 1415) Disregards the premium assistance tax credit and cost-sharing reductions in determining eligibility for federal and federally-assisted programs.

(Sec. 1416, as added by section 10105) Directs the HHS Secretary to study and report to Congress by January 1, 2013, on the feasibility and implication of adjusting the application of the federal poverty level under this subtitle for different geographic areas in the United States, including its territories.

Part II: Small Business Tax Credit - (Sec. 1421, as modified by section 10105) Allows qualified small employers to elect, beginning in 2010, a tax credit for 50% of their employee health care coverage expenses. Defines "qualified small employer" as an employer who has no more than 25 employees with average annual compensation levels not exceeding $50,000. Requires a phase-out of such credit based on employer size and employee compensation.

Subtitle F: Shared Responsibility for Health Care - Part I: Individual Responsibility - (Sec. 1501, as modified by section 10106) Requires individuals to maintain minimal essential health care coverage beginning in 2014. Imposes a penalty for failure to maintain such coverage beginning in 2014, except for certain low-income individuals who cannot afford coverage, members of Indian tribes, and individuals who suffer hardship. Exempts from the coverage requirement individuals who object to health care coverage on religious grounds, individuals not lawfully present in the United States, and individuals who are incarcerated.

(Sec. 1502) Requires providers of minimum essential coverage to file informational returns providing identifying information of covered individuals and the dates of coverage. Requires the IRS to send a notice to taxpayers who are not enrolled in minimum essential coverage about services available through the Exchange operating in their state.

Part II: Employer Responsibilities - (Sec. 1511) Amends the Fair Labor Standards Act of 1938 to: (1) require employers with more than 200 full-time employees to automatically enroll new employees in a health care plan and provide notice of the opportunity to opt-out of such coverage; and (2) provide notice to employees about an Exchange, the availability of a tax credit for premium assistance, and the loss of an employer's contribution to an employer-provided health benefit plan if the employee purchases a plan through an Exchange.

(Sec. 1513, as modified by section 10106) Imposes fines on large employers (employers with more than 50 full-time employees) who fail to offer their full-time employees the opportunity to enroll in minimum essential coverage or who have a waiting period for enrollment of more than 60 days.

Requires the Secretary of Labor to study and report to Congress on whether employees' wages are reduced due to fines imposed on employers.

(Sec. 1514, as modified by section 10106) Requires large employers to file a report with the Secretary of the Treasury on health insurance coverage provided to their full-time employees. Requires such reports to contain: (1) a certification as to whether such employers provide their full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan; (2) the length of any waiting period for such coverage; (3) the months during which such coverage was available; (4) the monthly premium for the lowest cost option in each of the enrollment categories under the plan; (5) the employer's share of the total allowed costs of benefits provided under the plan; and (6) identifying information about the employer and full-time employees. Imposes a penalty on employers who fail to provide such report. Authorizes the Secretary of the Treasury to review the accuracy of information provided by large employers.

(Sec. 1515) Allows certain small employers to include as a benefit in a tax-exempt cafeteria plan a qualified health plan offered through an Exchange.

Subtitle G: Miscellaneous Provisions - (Sec. 1551) Applies the definitions under the Public Health Service Act related to health insurance coverage to this title.

(Sec. 1552) Requires the HHS Secretary to publish on the HHS website a list of all of the authorities provided to the Secretary under this Act.

(Sec. 1553) Prohibits the federal government, any state or local government or health care provider that receives federal financial assistance under this Act, or any health plan created under this Act from discriminating against an individual or institutional health care entity on the basis that such individual or entity does not provide a health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(Sec. 1554) Prohibits the Secretary from promulgating any regulation that: (1) creates an unreasonable barrier to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the health care provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principle of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

(Sec. 1555) Declares that no individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any federal health insurance program created by or expanded under this Act. Prohibits any penalty from being imposed upon any such issuer for choosing not to participate in any such program.

(Sec. 1556) Amends the Black Lung Benefits Act, with respect to claims filed on or after the effective date of the Black Lung Benefits Amendments of 1981, to eliminate exceptions to: (1) the applicability of certain provisions regarding rebuttable presumptions; and (2) the prohibition against requiring eligible survivors of a miner determined to be eligible for black lung benefits to file a new claim or to refile or otherwise revalidate the miner's claim.

(Sec. 1557) Prohibits discrimination by any federal health program or activity on the grounds of race, color, national origin, sex, age, or disability.

(Sec. 1558) Amends the Fair Labor Standards Act of 1938 to prohibit an employer from discharging or discriminating against any employee because the employee: (1) has received a health insurance credit or subsidy; (2) provides information relating to any violation of any provision of such Act; or (3) objects to, or refuses to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of such Act.

(Sec. 1559) Gives the HHS Inspector General oversight authority with respect to the administration and implementation of this title.

(Sec. 1560) Declares that nothing in this title shall be construed to modify, impair, or supersede the operation of any antitrust laws.

(Sec. 1561) Amends the Public Health Service Act to require the Secretary to: (1) develop interoperable and secure standards and protocols that facilitate enrollment of individuals in federal and state health and human services programs; and (2) award grants to develop and adapt technology systems to implement such standards and protocols.

(Sec. 1562, as added by Sec. 10107) Directs the Comptroller General to study denials by health plans of coverage for medical services and of applications to enroll in health insurance.

(Sec. 1563, as added by Sec. 10107) Disallows the waiver of laws or regulations establishing procurement requirements relating to small business concerns with respect to any contract awarded under any program or other authority under this Act.

(Sec. 1563 [*sic*], as modified by Sec. 10107) Makes technical and conforming amendments.

(Sec. 1563 [*sic*]) Expresses the sense of the Senate that: (1) the additional surplus in the Social Security trust fund generated by this Act should be reserved for Social Security; and (2) the net savings generated by the CLASS program (established under Title VIII of this Act) should be reserved for such program.

Title II: Role of Public Programs - Subtitle A: Improved Access to Medicaid - (Sec. 2001, as modified by Sec. 10201) Amends title XIX (Medicaid) of the SSA to extend Medicaid

coverage, beginning in calendar 2014, to individuals under age 65 who are not entitled to or enrolled in Medicare and have incomes at or below 133% of the federal poverty line. Grants a state the option to expand Medicaid eligibility to such individuals as early as April 1, 2010. Provides that, for between 2014 and 2016, the federal government will pay 100% of the cost of covering newly-eligible individuals.

Increases the federal medical assistance percentage (FMAP): (1) with respect to newly eligible individuals; and (2) between January 1, 2014, and December 31, 2016, for states meeting certain eligibility requirements.

Requires Medicaid benchmark benefits to include coverage of prescription drugs and mental health services.

Grants states the option to extend Medicaid coverage to individuals who have incomes that exceed 133% of the federal poverty line beginning January 1, 2014.

(Sec. 2002) Requires a state to use an individual's or household's modified gross income to determine income eligibility for Medicaid for non-elderly individuals, without applying any income or expense disregards or assets or resources test.

Exempts from this requirement: (1) individuals eligible for Medicaid through another program; (2) the elderly or Social Security Disability Insurance (SSDI) program beneficiaries; (3) the medically needy; (4) enrollees in a Medicare Savings Program; and (5) the disabled.

(Sec. 2003) Revises state authority to offer a premium assistance subsidy for qualified employer-sponsored coverage to children under age 19 to extend such a subsidy to all individuals, regardless of age.

Prohibits a state from requiring, as a condition of Medicaid eligibility, that an individual (or the individual's parent) apply for enrollment in qualified employer-sponsored coverage.

(Sec. 2004, as modified by Sec. 10201) Extends Medicaid coverage to former foster care children who are under 26 years of age.

(Sec. 2005, as modified by Sec. 10201) Revises requirements for Medicaid payments to territories, including an increase in the limits on payments for FY2011 and thereafter.

(Sec. 2006, as modified by Sec. 10201) Prescribes an adjustment to the FMAP determination for certain states recovering from a major disaster.

(Sec. 2007) Rescinds any unobligated amounts available to the Medicaid Improvement Fund for FY2014-FY2018.

Subtitle B: Enhanced Support for the Children's Health Insurance Program - (Sec. 2101, as modified by Sec. 10201) Amends SSA title XXI (State Children's Health Insurance

Program) (CHIP, formerly known as SCHIP) to increase the FY2016-FY2019 enhanced FMAP for states, subject to a 100% cap.

Prohibits states from applying, before the end of FY2019, CHIP eligibility standards that are more restrictive than those under this Act.

Deems ineligible for CHIP any targeted low-income children who cannot enroll in CHIP because allotments are capped, but who are therefore eligible for tax credits in the Exchanges.

Requires the Secretary to: (1) review benefits offered for children, and related cost-sharing imposed, by qualified health plans offered through an Exchange; and (2) certify those plans whose benefits and cost-sharing are at least comparable to those provided under the particular state's CHIP plan.

Prohibits enrollment bonus payments for children enrolled in CHIP after FY2013.

Requires a state CHIP plan, beginning January 1, 2014, to use modified gross income and household income to determine CHIP eligibility.

Requires a state to treat as a targeted low-income child eligible for CHIP any child determined ineligible for Medicaid as a result of the elimination of an income disregard based on expense or type of income.

(Sec. 2102) Makes technical corrections to the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

Subtitle C: Medicaid and CHIP Enrollment Simplification - (Sec. 2201) Amends SSA title XIX (Medicaid) to require enrollment application simplification and coordination with state health insurance Exchanges and CHIP via state-run websites.

(Sec. 2202) Permits hospitals to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories.

Subtitle D: Improvements to Medicaid Services - (Sec. 2301) Requires Medicaid coverage of: (1) freestanding birth center services; and (2) concurrent care for children receiving hospice care.

(Sec. 2303) Gives states the option of extending Medicaid coverage to family planning services and supplies under a presumptive eligibility period for a categorically needy group of individuals.

Subtitle E: New Options for States to Provide Long-Term Services and Supports - (Sec. 2401) Authorizes states to offer home and community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require care in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases.

(Sec. 2402) Gives states the option of: (1) providing home and community-based services to individuals eligible for services under a waiver; and (2) offering home and community-based services to specific, targeted populations

Creates an optional eligibility category to provide full Medicaid benefits to individuals receiving home and community-based services under a state plan amendment.

(Sec. 2403) Amends the Deficit Reduction Act of 2005 to: (1) extend through FY2016 the Money Follows the Person Rebalancing Demonstration; and (2) reduce to 90 days the institutional residency period.

(Sec. 2404) Applies Medicaid eligibility criteria to recipients of home and community-based services, during calendar 2014 through 2019, in such a way as to protect against spousal impoverishment.

(Sec. 2405) Makes appropriations for FY2010-FY2014 to the Secretary, acting through the Assistant Secretary for Aging, to expand state aging and disability resource centers.

(Sec. 2406) Expresses the sense of the Senate that: (1) during the 111th session of Congress, Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and (2) long-term services and supports should be made available in the community in addition to institutions.

Subtitle F: Medicaid Prescription Drug Coverage - (Sec. 2501) Amends SSA title XIX (Medicaid) to: (1) increase the minimum rebate percentage for single source drugs and innovator multiple source drugs; (2) increase the rebate for other drugs; (3) require contracts with Medicaid managed care organizations to extend prescription drug rebates (discounts) to their enrollees; (4) provide an additional rebate for new formulations of existing drugs; and (5) set a maximum rebate amount.

(Sec. 2502) Eliminates the exclusion from Medicaid coverage of, thereby extending coverage to, certain drugs used to promote smoking cessation, as well as barbiturates and benzodiazepines.

(Sec. 2503) Revises requirements with respect to pharmacy reimbursements.

Subtitle G: Medicaid Disproportionate Share Hospital (DSH) Payments - (Sec. 2551, as modified by Sec. 10201) Reduces state disproportionate share hospital (DSH) allotments, except for Hawaii, by 50% or 35% once a state's uninsured rate decreases by 45%, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Requires a reduction of only 25% or 17.5% for low DSH states, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Prescribes allotment reduction requirements for subsequent fiscal years.

Revises DSH allotments for Hawaii for the last three quarters of FY2012 and for FY2013 and succeeding fiscal years.

Subtitle H: Improved Coordination for Dual Eligible Beneficiaries - (Sec. 2601) Declares that any Medicaid waiver for individuals dually eligible for both Medicaid and Medicare may be conducted for a period of five years, with a five-year extension, upon state request, unless the Secretary determines otherwise for specified reasons.

(Sec. 2602) Directs the Secretary to establish a Federal Coordinated Health Care Office to bring together officers and employees of the Medicare and Medicaid programs at the Centers for Medicare and Medicaid Services (CMS) to: (1) integrate Medicaid and Medicare benefits more effectively; and (2) improve the coordination between the federal government and states for dual eligible individuals to ensure that they get full access to the items and services to which they are entitled.

Subtitle I: Improving the Quality of Medicaid for Patients and Providers - (Sec. 2701) Amends SSA title XI, as modified by CHIPRA, to direct the Secretary to: (1) identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults; and (2) establish a Medicaid Quality Measurement Program.

(Sec. 2702) Requires the Secretary to identify current state practices that prohibit payment for health care-acquired conditions and to incorporate them, or elements of them, which are appropriate for application in regulations to the Medicaid program. Requires such regulations to prohibit payments to states for any amounts expended for providing medical assistance for specified health care-acquired conditions.

(Sec. 2703) Gives states the option to provide coordinated care through a health home for individuals with chronic conditions. Authorizes the Secretary to award planning grants to states to develop a state plan amendment to that effect.

(Sec. 2704) Directs the Secretary to establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary: (1) with respect to an episode of care that includes a hospitalization; and (2) for concurrent physicians services provided during a hospitalization.

(Sec. 2705) Requires the Secretary to establish a Medicaid Global Payment System Demonstration Project under which a participating state shall adjust payments made to an eligible safety net hospital or network from a fee-for-service payment structure to a global capitated payment model. Authorizes appropriations.

(Sec. 2706) Directs the Secretary to establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating state to allow pediatric medical providers meeting specified requirements to be recognized as an accountable care organization for the purpose of receiving specified incentive payments. Authorizes appropriations.

(Sec. 2707) Requires the Secretary to establish a three-year Medicaid emergency psychiatric demonstration project. Makes appropriations for FY2011.

Subtitle J: Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC) - (Sec. 2801) Revises requirements with respect to the Medicaid and CHIP Payment and Access Commission (MACPAC) and the Medicare Payment Advisory Commission (MEDPAC), including those for MACPAC membership, topics to be reviewed, and MEDPAC review of Medicaid trends in spending, utilization, and financial performance.

Requires MACPAC and MEDPAC to consult with one another on related issues.

Makes appropriations to MACPAC for FY2010.

Subtitle K: Protections for American Indians and Alaska Natives - (Sec. 2901) Sets forth special rules relating to Indians.

Declares that health programs operated by the Indian Health Service (IHS), Indian tribes, tribal organizations, and Urban Indian organizations shall be the payer of last resort for services they provide to eligible individuals.

Makes such organizations Express Lane agencies for determining Medicaid and CHIP eligibility.

(Sec. 2902) Makes permanent the requirement that the Secretary reimburse certain Indian hospitals and clinics for all Medicare part B services.

Subtitle L: Maternal and Child Health Services - (Sec. 2951) Amends SSA title V (Maternal and Child Health Services) to direct the Secretary to make grants to eligible entities for early childhood home visitation programs. Makes appropriations for FY2010-FY2014.

(Sec. 2952) Encourages the Secretary to continue activities on postpartum depression or postpartum psychosis, including research to expand the understanding of their causes and treatment.

Authorizes the Secretary to make grants to eligible entities for projects to establish, operate, and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with or at risk for postpartum conditions and their families. Authorizes appropriations for FY2010-FY2012.

(Sec. 2953, as modified by Sec. 10201) Directs the Secretary to allot funds to states to award grants to local organizations and other specified entities to carry out personal responsibility education programs to educate adolescents on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, as well as on certain adulthood preparation subjects. Makes appropriations for FY2010-FY2014.

(Sec. 2954) Makes appropriations for FY2010-FY2014 for abstinence education.

(Sec. 2955) Requires the case review system for children aging out of foster care and independent living programs to include information about the importance of having a health care power of attorney in transition planning.

Title III: Improving the Quality and Efficiency of Health Care - Subtitle A: Transforming the Health Care Delivery System - Part I: Linking Payment to Quality Outcomes under the Medicare Program - (Sec. 3001) Amends SSA title XVIII (Medicare) to direct the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet specified performance standards for a certain performance period.

Directs the Secretary to establish value-based purchasing demonstration programs for: (1) inpatient critical access hospital services; and (2) hospitals excluded from the program because of insufficient numbers of measures and cases.

(Sec. 3002) Extends through 2013 the authority for incentive payments under the physician quality reporting system. Prescribes an incentive (penalty) for providers who do not report quality measures satisfactorily, beginning in 2015.

Requires the Secretary to integrate reporting on quality measures with reporting requirements for the meaningful use of electronic health records.

(Sec. 3003) Requires specified new types of reports and data analysis under the physician feedback program.

(Sec. 3004) Requires long-term care hospitals, inpatient rehabilitation hospitals, and hospices, starting in rate year 2014, to submit data on specified quality measures. Requires reduction of the annual update of entities which do not comply.

(Sec. 3005) Directs the Secretary, starting FY2014, to establish quality reporting programs for inpatient cancer hospitals exempt from the prospective payment system.

(Sec. 3006, as modified by Sec. 10301) Directs the Secretary to develop a plan to implement value-based purchasing programs for Medicare payments for skilled nursing facilities (SNFs), home health agencies, and ambulatory surgical centers.

(Sec. 3007) Directs the Secretary to establish a value-based payment modifier, under the physician fee schedule, based upon the quality of care furnished compared to cost.

(Sec. 3008) Subjects hospitals to a penalty adjustment to hospital payments for high rates of hospital acquired conditions.

Part II: National Strategy to Improve Health Care Quality - (Sec. 3011, as modified by Sec. 10302) Amends the Public Health Service Act to direct the Secretary, through a transparent collaborative process, to establish a National Strategy for Quality Improvement in health care services, patient health outcomes, and population health,

taking into consideration certain limitations on the use of comparative effectiveness data.

(Sec. 3012) Directs the President to convene an Interagency Working Group on Health Care Quality.

(Sec. 3013, as modified by Sec. 10303) Directs the Secretary, at least triennially, to identify gaps where no quality measures exist as well as existing quality measures that need improvement, updating, or expansion, consistent with the national strategy for use in federal health programs.

Directs the Secretary to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding such quality measures.

Requires the Secretary to develop and update periodically provider-level outcome measures for hospitals and physicians, as well as other appropriate providers.

(Sec. 3014, as modified by Sec. 10304) Requires the convening of multi-stakeholder groups to provide input into the selection of quality and efficiency measures.

(Sec. 3015, as modified by Sec. 10305) Directs the Secretary to: (1) establish an overall strategic framework to carry out the public reporting of performance information; and (2) collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery. Authorizes the Secretary to award grants for such purpose.

Directs the Secretary to make available to the public, through standardized Internet websites, performance information summarizing data on quality measures.

Part III: Encouraging Development of New Patient Care Models - (Sec. 3021, as modified by Sec. 10306) Creates within CMS a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Makes appropriations for FY2010-FY2019.

(Sec. 3022, as modified by Sec. 10307) Directs the Secretary to establish a shared savings program that: (1) promotes accountability for a patient population; (2) coordinates items and services under Medicare parts A and B; and (3) encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(Sec. 3023, as modified by Sec. 10308) Directs the Secretary to establish a pilot program for integrated care (involving payment bundling) during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.

(Sec. 3024) Directs the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to applicable beneficiaries.

(Sec. 3025, as modified by Sec. 10309) Requires the Secretary to establish a hospital readmissions reduction program involving certain payment adjustments, effective for discharges on or after October 1, 2012, for certain potentially preventable Medicare inpatient hospital readmissions.

Directs the Secretary to make available a program for hospitals with a high severity adjusted readmission rate to improve their readmission rates through the use of patient safety organizations.

(Sec. 3026) Directs the Secretary to establish a Community-Based Care Transitions Program which provides funding to eligible entities that furnish improved care transitions services to high-risk Medicare beneficiaries.

(Sec. 3027) Amends the Deficit Reduction Act of 2005 to extend certain Gainsharing Demonstration Projects through FY2011.

Subtitle B: Improving Medicare for Patients and Providers - Part 1: Ensuring Beneficiary Access to Physician Care and Other Services - (Sec. 3101, deleted by section 10310) (Sec. 3102) Extends through calendar 2010 the floor on geographic indexing adjustments to the work portion of the physician fee schedule. Revises requirements for calculation of the practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011. Directs the Secretary to analyze current methods of establishing practice expense geographic adjustments and make appropriate further adjustments (a new methodology) to such adjustments for 2010 and subsequent years.

(Sec. 3103) Extends the process allowing exceptions to limitations on medically necessary therapy caps through December 31, 2010.

(Sec. 3104) Amends the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to extend until January 1, 2010, an exception to a payment rule that permits laboratories to receive direct Medicare reimbursement when providing the technical component of certain physician pathology services that had been outsourced by certain (rural) hospitals.

(Sec. 3105, as modified by Sec. 10311) Amends SSA title XVIII (Medicare) to extend the bonus and increased payments for ground ambulance services until January 1, 2011.

Amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to extend the payment of certain urban air ambulance services until January 1, 2011.

(Sec. 3106, as modified by Sec. 10312) Amends the Medicare, Medicaid, and SCHIP Extension Act of 2007, as modified by the American Recovery and Reinvestment Act, to extend for two years: (1) certain payment rules for long-term care hospital services; and (2) a certain moratorium on the establishment of certain hospitals and facilities.

(Sec. 3107) Amends MIPPA to extend the physician fee schedule mental health add-on payment provision through December 31, 2010.

(Sec. 3108) Allows a physician assistant who does not have an employment relationship with a SNF, but who is working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.

(Sec. 3109) Amends title XVIII, as modified by MIPPA, to exempt certain pharmacies from accreditation requirements until the Secretary develops pharmacy-specific standards.

(Sec. 3110) Creates a special part B enrollment period for military retirees, their spouses (including widows/ widowers), and dependent children, who are otherwise eligible for TRICARE (the health care plan under the Department of Defense [DOD]) and entitled to Medicare part A (Hospital Insurance) based on disability or end stage renal disease, but who have declined Medicare part B (Supplementary Medical Insurance).

(Sec. 3111) Sets payments for dual-energy x-ray absorptiometry services in 2010 and 2011 at 70% of the 2006 reimbursement rates. Directs the Secretary to arrange with the Institute of Medicine of the National Academies to study and report to the Secretary and Congress on the ramifications of Medicare reimbursement reductions for such services on beneficiary access to bone mass measurement benefits.

(Sec. 3112) Eliminates funding in the Medicare Improvement Fund FY2014.

(Sec. 3113) Directs the Secretary to conduct a demonstration project under Medicare part B of separate payments for complex diagnostic laboratory tests provided to individuals.

(Sec. 3114) Increases from 65% to 100% of the fee schedule amount provided for the same service performed by a physician the fee schedule for certified-midwife services provided on or after January 1, 2011.

Part II: Rural Protections - (Sec. 3121) Extends through 2010 hold harmless provisions under the prospective payment system for hospital outpatient department services.

Removes the 100-bed limitation for sole community hospitals so all such hospitals receive an 85% increase in the payment difference in 2010.

(Sec. 3122) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as modified by other federal law, to extend from July 1, 2010, until July 1,

2011, the reasonable cost reimbursement for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds.

(Sec. 3123, as modified by Sec. 10313) Extends the Rural Community Hospital Demonstration Program for five additional years. Expands the maximum number of participating hospitals to 30, and to 20 the number of demonstration states with low population densities.

(Sec. 3124) Extends the Medicare-dependent Hospital Program through FY2012.

(Sec. 3125, as modified by Sec. 10314) Modifies the Medicare inpatient hospital payment adjustment for low-volume hospitals for FY2011-FY2012.

(Sec. 3126) Revises requirements for the Demonstration Project on Community Health Integration Models in Certain Rural Counties to allow additional counties as well as physicians to participate.

(Sec. 3127) Directs MEDPAC to study and report to Congress on the adequacy of payments for items and services furnished by service providers and suppliers in rural areas under the Medicare program.

(Sec. 3128) Allows a critical access hospital to continue to be eligible to receive 101% of reasonable costs for providing: (1) outpatient care regardless of the eligible billing method such hospital uses; and (2) qualifying ambulance services.

(Sec. 3129) Extends through FY2012 FLEX grants under the Medicare Rural Hospital Flexibility Program. Allows the use of grant funding to assist small rural hospitals to participate in delivery system reforms.

Part III: Improving Payment Accuracy - (Sec. 3131, as modified by Sec. 10315) Requires the Secretary, starting in 2014, to rebase home health payments by an appropriate percentage, among other things, to reflect the number, mix, and level of intensity of home health services in an episode, and the average cost of providing care.

Directs the Secretary to study and report to Congress on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. Authorizes a Medicare demonstration project based on the study results.

(Sec. 3132) Requires the Secretary, by January 1, 2011, to begin collecting additional data and information needed to revise payments for hospice care.

Directs the Secretary, not earlier than October 1, 2013, to implement, by regulation, budget neutral revisions to the methodology for determining hospice payments for routine home care and other services, which may include per diem payments reflecting changes in resource intensity in providing such care and services during the course of an entire episode of hospice care.

Requires the Secretary to impose new requirements on hospice providers participating in Medicare, including requirements for: (1) a hospice physician or nurse practitioner to have a face-to-face encounter with the individual regarding eligibility and recertification; and (2) a medical review of any stays exceeding 180 days, where the number of such cases exceeds a specified percentage of them for all hospice programs.

(Sec. 3133, as modified by Sec. 10316) Specifies reductions to Medicare DSH payments for FY2015 and ensuing fiscal years, especially to subsection (d) hospitals, to reflect lower uncompensated care costs relative to increases in the number of insured. (Generally, a subsection [d] hospital is an acute care hospital, particularly one that receives payments under Medicare's inpatient prospective payment system when providing covered inpatient services to eligible beneficiaries.)

(Sec. 3134) Directs the Secretary periodically to identify physician services as being potentially misvalued and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.

(Sec. 3135) Increases the presumed utilization rate for calculating the payment for advanced imaging equipment other than low-tech imaging such as ultrasound, x-rays and EKGs.

Increases the technical component payment "discount" for sequential imaging services on contiguous body parts during the same visit.

(Sec. 3136) Restricts the lump-sum payment option for new or replacement chairs to the complex, rehabilitative power-driven wheelchairs only. Eliminates the lump-sum payment option for all other power-driven wheelchairs. Makes the rental payment for power-driven wheelchairs 15% of the purchase price for each of the first three months (instead of 10%), and 6% of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5%).

(Sec. 3137, as modified by Sec. 10317) Amends the Tax Relief and Health Care Act of 2006, as modified by other federal law, to extend "Section 508" hospital reclassifications until September 30, 2010, with a special rule for FY2010. ("Section 508" refers to Section 508 of the Medicare Modernization Act of 2003, which allows the temporary reclassification of a hospital with a low Medicare area wage index, for reimbursement purposes, to a nearby location with a higher Medicare area wage index, so that the "Section 508 hospital" will receive the higher Medicare reimbursement rate.)

Directs the Secretary to report to Congress a plan to reform the hospital wage index system.

(Sec. 3138) Requires the Secretary to determine if the outpatient costs incurred by inpatient prospective payment system-exempt cancer hospitals, including those for drugs and biologicals, with respect to Medicare ambulatory payment classification groups, exceed those costs incurred by other hospitals reimbursed under the outpatient

prospective payment system (OPPS). Requires the Secretary, if this is so, to provide for an appropriate OPPS adjustment to reflect such higher costs for services furnished on or after January 1, 2011.

(Sec. 3139) Allows a biosimilar biological product to be reimbursed at 6% of the average sales price of the brand biological product.

(Sec. 3140) Directs the Secretary to establish a Medicare Hospice Concurrent Care demonstration program under which Medicare beneficiaries are furnished, during the same period, hospice care and any other Medicare items or services from Medicare funds otherwise paid to such hospice programs.

(Sec. 3141) Requires application of the budget neutrality requirement associated with the effect of the imputed rural floor on the area wage index under the Balanced Budget Act of 1997 through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.

(Sec. 3142) Directs the Secretary to study and report to Congress on the need for an additional payment for urban Medicare-dependent hospitals for inpatient hospital services under Medicare.

(Sec. 3143) Declares that nothing in this Act shall result in the reduction of guaranteed home health benefits under the Medicare program.

Subtitle C: Provisions Relating to Part C - (Sec. 3201, as modified by Sec. 10318) Bases the MedicareAdvantage (MA) benchmark on the average of the bids from MA plans in each market.

Revises the formula for calculating the annual Medicare+Choice capitation rate to reduce the national MA per capita Medicare+Choice growth percentage used to increase benchmarks in 2011.

Increases the monthly MA plan rebates from 75% to 100% of the average per capita savings.

Requires that bid information which MA plans are required to submit to the Secretary be certified by a member of the American Academy of Actuaries and meet actuarial guidelines and rules established by the Secretary.

Directs the Secretary, acting through the CMS Chief Actuary, to establish actuarial guidelines for the submission of bid information and bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

Directs the Secretary to: (1) establish new MA payment areas for urban areas based on the Core Based Statistical Area; and (2) make monthly care coordination and management performance bonus payments, quality performance bonus payments, and quality bonuses for new and low enrollment MA plans, to MA plans that meet certain criteria.

Directs the Secretary to provide transitional rebates for the provision of extra benefits to enrollees.

(Sec. 3202) Prohibits MA plans from charging beneficiaries cost sharing for chemotherapy administration services, renal dialysis services, or skilled nursing care that is greater than what is charged under the traditional fee-for-service program.

Requires MA plans to apply the full amount of rebates, bonuses, and supplemental premiums according to the following order: (1) reduction of cost sharing, (2) coverage of preventive care and wellness benefits, and (3) other benefits not covered under the original Medicare fee-for-service program.

(Sec. 3203) Requires the Secretary to analyze the differences in coding patterns between MA and the original Medicare fee-for-service programs. Authorizes the Secretary to incorporate the results of the analysis into risk scores for 2014 and subsequent years.

(Sec. 3204) Allows beneficiaries to disenroll from an MA plan and return to the traditional Medicare fee-for-service program from January 1 to March 15 of each year.

Revises requirements for annual beneficiary election periods.

(Sec. 3205) Amends SSA title XVIII (Medicare), as modified by MIPPA, to extend special needs plan (SNP) authority through December 31, 2013.

Authorizes the Secretary to establish a frailty payment adjustment under PACE payment rules for fully-integrated, dual-eligible SNPs.

Extends authority through calendar 2012 for SNPs that do not have contracts with state Medicaid programs to continue to operate, but not to expand their service areas.

Directs the Secretary to require an MA organization offering a specialized MA plan for special needs individuals to be approved by the National Committee for Quality Assurance.

Requires the Secretary to use a risk score reflecting the known underlying risk profile and chronic health status of similar individuals, instead of the default risk score, for new enrollees in MA plans that are not specialized MA SNPs.

(Sec. 3206) Extends through calendar 2012 the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

(Sec. 3208) Creates a new type of MA plan called an MA Senior Housing Facility Plan, which would be allowed to limit its service area to a senior housing facility (continuing care retirement community) within a geographic area.

(Sec. 3209) Declares that the Secretary is not required to accept any or every bid submitted by an MA plan or Medicare part D prescription drug plan that proposes to increase significantly any beneficiary cost sharing or decrease benefits offered.

(Sec. 3210) Directs the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new standards for certain Medigap plans.

Subtitle D: Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans - (Sec. 3301) Amends Medicare part D (Voluntary Prescription Drug Benefit Program) to establish conditions for the availability of coverage for part D drugs. Requires the manufacturer to participate in the Medicare coverage gap discount program. Directs the Secretary to establish such a program.

(Sec. 3302) Excludes the MA rebate amounts and quality bonus payments from calculation of the regional low-income subsidy benchmark premium for MA monthly prescription drug beneficiaries.

(Sec. 3303) Directs the Secretary to permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is *de minimis*. Provides that, if such premium is waived, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

Authorizes the Secretary to auto-enroll subsidy eligible individuals in plans that waive *de minimis* premiums.

(Sec. 3304) Sets forth a special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an eligible couple to delay redetermination of eligibility for one year after the death of a spouse.

(Sec. 3305) Directs the Secretary, in the case of a subsidy eligible individual enrolled in one prescription drug plan but subsequently reassigned by the Secretary to a new prescription drug plan, to provide the individual with: (1) information on formulary differences between the individual's former plan and the new plan with respect to the individual's drug regimens; and (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

(Sec. 3306) Amends MIPPA to provide additional funding for FY2010-FY2012 for outreach and education activities related to specified Medicare low-income assistance programs.

(Sec. 3307) Authorizes the Secretary to identify classes of clinical concern through rulemaking, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Requires prescription drug plan sponsors to include all drugs in these classes in their formularies.

(Sec. 3308) Requires part D enrollees who exceed certain income thresholds to pay higher premiums. Revises the current authority of the IRS to disclose income

information to the Social Security Administration for purposes of adjusting the part B subsidy.

(Sec. 3309) Eliminates cost sharing for certain dual eligible individuals receiving care under a home and community-based waiver program who would otherwise require institutional care.

(Sec. 3310) Directs the Secretary to require sponsors of prescription drug plans to utilize specific, uniform techniques for dispensing covered part D drugs to enrollees who reside in an long-term care facility in order to reduce waste associated with 30-day refills.

(Sec. 3311) Directs the Secretary to develop and maintain an easy to use complaint system to collect and maintain information on MA-PD plan and prescription drug complaints received by the Secretary until the complaint is resolved.

(Sec. 3312) Requires a prescription drug plan sponsor to: (1) use a single, uniform exceptions and appeals process for determination of a plan enrollee's prescription drug coverage; and (2) provide instant access to this process through a toll-free telephone number and an Internet website.

(Sec. 3313) Requires the HHS Inspector General to study and report to Congress on the inclusion in formularies of: (1) drugs commonly used by dual eligibles; and (2) prescription drug prices under Medicare part D and Medicaid.

(Sec. 3314) Allows the costs incurred by AIDS drug assistance programs and by IHS in providing prescription drugs to count toward the annual out-of-pocket threshold.

(Sec. 3315) Increases by $500 the 2010 standard initial coverage limit (thus decreasing the time that a part D enrollee would be in the coverage gap).

Subtitle E: Ensuring Medicare Sustainability - (Sec. 3401, as modified by Sec. 10319 and Sec. 10322) Revises certain market basket updates and incorporates a full productivity adjustment into any updates that do not already incorporate such adjustments, including inpatient hospitals, home health providers, nursing homes, hospice providers, inpatient psychiatric facilities, long-term care hospitals, inpatient rehabilitation facilities, and Part B providers.

Establishes a quality measure reporting program for psychiatric hospitals beginning in FY2014.

(Sec. 3402) Revises requirements for reduction of the Medicare part B premium subsidy based on income. Maintains the current 2010 income thresholds for the period of 2011 through 2019.

(Sec. 3403, as modified by Sec. 10320) Establishes an Independent Payment Advisory Board to develop and submit detailed proposals to reduce the per capita rate of growth in Medicare spending to the President for Congress to consider. Establishes a

consumer advisory council to advise the Board on the impact of payment policies under this title on consumers.

Subtitle F: Health Care Quality Improvements - (Sec. 3501) Amends the Public Health Service Act to direct the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to conduct or support activities for best practices in the delivery of health care services and support research on the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Authorizes appropriations for FY2010-FY2014.

Requires the AHRQ Director, through the AHRQ Center for Quality Improvement and Patient Safety, to award grants or contracts to eligible entities to provide technical support or to implement models and practices identified in the research conducted by the Center.

(Sec. 3502, as modified by Sec. 10321) Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

(Sec. 3503) Directs the Secretary, acting through the Patient Safety Research Center, to establish a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists, as a collaborative multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such disease.

(Sec. 3504) Directs the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award at least four multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

Requires the Secretary to support federal programs administered by the National Institutes of Health (NIH), the AHRQ, the Health Resources and Services Administration (HRSA), the CMS, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine.

Directs the Secretary to support federal programs administered by the such agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine.

Authorizes appropriations for FY2010-FY2014.

(Sec. 3505) Requires the Secretary to establish three programs to award grants to qualified public, nonprofit IHS, Indian tribal, and urban Indian trauma centers to: (1) assist in defraying substantial uncompensated care costs; (2) further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer; and (3) provide emergency relief to ensure the continued and future availability of trauma services. Authorizes appropriations for FY2010-FY2015.

Directs the Secretary to provide funding to states to enable them to award grants to eligible entities for trauma services. Authorizes appropriations for FY2010-FY2015.

(Sec. 3506) Directs the Secretary to: (1) establish a program to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients; (2) establish a program to provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options; and (3) award grants for establishment and support of Shared Decisionmaking Resource Centers. Authorizes appropriations for FY2010 and subsequent fiscal years.

(Sec. 3507) Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve heath care decisionmaking by clinicians and patients and consumers.

(Sec. 3508) Authorizes the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical education of health professionals.

(Sec. 3509) Establishes an Office on Women's Health within the Office of the Secretary, the Office of the Director of the Centers for Disease Control and Prevention (CDC), the Office of the AHRQ Director, the Office of the Administrator of HRSA, and the Office of the Commissioner of Food and Drugs.

Authorizes appropriations for FY2010-FY2014 for all such Offices on Women's Health.

(Sec. 3510) Extends from three years to four years the duration of a patient navigator grant.

Prohibits the Secretary from awarding such a grant unless the recipient entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies tailored for the main focus or intervention of the navigator involved.

Authorizes appropriations for FY2010-FY2015.

(Sec. 3511) Authorizes appropriations to carry out this title, except where otherwise provided in the title.

(Sec. 3512, as added by Sec. 10201) Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any guideline or other standards under specified provisions of this Act would result in the establishment of a new cause of action or claim.

Subtitle G: Protecting and Improving Guaranteed Medicare Benefits - (Sec. 3601) Provides that nothing in this Act shall result in a reduction of guaranteed benefits under the Medicare program.

States that savings generated for the Medicare program under this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.

(Sec. 3602) Declares that nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in MA plans.

Title IV: Prevention of Chronic Disease and Improving Public Health - Subtitle A: Modernizing Disease Prevention and Public Health Systems - (Sec. 4001, as modified by Sec. 10401) Requires the President to: (1) establish the National Prevention, Health Promotion and Public Health Council; (2) establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; and (3) appoint the Surgeon General as Chairperson of the Council in order to develop a national prevention, health promotion, and public health strategy.

Requires the Secretary and the Comptroller General to conduct periodic reviews and evaluations of every federal disease prevention and health promotion initiative, program, and agency.

(Sec. 4002, as modified by Sec. 10401) Establishes a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Authorizes appropriations and appropriates money to such Fund.

(Sec. 4003) Requires (currently, allows) the Director of AHRQ to convene the Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community.

Requires the Director of CDC to convene an independent Community Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the

purpose of developing recommendations for individuals and organizations delivering populations-based services and other policy makers

(Sec. 4004, as modified by Sec. 10401) Requires the Secretary to provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.

Requires the Secretary, acting through the Director of CDC, to: (1) establish and implement a national science-based media campaign on health promotion and disease prevention; and (2) enter into a contract for the development and operation of a federal website personalized prevention plan tool.

Subtitle B: Increasing Access to Clinical Preventive Services - (Sec. 4101, as modified by Sec. 10402) Requires the Secretary to establish a program to award grants to eligible entities to support the operation of school-based health centers.

(Sec. 4102) Requires the Secretary, acting through the Director of CDC, to carry out oral health activities, including: (1) establishing a national public education campaign that is focused on oral health care prevention and education; (2) awarding demonstration grants for research-based dental caries disease management activities; (3) awarding grants for the development of school-based dental sealant programs; and (4) entering into cooperative agreements with state, territorial, and Indian tribes or tribal organizations for oral health data collection and interpretation, a delivery system for oral health, and science-based programs to improve oral health.

Requires the Secretary to: (1) update and improve the Pregnancy Risk Assessment Monitoring System as it relates to oral health care; (2) develop oral health care components for inclusion in the National Health and Nutrition Examination Survey; and (3) ensure that the Medical Expenditures Panel Survey by AHRQ includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(Sec. 4103, as modified by Sec. 10402) Amends SSA title XVIII (Medicare) to provide coverage of personalized prevention plan services, including a health risk assessment, for individuals. Prohibits cost-sharing for such services.

(Sec. 4104, as modified by Sec. 10406) Eliminates cost-sharing for certain preventive services recommended by the United States Preventive Services Task Force.

(Sec. 4105) Authorizes the Secretary to modify Medicare coverage of any preventive service consistent with the recommendations of such Task Force.

(Sec. 4106) Amends SSA title XIX (Medicaid) to provide Medicaid coverage of preventive services and approved vaccines. Increases the FMAP for such services and vaccines.

(Sec. 4107) Provides for Medicaid coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women.

(Sec. 4108) Requires the Secretary to award grants to states to carry out initiatives to provide incentives to Medicaid beneficiaries who participate in programs to lower health risk and demonstrate changes in health risk and outcomes.

Subtitle C: Creating Healthier Communities - (Sec. 4201, as modified by Sec. 10403) Requires the Secretary, acting through the Director of CDC, to award grants to state and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base of effective prevention programming.

(Sec. 4202) Requires the Secretary, acting through the Director of CDC, to award grants to state or local health departments and Indian tribes to carry out pilot programs to provide public health community interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age.

Requires the Secretary to: (1) conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries; and (2) evaluate community prevention and wellness programs that have demonstrated potential to help Medicare beneficiaries reduce their risk of disease, disability, and injury by making healthy lifestyle choices.

(Sec. 4203) Amends the Rehabilitation Act of 1973 to require the Architectural and Transportation Barriers Compliance Board to promulgate standards setting forth the minimum technical criteria for medical diagnostic equipment used in medical settings to ensure that such equipment is accessible to, and usable by, individuals with accessibility needs.

(Sec. 4204) Authorizes the Secretary to negotiate and enter into contracts with vaccine manufacturers for the purchase and delivery of vaccines for adults. Allows a state to purchase additional quantities of adult vaccines from manufacturers at the applicable price negotiated by the Secretary. Requires the Secretary, acting through the Director of CDC, to establish a demonstration program to award grants to states to improve the provision of recommended immunizations for children and adults through the use of evidence-based, population-based interventions for high-risk populations.

Reauthorizes appropriations for preventive health service programs to immunize children and adults against vaccine-preventable diseases without charge.

Requires the Comptroller General to study the ability of Medicare beneficiaries who are 65 years or older to access routinely recommended vaccines covered under the prescription drug program since its establishment.

(Sec. 4205) Amends the Federal Food, Drug, and Cosmetic Act to require the labeling of a food item offered for sale in a retail food establishment that is part of a chain with 20 or more locations under the same name to disclose on the menu and menu board: (1) the number of calories contained in the standard menu item; (2) the suggested daily caloric intake; and (3) the availability on the premises and upon request of specified additional nutrient information. Requires self-service facilities to place adjacent to each food offered a sign that lists calories per displayed food item or per serving. Requires vending machine operators who operate 20 or more vending machines to provide a sign disclosing the number of calories contained in each article of food.

(Sec. 4206) Requires the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers an individualized wellness plan designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(Sec. 4207) Amends the Fair Labor Standards Act of 1938 to require employers to provide a reasonable break time and a suitable place, other than a bathroom, for an employee to express breast milk for her nursing child. Excludes an employer with fewer than 50 employees if such requirements would impose an undue hardship.

Subtitle D: Support for Prevention and Public Health Innovation - (Sec. 4301) Requires the Secretary, acting through the Director of CDC, to provide funding for research in the area of public health services and systems.

(Sec. 4302) Requires the Secretary to ensure that any federally conduced or supported health care or public health program, activity, or survey collects and reports specified demographic data regarding health disparities.

Requires the Secretary, acting through the National Coordinator for Health Information Technology, to develop: (1) national standards for the management of data collected; and (2) interoperability and security systems for data management.

(Sec. 4303, as modified by Sec. 10404) Requires the Director of CDC to: (1) provide employers with technical assistance, consultation, tools, and other resources in evaluating employer-based wellness programs; and (2) build evaluation capacity among workplace staff by training employers on how to evaluate such wellness programs and ensuring that evaluation resources, technical assistance, and consultation are available.

Requires the Director of CDC to conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(Sec. 4304) Requires the Secretary, acting through the Director of CDC, to establish an Epidemiology and Laboratory Capacity Grant Program to award grants to assist public

health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance.

(Sec. 4305) Requires the Secretary to: (1) enter into an agreement with the Institute of Medicine to convene a Conference on Pain, the purposes of which shall include to increase the recognition of pain as a significant public health problem in the United States; and (2) establish the Interagency Pain Research Coordinating Committee.

(Sec. 4306) Appropriates funds to carry out childhood obesity demonstration projects.

Subtitle E: Miscellaneous Provisions - (Sec. 4402) Requires the Secretary to evaluate programs to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals.

Title V: Health Care Workforce - Subtitle A: Purpose and Definitions - (Sec. 5001) Declares that the purpose of this title is to improve access to and the delivery of health care services for all individuals, particularly low-income, underserved, uninsured, minority, health disparity, and rural populations.

Subtitle B: Innovations in the Health Care Workforce - (Sec. 5101, as modified by Sec. 10501) Establishes a National Health Care Workforce Commission to: (1) review current and projected health care workforce supply and demand; and (2) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies.

(Sec. 5102) Establishes a health care workforce development grant program.

(Sec. 5103) Requires the Secretary to establish the National Center for Health Care Workforce Analysis to provide for the development of information describing and analyzing the health care workforce and workforce related issues. Transfers the responsibilities and resources of the National Center for Health Workforce Analysis to the Center created under this section.

(Sec. 5104, as added by Sec. 10501) Establishes the Interagency Access to Health Care in Alaska Task Force to: (1) assess access to health care for beneficiaries of federal health care systems in Alaska; and (2) develop a strategy to improve delivery to such beneficiaries.

Subtitle C: Increasing the Supply of the Health Care Workforce - (Sec. 5201) Revises student loan repayment provisions related to the length of service requirement for the primary health care loan repayment program.

(Sec. 5202) Increases maximum amount of loans made by schools of nursing to students.

(Sec. 5203) Directs the Secretary to establish and carry out a pediatric specialty loan repayment program.

(Sec. 5204) Requires the Secretary to establish the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in federal, state, local, and tribal public health agencies.

(Sec. 5205) Amends the Higher Education Act of 1965 to expand student loan forgiveness to include allied health professionals employed in public health agencies.

(Sec. 5206) Includes public health workforce loan repayment programs as permitted activities under a grant program to increase the number of individuals in the public health workforce.

Authorizes the Secretary to provide for scholarships for mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(Sec. 5207) Authorizes appropriations for the National Health Service Corps Scholarship Program and the National Health Service Corps Loan Repayment Program.

(Sec. 5208) Requires the Secretary to award grants for the cost of the operation of nurse-managed health clinics.

(Sec. 5209) Eliminates the cap on the number of commissioned officers in the Public Health Service Regular Corps.

(Sec. 5210) Revises the Regular Corps and the Reserve Corps (renamed the Ready Reserve Corps) in the Public Health Service. Sets forth the uses of the Ready Reserve Corps.

Subtitle D: Enhancing Health Care Workforce Education and Training - (Sec. 5301) Sets forth provisions providing for health care professional training programs.

(Sec. 5302) Requires the Secretary to award grants for new training opportunities for direct care workers who are employed in long-term care settings.

(Sec. 5303) Sets forth provisions providing for dentistry professional training programs.

(Sec. 5304) Authorizes the Secretary to award grants for demonstration programs to establish training programs for alternative dental health care providers in order to increase access to dental health services in rural and other underserved communities.

(Sec. 5305) Requires the Secretary to award grants or contracts to entities that operate a geriatric education center to offer short-term, intensive courses that focus on geriatrics, chronic care management, and long-term care.

Expands geriatric faculty fellowship programs to make dentists eligible.

Reauthorizes and revises the geriatric education programs to allow grant funds to be used for the establishment of traineeships for individuals who are preparing for

advanced education nursing degrees in areas that specialize in the care of elderly populations.

(Sec. 5306) Authorizes the Secretary to award grants to institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in, social work programs, psychology programs, child and adolescent mental health, and training of paraprofessional child and adolescent mental health workers.

(Sec. 5307) Authorizes the Secretary, acting through the Administrator of HRSA, to award grants, contracts, or cooperative agreements for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for health professions training in cultural competency, prevention, public health proficiency, reducing health disparities, and working with individuals with disabilities.

(Sec. 5308) Requires nurse-midwifery programs, in order to be eligible for advanced education nursing grants, to have as their objective the education of midwives and to be accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(Sec. 5309) Authorizes the Secretary to award grants or enter into contracts to enhance the nursing workforce by initiating and maintaining nurse retention programs.

(Sec. 5310) Makes nurse faculty at an accredited school of nursing eligible for the nursing education loan repayment program.

(Sec. 5311) Revises the nurse faculty loan repayment program, including to increase the amount of such loans.

Authorizes the Secretary, acting through the Administrator of HRSA, to enter into an agreement for the repayment of education loans in exchange for service as a member of a faculty at an accredited school of nursing.

(Sec. 5312) Authorizes appropriations for carrying out nursing workforce programs.

(Sec. 5313, as modified by Sec. 10501) Requires the Director of CDC to award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(Sec. 5314) Authorizes the Secretary to carry out activities to address documented workforce shortages in state and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics.

(Sec. 5315) Authorizes the establishment of the United States Public Health Sciences Track, which is authorized to award advanced degrees in public health, epidemiology, and emergency preparedness and response.

Directs the Surgeon General to develop: (1) an integrated longitudinal plan for health professions continuing education; and (2) faculty development programs and curricula in decentralized venues of health care to balance urban, tertiary, and inpatient venues.

(Sec. 5316, as added by Sec. 10501) Requires the Secretary to establish a training demonstration program for family nurse practitioners to employ and provide one-year training for nurse practitioners serving as primary care providers in federally qualified health centers or nurse-managed health centers.

Subtitle E: Supporting the Existing Health Care Workforce - (Sec. 5401) Revises the allocation of funds to assist schools in supporting programs of excellence in health professions education for underrepresented minority individuals and schools designated as centers of excellence.

(Sec. 5402, as modified by Sec. 10501) Makes schools offering physician assistant education programs eligible for loan repayment for health profession faculty. Increases the amount of loan repayment for such program.

Authorizes appropriations for: (1) scholarships for disadvantaged students attending health professions or nursing schools; (2) loan repayment for health professions faculty; and (3) grants to health professions school to assist individuals from disadvantaged backgrounds.

(Sec. 5403) Requires the Secretary to: (1) make awards for area health education center programs; and (2) provide for timely dissemination of research findings using relevant resources.

(Sec. 5404) Makes revisions to the grant program to increase nursing education opportunities for individuals from disadvantaged backgrounds to include providing: (1) stipends for diploma or associate degree nurses to enter a bridge or degree completion program; (2) student scholarships or stipends for accelerated nursing degree programs; and (3) advanced education preparation.

(Sec. 5405, as modified by Sec. 10501) Requires the Secretary, acting through the Director of AHRQ, to establish a Primary Care Extension Program to provide support and assistance to educate primary care providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services, and evidence-based and evidence-informed therapies and techniques.

Requires the Secretary to award grants to states for the establishment of Primary Care Extension Program State Hubs to coordinate state health care functions with quality improvement organizations and area health education centers.

Subtitle F: Strengthening Primary Care and Other Workforce Improvements - (Sec. 5501, as modified by Sec. 10501) Requires Medicare incentive payments to: (1) primary care practitioners providing primary care services on or after January 1, 2011, and before January 1, 2016; and (2) general surgeons performing major surgical procedures

on or after January 1, 2011, and before January 1, 2016, in a health professional shortage area.

(Sec. 5502, deleted by Sec. 10501)

(Sec. 5503) Reallocates unused residency positions to qualifying hospitals for primary care residents for purposes of payments to hospitals for graduate medical education costs.

(Sec. 5504) Revises provisions related to graduate medical education costs to count the time residents spend in nonprovider settings toward the full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of such residents during such time.

(Sec. 5505, as modified by Sec. 10501) Includes toward the determination of full-time equivalency for graduate medical education costs time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care in nonpatient care activities.

(Sec. 5506) Directs the Secretary, when a hospital with an approved medical residency program closes, to increase the resident limit for other hospitals based on proximity criteria.

(Sec. 5507) Requires the Secretary to: (1) award grants for demonstration projects that are designed to provide certain low-income individuals with the opportunity to obtain education and training for health care occupations that pay well and that are expected to experience labor shortages or be in high demand; and (2) award grants to states to conduct demonstration projects for purposes of developing core training competencies and certification programs for personal or home care aides.

Authorizes appropriations for FY2009-FY2012 for family-to-family health information centers.

(Sec. 5508) Authorizes the Secretary to award grants to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

Allows up to 50% of time spent teaching by a member of the National Health Service Corps to be considered clinical practice for purposes of fulfilling the service obligation.

Requires the Secretary to make payments for direct and indirect expenses to qualified teaching health centers for expansion or establishment of approved graduate medical residency training programs.

(Sec. 5509) Requires the Secretary to establish a graduate nurse education demonstration under which a hospital may receive payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice nurses.

Subtitle G: Improving Access to Health Care Services - (Sec. 5601) Reauthorizes appropriations for health centers to serve medically underserved populations.

(Sec. 5602) Requires the Secretary to establish through the negotiated rulemaking process a comprehensive methodology and criteria for designation of medically underserved populations and health professions shortage areas.

(Sec. 5603) Reauthorizes appropriations for FY2010-FY2014 for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care.

(Sec. 5604) Authorizes the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to award grants and cooperative agreements for demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

(Sec. 5605) Establishes a Commission on Key National Indicators to: (1) conduct comprehensive oversight of a newly established key national indicators system; and (2) make recommendations on how to improve such system. Directs the National Academy of Sciences to enable the establishment of such system by creating its own institutional capability or by partnering with an independent private nonprofit organization to implement such system. Directs the Comptroller General to study previous work conducted by all public agencies, private organizations, or foreign countries with respect to best practices for such systems.

(Sec. 5606, as added by Sec. 10501) Authorizes a state to award grants to health care providers who treat a high percentage of medically underserved populations or other special populations in the state.

Subtitle H: General Provisions - (Sec. 5701) Requires the Secretary to submit to the appropriate congressional committees a report on activities carried out under this title and the effectiveness of such activities.

Title VI: Transparency and Program Integrity - Subtitle A: Physician Ownership and Other Transparency - (Sec. 6001, as modified by Sec. 10601) Amends SSA title XVIII (Medicare) to prohibit physician-owned hospitals that do not have a provider agreement by August 1, 2010, to participate in Medicare. Allows their participation in Medicare under a rural provider and hospital exception to the ownership or investment prohibition if they meet certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.

(Sec. 6002) Amends SSA title XI to require drug, device, biological and medical supply manufacturers to report to the Secretary transfers of value made to a physician, physician medical practice, a physician group practice, and/or teaching hospital, as well

as information on any physician ownership or investment interest in the manufacturer. Provides penalties for noncompliance. Preempts duplicative state or local laws.

(Sec. 6003) Amends SSA title XVIII (Medicare), with respect to the Medicare in-office ancillary exception to the prohibition against physician self-referrals, to require a referring physician to inform the patient in writing that the patient may obtain a specified imaging service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice. Requires the referring physician also to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

(Sec. 6004) Amends SSA title XI to require prescription drug manufacturers and authorized distributors of record to report to the Secretary specified information pertaining to drug samples.

(Sec. 6005) Amends SSA title XI to require a pharmacy benefit manager (PBM) or a health benefits plan that manages prescription drug coverage under a contract with a Medicare or Exchange health plan to report to the Secretary information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.

Subtitle B: Nursing Home Transparency and Improvement - Part I: Improving Transparency of Information - (Sec. 6101) Amends SSA title XI to require SNFs under Medicare and nursing facilities (NFs) under Medicaid to make available, upon request by the Secretary, the HHS Inspector General, the states, or a state long-term care ombudsman, information on ownership of the SNF or NF, including a description of the facility's governing body and organizational structure, as well as information regarding additional disclosable parties.

(Sec. 6102) Requires SNFs and NFs to operate a compliance and ethics program effective in preventing and detecting criminal, civil, and administrative violations.

Directs the Secretary to establish and implement a quality assurance and performance improvement program for SNFs and NFs, including multi-unit chains of facilities.

(Sec. 6103) Amends SSA title XVIII (Medicare) to require the Secretary to publish on the Nursing Home Compare Medicare website: (1) standardized staffing data; (2) links to state websites regarding state survey and certification programs; (3) the model standardized complaint form; (4) a summary of substantiated complaints; and (5) the number of adjudicated instances of criminal violations by a facility or its employees.

(Sec. 6104) Requires SNFs to report separately expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(Sec. 6105) Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a state survey and certification agency and a state long-term care ombudsman program. Requires states to to establish complaint resolution processes.

(Sec. 6106) Amends SSA title XI to require the Secretary to develop a program for facilities to report direct care staffing information on payroll and other verifiable and auditable data in a uniform format based.

(Sec. 6107) Requires the Comptroller General to study and report to Congress on the Five-Star Quality Rating System for nursing homes of CMS.

Part II: Targeting Enforcement - (Sec. 6111) Amends SSA title XVIII (Medicare) to authorize the Secretary to reduce civil monetary penalties by 50% for certain SNFs and NFs that self-report and promptly correct deficiencies within 10 calendar days of imposition of the penalty. Directs the Secretary to issue regulations providing for an informal dispute resolution process after imposition of a penalty, as well as an escrow account for money penalties pending resolution of any appeals.

(Sec. 6112) Directs the Secretary to establish a demonstration project for developing, testing, and implementing a national independent monitor program to oversee interstate and large intrastate chains of SNFs and NFs.

(Sec. 6113) Requires the administrator of a SNF or a NF that is preparing to close to notify in writing residents, legal representatives of residents or other responsible parties, the Secretary, and the state long-term care ombudsman program in advance of the closure by at least 60 days. Requires the notice to include a plan for the transfer and adequate relocation of residents to another facility or alternative setting. Requires the state to ensure a successful relocation of residents.

(Sec. 6114) Requires the Secretary to conduct two SNF- and NF-based demonstration projects to develop best practice models in two areas: (1) one for facilities involved in the "culture change" movement; and (2) one for the use of information technology to improve resident care.

Part III: Improving Staff Training - (Sec. 6121) Requires SNFs and NFs to include dementia management and abuse prevention training as part of pre-employment initial training and, if appropriate, as part of ongoing in-service training for permanent and contract or agency staff.

Subtitle C: Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers - (Sec. 6201) Requires the Secretary to establish a nationwide program for national and state background checks on prospective direct patient access employees of long-term care facilities and providers.

Subtitle D: Patient-Centered Outcomes Research - (Sec. 6301, as modified by Sec. 10602) Amends SSA title XI to establish the Patient-Centered Outcomes Research Institute to identify priorities for, and establish, update, and carry out, a national comparative outcomes research project agenda. Provides for a peer review process for primary research.

Prohibits the Institute from allowing the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved by the Institute under a data use agreement.

Amends the Public Health Service Act to direct the Office of Communication and Knowledge Transfer at AHRQ to disseminate broadly the research findings published by the Institute and other government-funded research relevant to comparative clinical effective research.

Prohibits the Secretary from using evidence and findings from Institute research to make a determination regarding Medicare coverage unless such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

Amends the Internal Revenue Code to establish in the Treasury the Patient-Centered Outcomes Research Trust Fund. Directs the Secretary to make transfers to that Trust Fund from the Medicare Trust Funds.

Imposes annual fees of $2 times the number of insured lives on each specified health insurance policy and on self-insured health plans.

(Sec. 6302) Terminates the Federal Coordinating Council for Comparative Effectiveness Research upon enactment of this Act.

Subtitle E: Medicare, Medicaid, and CHIP Program Integrity Provisions - (Sec. 6401, as modified by Sec. 10603) Amends SSA title XVIII (Medicare) to require the Secretary to: (1) establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP; and (2) determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier.

Requires providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating in a federal health care program; or (4) has had billing privileges revoked. Authorizes the Secretary to deny enrollment in a program if these affiliations pose an undue risk to it.

Requires providers and suppliers to establish a compliance program containing specified core elements.

Directs the CMS Administrator to establish a process for making available to each state agency with responsibility for administering a state Medicaid plan or a child health plan under SSA title XXI the identity of any provider or supplier under Medicare or CHIP who is terminated.

(Sec. 6402) Requires CMS to include in the integrated data repository claims and payment data from Medicare, Medicaid, CHIP, and health-related programs administered by the Departments of Veterans Affairs (VA) and DOD, the Social Security Administration, and IHS.

Directs the Secretary to enter into data-sharing agreements with the Commissioner of Social Security, the VA and DOD Secretaries, and the IHS Director to help identity fraud, waste, and abuse.

Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

Directs the Secretary to issue a regulation requiring all Medicare, Medicaid, and CHIP providers to include their National Provider Identifier on enrollment applications.

Authorizes the Secretary to withhold the federal matching payment to states for medical assistance expenditures whenever a state does not report enrollee encounter data in a timely manner to the state’s Medicaid Management Information System.

Authorizes the Secretary to exclude providers and suppliers participation in any federal health care program for providing false information on any application to enroll or participate.

Subjects to civil monetary penalties excluded individuals who: (1) order or prescribe an item or service; (2) make false statements on applications or contracts to participate in a federal health care program; or (3) know of an overpayment and do not return it. Subjects the latter offense to civil monetary penalties of up to $50,000 or triple the total amount of the claim involved.

Authorizes the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question.

Requires the Secretary take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond. Authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Appropriates an additional $10 million, adjusted for inflation, to the Health Care Fraud and Abuse Control each of FY2011-FY2020. Applies inflation adjustments as well to Medicare Integrity Program funding.

Requires the Medicaid Integrity Program and Program contractors to provide the Secretary and the HHS Office of Inspector General with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities.

(Sec. 6403) Requires the Secretary to furnish the National Practitioner Data Bank (NPDB) with all information reported to the national health care fraud and abuse data collection program on certain final adverse actions taken against health care providers, suppliers, and practitioners.

Requires the Secretary to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in it is transferred to the NPDB.

(Sec. 6404) Reduces from three years to one year after the date of service the maximum period for submission of Medicare claims.

(Sec. 6405, as modified by Sec. 10604) Requires DME or home health services to be ordered by an enrolled Medicare eligible professional or physician. Authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

(Sec. 6406) Authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services.

Authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

(Sec. 6407, as modified by Sec. 10605) Requires a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant to have a face-to-face encounter with an individual before issuing a certification for home health services or DME.

Authorizes the Secretary to apply the same face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse. Applies the same requirement, as well, to physicians making certifications for home health services under Medicaid.

(Sec. 6408) Revises civil monetary penalties for making false statements or delaying inspections.

Applies specified enhanced sanctions and civil monetary penalties to MA or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent; (2) transfer an individual from one plan to another for the purpose of earning a commission; (3) fail to comply with marketing requirements and CMS guidance; or (4) employ or contract with an individual or entity that commits a violation.

(Sec. 6409) Requires the Secretary to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.

Authorizes the Secretary to reduce the amount due and owing for all violations of such law.

(Sec. 6410) Requires the Secretary to: (1) expand the number of areas to be included in round two of the competitive bidding program from 79 to 100 of the largest metropolitan statistical areas; and (2) use competitively bid prices in all areas by 2016.

(Sec. 6411) Requires states to establish contracts with one or more Recovery Audit Contractors (RACs), which shall identify underpayments and overpayments and recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

Requires the Secretary to expand the RAC program to Medicare parts C (Medicare+Choice) and D (Prescription Drug Program).

Subtitle F: Additional Medicaid Program Integrity Provisions - (Sec. 6501) Amends SSA title XIX (Medicaid) to require states to terminate individuals or entities (providers) from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.

(Sec. 6502) Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

(Sec. 6503) Requires state Medicaid plans to require any billing agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary.

(Sec. 6504) Requires states to submit data elements from the state mechanized claims processing and information retrieval system (under the Medicaid Statistical Information System) that the Secretary determines necessary for program integrity, program oversight, and administration.

Requires a Medicaid managed care entity contract to provide for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients (as under current law) at a frequency and level of detail to be specified by the Secretary.

(Sec. 6505) Requires a state Medicaid plan to prohibit the state from making any payments for items or services under a Medicaid state plan or a waiver to any financial institution or entity located outside of the United States.

(Sec. 6506) Extends the period for states to recover overpayments from 60 days to one year after discovery of the overpayment. Declares that, when overpayments due to fraud are pending, state repayments of the federal portion of such overpayments shall not be due until 30 days after the date of the final administrative or judicial judgment on the matter.

(Sec. 6507) Requires state mechanized Medicaid claims processing and information retrieval systems to incorporate methodologies compatible with Medicare's National Correct Coding Initiative.

Subtitle G: Additional Program Integrity Provisions - (Sec. 6601) Amends the Employee Retirement Income Security Act of 1974 (ERISA) to prohibit employees and agents of multiple employer welfare arrangements (MEWAs), subject to criminal penalties, from making false statements in marketing materials regarding an employee welfare benefit plan's financial solvency, benefits, or regulatory status.

(Sec. 6603) Amends the Public Health Service Act to direct the Secretary to request NAIC to develop a model uniform report form for a private health insurance issuer seeking to refer suspected fraud and abuse to state insurance departments or other responsible state agencies for investigation.

(Sec. 6604) Amends ERISA to direct the Secretary of Labor to adopt regulatory standards and/or issue orders to subject MEWAs to state law relating to fraud and abuse.

(Sec. 6605) Authorizes the Secretary of Labor to: (1) issue cease-and-desist orders to shut down temporarily the operations of MEWAs conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed; and (2) seize a plan's assets if it appears that the plan is in a financially hazardous condition.

(Sec. 6606) Directs the Secretary of Labor to require MEWAs which are not group health plans to register with the Department of Labor before operating in a state.

(Sec. 6607) Authorizes the Secretary of Labor to promulgate a regulation providing an evidentiary privilege that allows confidential communication among specified federal and state officials relating to investigation of fraud and abuse.

Subtitle H: Elder Justice Act - Elder Justice Act of 2009 - (Sec. 6702) Amends SSA title XX (Block Grants to States for Social Services) with respect to elder abuse, neglect, and exploitation and their prevention. Requires the HHS Secretary to award grants and carry out activities that provide: (1) greater protection to those individuals seeking care in facilities that provide long-term care services and supports; and (2) greater incentives for individuals to train and seek employment at such facilities.

Requires facility owners, operators, and certain employees to report suspected crimes committed at a facility.

Requires facility owners or operators also to: (1) submit to the Secretary and to the state written notification of an impending closure of a facility within 60 days before the closure; and (2) include a plan for transfer and adequate relocation of all residents.

Establishes an Elder Justice Coordinating Council.

Subtitle I: Sense of the Senate Regarding Medical Malpractice - (Sec. 6801) Expresses the sense of the Senate that: (1) health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test alternative models to the existing civil litigation system; and (3) Congress should consider state demonstration projects to evaluate such alternatives.

Title VII: Improving Access to Innovative Medical Therapies - Subtitle A: Biologics Price Competition and Innovation - Biologics Price Competition and Innovation Act of 2009 - (Sec. 7002) Amends the Public Health Service Act to allow a person to submit an application for licensure of a biological product based on its similarity to a licensed biological product (the reference product). Requires the Secretary to license the biological product if it is biosimilar to or interchangeable with the reference product.

Prohibits the Secretary from determining that a second or subsequent biological product is interchangeable with a reference product for any condition of use for specified periods based on the marketing of, and the presence or status of litigation involving, the first biosimilar biological product deemed interchangeable with the same reference product.

Prohibits the Secretary from making approval of an application under this Act effective until 12 years after the date on which the reference product was first licensed.

Subtitle B: More Affordable Medicine for Children and Underserved Communities - (Sec. 7101) Expands the 340B drug discount program (a program limiting the cost of covered outpatient drugs to certain federal grantees) to allow participation as a covered entity by certain: (1) children's hospitals; (2) freestanding cancer hospitals; (3) critical access hospitals; (4) rural referral centers; and (5) sole community hospitals. Expands the program to include drugs used in connection with an inpatient or outpatient service by enrolled hospitals (currently, only outpatient drugs are covered under the program).

Requires the Secretary to establish reasonable exceptions to the prohibition on enrolled hospitals obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, including for drugs unavailable through the program and to facilitate generic substitution when a generic covered drug is available at a lower price. Allows such hospitals to purchase covered drugs for inpatients through any such arrangement.

Requires a hospital enrolled in the 340B drug discount program to issue a credit to a state Medicaid program for inpatient covered drugs provided to Medicaid recipients.

(Sec. 7102) Requires the Secretary to: (1) provide for improvements in compliance by manufacturers and covered entities with the requirements of the 340B drug discount program; and (2) establish and implement an administrative process for resolving claims by covered entities and manufacturers of violations of such requirements.

Requires manufacturers to offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price.

(Sec. 7103) Requires the Comptroller General to report to Congress on whether those individuals served by the covered entities under the 340B drug discount program are receiving optimal health care services.

Title VIII: Class Act - Community Living Assistance Services and Supports Act or the CLASS Act - (Sec. 8002, as modified by Sec. 10801) Establishes a national, voluntary insurance program for purchasing community living assistance services and supports (CLASS program) under which: (1) all employees are automatically enrolled, but are allowed to waive enrollment; (2) payroll deductions pay monthly premiums; and (3) benefits under a CLASS Independence Benefit Plan provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community.

Title IX: Revenue Provisions - Subtitle A: Revenue Offset Provisions - (Sec. 9001, as modified by section 10901) Amends the Internal Revenue Code to impose an excise tax of 40% of the excess benefit from certain high cost employer-sponsored health coverage. Deems any amount which exceeds payment of $8,500 for an employee self-only coverage plan and $23,000 for employees with other than self-only coverage (family plans) as an excess benefit. Increases such amounts for certain retirees and employees who are engaged in high-risk professions (e.g., law enforcement officers, emergency medical first responders, or longshore workers). Imposes a penalty on employers and coverage providers for failure to calculate the proper amount of an excess benefit.

(Sec. 9002) Requires employers to include in the W-2 form of each employee the aggregate cost of applicable employer-sponsored group health coverage that is

excludable from the employee's gross income (excluding the value of contributions to flexible spending arrangements).

(Sec. 9003) Restricts payments from health savings accounts, medical savings accounts, and health flexible spending arrangements for medications to prescription drugs or insulin.

(Sec. 9004) Increases to 20% the penalty for distributions from a health savings account or Archer medical savings account not used for qualified medical expenses.

(Sec. 9005, as modified by section 10902) Limits annual salary reduction contributions by an employee to a health flexible spending arrangement under a cafeteria plan to $2,500. Allows an annual inflation adjustment to such amount after 2011.

(Sec. 9006) Applies to corporations reporting requirements for payments of $600 or more to persons engaged in a trade or business.

(Sec. 9007, as modified by section 10903) Requires tax-exempt charitable hospitals to: (1) conduct a community health needs assessment every two years; (2) adopt a written financial assistance policy for patients who require financial assistance for hospital care; and (3) refrain from taking extraordinary collection actions against a patient until the hospital has made reasonable efforts to determine whether the patient is eligible for financial assistance. Imposes a penalty tax on hospitals who fail to comply with the requirements of this Act.

Requires the Secretary of the Treasury to report to Congress on information with respect to private tax-exempt, taxable, and government-owned hospitals regarding levels of charity care provided, bad debt expenses, unreimbursed costs, and costs for community benefit activities.

(Sec. 9008) Imposes an annual fee on the branded prescription drug sales exceeding $5 million of manufacturers and importers of such drugs beginning in 2010. Requires the HHS, VA, and DOD Secretaries to report to the Secretary of the Treasury on the total branded prescription drug sales within government programs within their departments.

(Sec. 9009, as modified by section 10904) Imposes an annual fee on the gross sales receipts exceeding $5 million of manufacturers and importers of certain medical devices beginning in 2011.

(Sec. 9010, as modified by section 10905) Imposes on any entity that provides health insurance for any United States health risk an annual fee beginning in 2011. Defines "United States health risk" as the health risk of an individual who is a U.S. citizen or resident or is located in the United States with respect to the period the individual is so located. Exempts entities whose net premiums written are not more than $25 million. Requires all entities subject to such fee to report to the Secretary of the Treasury on their net written premiums and imposes a penalty for failure to report.

(Sec. 9011) Requires the VA Secretary to study and report to Congress by December 31, 2012, on the effect of fees assessed by this Act on the cost of medical care provided to veterans and on veterans' access to medical devices and branded prescription drugs.

(Sec. 9012) Eliminates the tax deduction for expenses for determining the subsidy for employers who maintain prescription drug plans for Medicare Part D eligible retirees.

(Sec. 9013) Increases the adjusted gross income threshold for claiming the itemized deduction for medical expenses from 7.5% to 10% beginning after 2012. Retains the 7.5% threshold through 2016 for individual taxpayers who have attained age 65 before the close of an applicable taxable year.

(Sec. 9014) Imposes a limitation after December 31, 2012, of $500,000 on the deductibility of remuneration paid to officers, directors, employees, and service providers of health insurance issuers who derive at least 25% of their gross premiums from providing health insurance coverage that meets the minimum essential coverage requirements established by this Act.

(Sec. 9015, as modified by section 10906) Increases after December 31, 2012, the hospital insurance tax rate by .9% for individual taxpayers earning over $200,000 ($250,000 for married couples filing joint tax returns).

(Sec. 9016) Requires Blue Cross or Blue Shield organizations or other nonprofit organizations that provide health insurance to reimburse at least 85% of the cost of clinical services provided to their enrollees to be eligible for special tax benefits currently provided to such organizations.

Subtitle B: Other Provisions - (Sec. 9021) Excludes from gross income the value of certain health benefits provided to members of Indian tribes, including: (1) health services or benefits provided or purchased by IHS; (2) medical care provided by an Indian tribe or tribal organization to a member of an Indian tribe; (3) accident or health plan coverage provided by an Indian tribe or tribal organization for medical care to a member of an Indian tribe and dependents; and (4) any other medical care provided by an Indian tribe that supplements, replaces, or substitutes for federal programs.

(Sec. 9022) Establishes a new employee benefit cafeteria plan to be known as a Simple Cafeteria Plan, defined as a plan that: (1) is established and maintained by an employer with an average of 100 or fewer employees during a two-year period; (2) requires employers to make contributions or match employee contributions to the plan; and (3) requires participating employees to have at least 1,000 hours of service for the preceding plan year; and (4) allows such employees to elect any benefit available under the plan.

(Sec. 9023) Allows a 50% tax credit for investment in any qualifying therapeutic discovery project, defined as a project that is designed to: (1) treat or prevent diseases by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out

research projects to approve new drugs or other biologic products; (2) diagnose diseases or conditions to determine molecular factors related to diseases or conditions; or (3) develop a product, process, or technology to further the delivery or administration of therapeutics. Directs the Secretary of the Treasury to award grants for 50% of the investment in 2009 or 2010 in such a project, in lieu of the tax credit.

Title X: Strengthening Quality, Affordable Health Care for All Americans - Subtitle A: Provisions Relating to Title I - (Sec. 10101) Revises provisions of or related to Subtitles A, B, and C of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10104) Revises provisions of or related to Subtitle D of Title I of this Act (as reflected in the summary of those provisions). Makes changes to the False Claims Act related to the public disclosure bar on filing civil claims.

(Sec. 10105) Revises provisions of or related to Subtitles E, F, and G of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10108) Requires an offering employer to provide free choice vouchers to each qualified employee. Defines "offering employer" to mean any employer who offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan and who pays any portion of the costs of such plan. Defines "qualified employee" as an employee whose required contribution for such coverage and household income fall within a specified range. Requires: (1) a Health Insurance Exchange to credit the amount of any free choice voucher to the monthly premium of any qualified health plan in which the employee is enrolled; and (2) the offering employer to pay any amounts so credited to the Exchange. Excludes the amount of any free choice voucher from the gross income of the employee. Permits a deduction by employers for such costs.

(Sec. 10109) Amends the SSA to require the HHS Secretary to seek input to determine if there could be greater uniformity in financial and administrative health care activities and items.

Requires the Secretary to: (1) task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input regarding and recommend revisions to the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases; and (2) make appropriate revisions to such crosswalk.

Subtitle B: Provisions Relating to Title II - Part I: Medicaid and CHIP - (Sec. 10201) Revises provisions of Subtitles A through L of Title II of this Act (as reflected in the summary of those provisions).

Amends SSA title XIX (Medicaid) to set the FMAP for the state of Nebraska, with respect to all or any portion of a fiscal year that begins on or after January 1, 2017, at 100% (thus requiring the federal government to pay 100% of the cost of covering newly-eligible individuals in Nebraska).

Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any specified health care quality guideline or other standards would result in the establishment of a new cause of action or claim.

(Sec. 10202) Creates a State Balancing Incentive Payments Program to increase the FMAP for states which offer home and community-based services as a long-term care alternative to nursing homes.

(Sec. 10203) Amends SSA title XXI (CHIP) to make appropriations for CHIP through FY2015 and revise other CHIP-related requirements.

Part II: Support for Pregnant and Parenting Teens and Women - (Sec. 10212) Requires the Secretary to establish a Pregnancy Assistance Fund for grants to states to assist pregnant and parenting teens and women.

(Sec. 10214) Authorizes appropriations for FY2010-FY2019.

Part III: Indian Health Care Improvement - (Sec. 10221) Enacts into law the Indian Health Care Improvement Reauthorization and Extension Act of 2009 (S. 1790) as reported by the Senate Committee on Indian Affairs in December 2009 and with the following changes.

Amends the Indian Health Care Improvement Act, as amended by the Indian Health Care Improvement Reauthorization and Extension Act of 2009, to make an exception to the requirement that a national Community Health Aide Program exclude dental health aide therapist services. Declares that the exclusion of dental health aide therapist services from services covered under the national program shall not apply where an Indian tribe or tribal organization, located in a state (other than Alaska) in which state law authorizes the use of dental health aide therapist services or midlevel dental health provider services, elects to supply such services in accordance with state law.

Subtitle C: Provisions Relating to Title III - (Sec. 10301) Revises provisions of Subtitles A through G of Title III of this Act (as reflected in the summary of those provisions).

(Sec. 10323) Amends SSA title XVIII (Medicare) to deem eligible for Medicare coverage certain individuals exposed to environmental health hazards.

Directs the Secretary to establish a pilot program for care of certain individuals residing in emergency declaration areas.

Amends SSA title XX (Block Grants to States for Social Services) to direct the Secretary to establish a program for early detection of certain medical conditions related to environmental health hazards. Makes appropriations for FY2012-FY2019.

(Sec. 10324) Establishes floors: (1) on the area wage index for hospitals in frontier states; (2) on the area wage adjustment factor for hospital outpatient department

services in frontier states; and (3) for the practice expense index for services furnished in frontier states.

(Sec. 10325) Revises the SNF prospective payment system to delay specified changes until FY2011.

(Sec. 10326) Directs the Secretary to conduct separate pilot programs, for specified kinds of hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.

(Sec. 10327) Authorizes an additional incentive payment under the physician quality reporting system in 2011 through 2014 to eligible professionals who report quality measures to CMS via a qualified Maintenance of Certification program. Eliminates the MedicareAdvantage Regional Plan Stabilization Fund.

(Sec. 10328) Requires Medicare part D prescription drug plans to include a comprehensive review of medications as part of their medication therapy management programs. Requires automatic quarterly enrollment of qualified beneficiaries, with an allowance for them to opt out.

(Sec. 10329) Requires the Secretary to develop a methodology to measure health plan value.

(Sec. 10330) Directs the Secretary to develop a plan to modernize CMS computer and data systems.

(Sec. 10331) Requires the Secretary to: (1) develop a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative; and (2) implement a plan to make information on physician performance public through Physician Compare, particularly quality and patient experience measures.

Authorizes the Secretary to provide financial incentives to Medicare beneficiaries furnished services by high quality physicians.

(Sec. 10332) Directs the Secretary to make available to qualified entities standardized extracts of Medicare claims data for the evaluation of the performance of service providers and suppliers.

(Sec. 10333) Amends the Public Health Service Act to authorize the Secretary to award grants to eligible entities to support community-based collaborative care networks for low-income populations.

(Sec. 10334) Transfers the Office of Minority Health to the Office of the Secretary. Authorizes appropriations for FY2011-FY2016.

Establishes individual offices of minority health within HHS.

Redesignates the National Center on Minority Health and Health Disparities in NIH as the National Institute on Minority Health and Health Disparities.

(Sec. 10336) Directs the Comptroller General to study and report to Congress on the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs furnished to them for the treatment of end stage renal disease in the related bundled prospective payment system.

Subtitle D: Provisions Relating to Title IV - (Sec. 10401) Revises provisions of or related to Subtitles A, B, C, D, and E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10407) Catalyst to Better Diabetes Care Act of 2009 - Requires the Secretary to prepare biennially a national diabetes report card and, to the extent possible, one for each state.

Requires the Secretary, acting through the Director of CDC, to: (1) promote the education and training of physicians on the importance of birth and death certificate data and on how to properly complete these documents; (2) encourage state adoption of the latest standard revisions of birth and death certificates; and (3) work with states to reengineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data. Allows the Secretary to promote improvements to the collection of diabetes mortality data.

Directs the Secretary to conduct a study of the impact of diabetes on the practice of medicine in the United States and the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(Sec. 10408) Requires the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs.

(Sec. 10409) Cures Acceleration Network Act of 2009 - Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to implement the Cures Acceleration Network under which grants and contracts will be awarded to accelerate the development of high need cures. Defines "high need cure" as a drug, biological product, or device: (1) that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Establishes a Cures Acceleration Network Review Board.

(Sec. 10410) Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009 or the ENHANCED Act of 2009 - Requires the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to: (1) award grants to establish national centers of excellence for depression; and (2) designate one such center as a coordinating center. Requires the coordinating center to establish and maintain a national, publicly available database

to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders using data collected from the national centers.

(Sec. 10411) Congenital Heart Futures Act - Authorizes the Secretary, acting through the Director of CDC, to: (1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into the National Congenital Heart Disease Surveillance System; or (2) award a grant to an eligible entity to undertake such activities.

Authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate research and related Institute activities on congenital heart disease.

(Sec. 10412) Reauthorizes appropriations for grants for public access defibrillation programs. Requires an information clearinghouse to increase public access to defibrillation in schools established under such program to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death.

(Sec. 10413) Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009 or the EARLY Act - Requires the Secretary, acting through the Director of CDC, to conduct: (1) a national education campaign to increase awareness of young women's knowledge regarding breast health and breast cancer; (2) an education campaign among physicians and other health care professionals to increase awareness of breast health of young women; and (3) prevention research on breast cancer in younger women.

Requires the Secretary, acting through the Director of NIH, to conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

Directs the Secretary to award grants for the provision of health information to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

Subtitle E: Provisions Relating to Title V - (Sec. 10501) Revises provisions of or related to Title V of this Act (as reflected in the summary of those provisions).

Requires the Secretary, acting through the Director of CDC, to establish a national diabetes prevention program targeted at adults at high risk for diabetes.

Directs the Secretary to develop a Medicare prospective payment system for payment for services furnished by federally qualified health centers.

Requires the Secretary, acting through the Administrator of the HRSA, to establish a grant program to assist accredited schools of allopathic or osteopathic medicine in: (1) recruiting students most likely to practice medicine in underserved rural communities;

(2) providing rural-focused training and experience; and (3) increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

Directs the Secretary, acting through the Administrator of HRSA, to award grants or enter into contracts with eligible entities to provide training to graduate medical residents in preventive medicine specialties.

Reauthorizes appropriations for public health workforce activities.

Revises provisions related to fulfillment of service obligations under the National Health Service Corps related to half-time clinical practice and teaching.

(Sec. 10502) Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services and that meets certain requirements, including that it is critical for the provision of greater access to health care within the state.

(Sec. 10503) Establishes a Community Health Center Fund to provide for expanded and sustained national investment in community health centers. Authorizes appropriations to such Fund.

(Sec. 10504) Requires the Secretary, acting through the Administrator of HRSA, to establish a demonstration project to provide access to comprehensive health care services to the uninsured at reduced fees.

Subtitle F: Provisions Relating to Title VI - (Sec. 10601) Revises provisions of Subtitles A through E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10606) Directs the U.S. Sentencing Commission to amend the Federal Sentencing Guidelines to provide two-level, three-level, and four-level increases in the offense level for any defendant convicted of a federal health care offense relating to a government health care program of a loss between $1 million and $7 million, between $7 million and $20 million, and at least $20 million, respectively.

Provides that a person need not have actual knowledge of the prohibition against health care fraud nor specific intent to violate it in order to commit health care fraud.

Expands the scope of violations constituting a federal health care offense.

Amends the Civil Rights of Institutionalized Persons Act to authorize the Attorney General to require access to an institution by subpoena to investigate conditions depriving residents of specified constitutional or federal rights.

(Sec. 10607) Authorizes the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for

resolving disputes over injuries allegedly caused by health care providers or health care organizations.

(Sec. 10608) Amends the Public Health Service Act to extend medical malpractice coverage to free clinics by deeming their officers, employees, board members, and contractors to be employees of the Public Health Service.

(Sec. 10609) Amends the Federal Food, Drug, and Cosmetic Act to set forth circumstances under which a generic drug may be approved with a label different from the listed drug.

Subtitle G: Provisions Relating to Title VIII - (Sec. 10801) Revises provisions of or related to Title VIII of this Act (as reflected in the summary of those provisions).

Subtitle H: Provisions Relating to Title IX: (Sec. 10901) Revises provisions of or related to Title IX of this Act (as reflected in the summary of those provisions).

(Sec. 10907) Amends the Internal Revenue Code to impose a 10% excise tax on any amount paid for indoor tanning services on or after July 1, 2010. Exempts phototherapy services performed by a licensed medical professional from the definition of "indoor tanning services."

(Sec. 10908) Excludes from gross income any payments under the National Health Service Corps Loan Repayment Program and any other state loan repayment or forgiveness programs intended to increase the availability of health care services in underserved or health professional shortage areas.

(Sec. 10909) Increases from $10,000 to $13,170 the dollar limitation on: (1) the tax credit for adoption expenses; and (2) the tax exclusion for employer-provided adoption assistance. Allows an inflation adjustment to such limitation after 2010. Makes such credit refundable. Extends through 2011 the general terminating date of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to such credit and exclusion.

Issue 12: The Biden Build Back Better Act

In late 2021, the Biden administration introduced the Build Back Better program to address climate change, various social equity issues and improve the Affordable Care Act. The ultimate fate of each component is unclear as of the publication date of this text. Below, we summarize the Affordable Care Act section of the Plan as passed by the US House of Representatives on November 19, 2021.

Read this as the Biden administration's vision for healthcare reform.

Major Provisions of the Build Back Better Act and their Potential Costs and Impact

1. ACA Marketplace Subsidies

BACKGROUND

Under the Affordable Care Act, people purchasing Marketplace coverage could only qualify for subsidies if they met other eligibility requirements and had incomes between one and four times the federal poverty level. People eligible for subsidies would have to contribute a sliding-scale percentage of their income toward a benchmark premium, ranging from 2.07% to 9.83%. Once income passed 400% FPL, subsidies stopped and many individuals and families were unable to afford coverage.

In 2021, the American Rescue Plan Act (ARPA) temporarily expanded eligibility for subsidies by removing the upper income threshold. It also temporarily increased the dollar value of premium subsidies across the board, meaning nearly everyone on the Marketplace paid lower premiums, and the lowest income people pay *zero* premium for coverage with very low deductibles. The ARPA also made people who received unemployment insurance (UI) benefits during 2021 eligible for zero-premium, low-deductible plans.

However, the ARPA provisions removing the upper income threshold and increasing tax credit amounts are only in effect for 2021 and 2022. The unemployment provision is only in effect for 2021.

PROVISION DESCRIPTION

Section 137301 of The Build Back Better Act would extend the ARPA subsidy changes that eliminate the income eligibility cap and increase the amount of APTC for individuals across the board through the end of 2025.

Additionally, Section 30605 of The Build Back Better Act would extend the special Marketplace subsidy rule for individuals receiving UI benefits for an additional 4 years, through the end of 2025.

Section 137303 of the Act would, for purposes of determining eligibility for premium tax credits, disregard any lump sum Social Security benefit payments in a year. This provision would be permanent and effective starting in the 2022 tax year. Starting in 2026, people would have the option to have the lump sum benefit included in their income for purposes of determining tax credit eligibility.

Finally, Section 137302 modifies the affordability test for employer-sponsored health coverage. The ACA makes people ineligible for marketplace subsidies if they have an offer of affordable coverage from an employer, currently defined as requiring an employee contribution of no more than 9.61% of household income in 2022. The Build Back Better Act would reduce this affordability threshold to 8.5% of income, bringing it in line with the maximum contribution required to enroll in the benchmark marketplace plan. This provision would take effect for tax years starting in 2022 through 2025. Thereafter the affordability threshold would be set at 9.5% of household income with no indexing.

PEOPLE AFFECTED

CBO projects that the enhanced tax credits in Section 137301 would reduce the number of uninsured by 1.2 million people. As of August 2021, 12.2 million people were actively enrolled in Marketplace plans – an 8% increase from 11.2 million people enrollees as of the close of Open Enrollment for the 2021 plan year. HealthCare.gov and all state Marketplaces reopened for a special enrollment period of at least 6 months in 2021, enrolling 2.8 million people (not all of whom were necessarily previously uninsured). Of these, 44% selected plans with monthly premiums of $10 or less.

The US Department of Health and Human Services (HHS) reports that ARPA reduced Marketplace premiums for the 8 million existing Healthcare.gov enrollees by $67 per month, on average. If the ARPA subsidies are allowed to expire, these enrollees will likely see their premium payments double.

HHS also reports that between July 1 and August 15, more than 280,000 individuals received enhanced subsidies due to the ARPA UI provisions. Individuals eligible for these UI benefits can continue to enroll in 2021 coverage through the end of this year.

The ARPA changes made people with income at or below 150% FPL eligible for zero-premium silver plans with comprehensive cost sharing subsidies. 40% of new consumers who signed up during the SEP are in a plan that covers 94% of expected

costs (with average deductibles below $200). As a result of the ARPA, HHS reports the median deductible for new consumers selecting plan during the COVID-SEP decreased by more than 90% (from $750 in 2020 to $50 in 2021).

With the ARPA and ACA subsidies, as well as Medicaid in states that expanded the program, we estimate that at least 46% of non-elderly uninsured people in the U.S. are eligible for free or nearly-free health plans, often with low or no deductibles.

BUDGETARY IMPACT

CBO estimates that extension of the ARPA marketplace subsidy improvements through 2025 (Section 13701) will cost $73.9 billion over the ten-year budget window, with “cost” reflecting both direct spending and on-budget revenue losses. This total also includes the cost of modifying the affordability threshold for employer-sponsored coverage (Section 13602)

CBO further estimates the cost of extending the enhanced marketplace subsidies for people receiving unemployment benefits (Section 13705) will be $1.8 billion over the ten-year budget window.

The cost of disregarding lump sum Social Security benefits payments for purposes of determining premium tax credit eligibility (Section 13703) is $416 million over the ten-year budget window.

2. New Medicare Hearing Benefit

BACKGROUND

Medicare currently does not cover hearing services, except under limited circumstances, such as cochlear implantation when beneficiaries meet certain eligibility criteria. Hearing services are typically offered as an extra benefit by Medicare Advantage plans, and in 2021, 97% of Medicare Advantage enrollees in individual plans, or 17.1 million people, are offered some hearing benefits, but according to our analysis, the extent of that coverage and the value of these benefits varies. Some beneficiaries in traditional Medicare may have private coverage or coverage through Medicaid for these services, but many do not.

PROVISION DESCRIPTION

Section 30901 of the Build Back Better Act would add coverage of hearing services to Medicare Part B, beginning in 2023. Coverage for hearing care would include hearing rehabilitation and treatment services by qualified audiologists, and hearing aids. Hearing aids would be available once per ear, every 5 years, to individuals diagnosed with moderately severe, severe, or profound hearing loss. Hearing services would be subject to the Medicare Part B deductible and 20% coinsurance. Hearing aids would be covered similar to other Medicare prosthetic devices and would also be subject to the Part B deductible and 20% coinsurance. For people in traditional Medicare who have other

sources of coverage such as Medigap or Medicaid, their cost sharing for these services might be covered. Payment for hearing aids would only be on an assignment-related basis. As with other Medicare-covered benefits, Medicare Advantage plans would be required to cover these hearing benefits.

Effective Date: The Medicare hearing benefit provision would take effect in 2023.

PEOPLE AFFECTED

Adding coverage of hearing services, including hearing aids, to Medicare would help beneficiaries with hearing loss who might otherwise go without treatment by an audiologist or hearing aids, particularly those who cannot afford the cost of hearing aids. It would also lower out-of-pocket costs for some beneficiaries who would otherwise pay the full cost of their hearing aids without the benefit. Among beneficiaries who used hearing services in 2018, average out-of-pocket spending according to our analysis was $914, although many hearing aids are considerably more expensive than the average.

While the majority of enrollees in Medicare Advantage plans have access to a hearing benefit, a new defined Medicare Part B benefit could also lead to enhanced and more affordable hearing benefits for Medicare Advantage enrollees. Because costs are often a barrier to care, adding this benefit to Medicare could increase use of these services, and contribute to better health outcomes.

BUDGETARY IMPACT

CBO estimates that the new Medicare Part B hearing benefit would increase federal spending by $36.7 billion over 10 years (2022-2031).

3. Lowering Prescription Drug Prices and Spending

BACKGROUND

Currently, under the Medicare Part D program, which covers retail prescription drugs, Medicare contracts with private plan sponsors to provide a prescription drug benefit. The law that established the Part D benefit includes a provision known as the "noninterference" clause, which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." For drugs administered by physicians that are covered under Medicare Part B, Medicare reimburses providers 106% of the Average Sales Price (ASP), which is the average price to all non-federal purchasers in the U.S, inclusive of rebates, A recent KFF Tracking Poll finds large majorities support allowing the federal government to negotiate and this support holds steady even after the public is provided the arguments being presented by parties on both sides of the legislative debate (83% total, 95% of Democrats, 82% of independents, and 71% of Republicans).

In addition to the inability to negotiate drug prices under Part D, Medicare lacks the ability to limit annual price increases for drugs covered under Part B (which includes those administered by physicians) and Part D. In contrast, Medicaid has an inflationary rebate in place. Year-to-year drug price increases exceeding inflation are not uncommon and affect people with both Medicare and private insurance. Our analysis shows that half of all covered Part D drugs had list price increases that exceeded the rate of inflation between 2018 and 2019.

PROVISION DESCRIPTION

Drug Price Negotiations. Sections 139001, 139002, and 139003 of the Build Back Better Act would amend the non-interference clause by adding an exception that would allow the federal government to negotiate prices with drug companies for a small number of high-cost drugs lacking generic or biosimilar competitors covered under Medicare Part B and Part D. The negotiation process would apply to no more than 10 (in 2025), 15 (in 2026 and 2027), and 20 (in 2028 and later years) single-source brand-name drugs lacking generic or biosimilar competitors, selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending (for 2027 and later years). The negotiation process would also apply to all insulin products.

The legislation exempts from negotiation drugs that are less than 9 years (for small-molecule drugs) or 13 years (for biological products, based on the Manager's Amendment) from their FDA-approval or licensure date. The legislation also exempts "small biotech drugs" from negotiation until 2028, defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part on that manufacturer's drugs.

The proposal establishes an upper limit for the negotiated price (the "maximum fair price") equal to a percentage of the non-federal average manufacturer price: 75% for small-molecule drugs more than 9 years but less than 12 years beyond approval; 65% for drugs between 12 and 16 years beyond approval or licensure; and 40% for drugs more than 16 years beyond approval or licensure. Part D drugs with prices negotiated under this proposal would be required to be covered by all Part D plans. Medicare's payment to providers for Part B drugs with prices negotiated under this proposal would be 106% of the maximum fair price (rather than 106% of the average sales price under current law).

An excise tax would be levied on drug companies that do not comply with the negotiation process, and civil monetary penalties on companies that do not offer the agreed-upon negotiated price to eligible purchasers.

Effective Date: The negotiated prices for the first set of selected drugs (covered under Part D) would take effect in 2025. For drugs covered under Part B, negotiated prices would first take effect in 2027.

Inflation Rebates. Sections 139101 and 139102 of the Build Back Better Act would require drug manufacturers to pay a rebate to the federal government if their prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI-U). Under these provisions, price changes would be measured based on the average sales price (for Part B drugs) or the average manufacturer price (for Part D drugs). For price increase higher than inflation, manufacturers would be required to pay the difference in the form of a rebate to Medicare. The rebate amount is equal to the total number of units multiplied by the amount if any by which the manufacturer price exceeds the inflation-adjusted payment amount, including all units sold outside of Medicaid and therefore applying not only to use by Medicare beneficiaries but by privately insured individuals as well. Rebate dollars would be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund.

Manufacturers that do not pay the requisite rebate amount would be required to pay a penalty equal to at least 125% of the original rebate amount. The base year for measuring price changes is 2021.

Effective Date: These provisions would take effect in 2023.

Limits on Cost Sharing for Insulin Products. Sections 27001, 30604, 137308, and 139401 would require insurers, including Medicare Part D plans and private group or individual health plans, to charge no more than $35 for insulin products. Part D plans would be required to charge no more than $35 for whichever insulin products they cover for 2023 and 2024 and all insulin products beginning in 2025. Coverage of all insulin products would be required beginning in 2025 because the drug negotiation provision (described earlier) would require all Part D plans to cover all drugs that are selected for price negotiation, and all insulin products are subject to negotiation under that provision. Private group or individual plans do not have to cover all insulin products, just one of each dosage form (vial, pen) and insulin type (rapid-acting, short-acting, intermediate-acting, and long-acting) for no more than $35.

Effective Date: These provisions would take effect in 2023.

Vaccines. Section 139402 would require that adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles, be covered at no cost. This would be consistent with coverage of vaccines under Medicare Part B, such as the flu and COVID-19 vaccines.

Effective Date: This provision would take effect in 2024.

Repealing the Trump Administration's Drug Rebate Rule. Section 139301 would prohibit implementation of the November 2020 final rule issued by the Trump Administration that would have eliminated rebates negotiated between drug manufacturers and pharmacy benefit managers (PBMs) or health plan sponsors in Medicare Part D by removing the safe harbor protection currently extended to these rebate arrangements under the

federal anti-kickback statute. This rule was slated to take effect on January 1, 2022, but the Biden Administration delayed implementation to 2023 and the infrastructure legislation passed by the House and Senate includes a further delay to 2026.

Effective Date: This provision would take effect in 2026.

PEOPLE AFFECTED

The number of Medicare beneficiaries and privately insured individuals who would see lower out-of-pocket drug costs in any given year under these provisions would depend on how many and which drugs were subject to the negotiation process, and how many and which drugs had lower price increases, and the magnitude of price reductions relative to current prices under each provision.

Neither CBO nor the Biden Administration have published estimates of beneficiary premium and out-of-pocket budget effects associated with the provision to allow the HHS Secretary to negotiate drug prices. An earlier version of the negotiations proposal in H.R.3 that passed the House of Representatives in 2019 would have lowered cost sharing for Part D enrollees by $102.6 billion in the aggregate (2020-2029) and Part D premiums for Medicare beneficiaries by $14.3 billion. Based on our analysis of the H.R. 3 version of this provision, the negotiations provision in H.R. 3 would have reduced Medicare Part D premiums for Medicare beneficiaries by an estimated 9% of the Part D base beneficiary premium in 2023 and by as much as 15% in 2029. However, the effects on beneficiary premiums and cost sharing under the drug negotiation provision in the BBBA are expected to be more modest than the effects of H.R. 3 due to the smaller number of drugs eligible for negotiation and a different method of calculating the maximum fair price.

While it is expected that some people would face lower cost sharing under these provisions, it is also possible that drug manufacturers could respond to the inflation rebate by increasing launch prices for new drugs. In this case, some individuals could face higher out-of-pocket costs for new drugs that come to market, with potential spillover effects on total costs incurred by payers as well.

In terms of insulin costs, a $35 cap on monthly cost sharing for insulin products could lower out-of-pocket costs for many insulin users with private insurance and those in Medicare Part D without low-income subsidies. While formulary coverage and tier placement of insulin products vary across Medicare Part D plans, our analysis shows that in 2019, a large number of Part D plans placed insulin products on Tier 3, the preferred drug tier, which typically had a $47 copayment per prescription during the initial coverage phase. However, once enrollees reach the coverage gap phase, they face a 25% coinsurance rate, which equates to $100 or more per prescription in out-of-pocket costs for many insulin therapies, unless they qualify for low-income subsidies. Paying a flat $35 copayment rather than 25% coinsurance could reduce out-of-pocket costs for many people with diabetes who use insulin products.

In terms of vaccines, providing for coverage of adult vaccines under Medicare Part D at no cost could help with vaccine uptake among older adults and would lower out-of-pocket costs for those who need Part D-covered vaccines. Our analysis shows that in 2018, Part D enrollees without low-income subsidies paid an average of $57 out-of-pocket for each dose of the shingles shot, which is generally free to most other people with private coverage.

BUDGETARY IMPACT

Drug Price Negotiations. CBO estimates $78.8 billion in Medicare savings over 10 years (2022-2031) from the drug negotiation provisions.

Inflation Rebates. CBO estimates a net federal deficit reduction of $83.6 billion over 10 years (2022-2031) from the drug inflation rebate provisions in the BBBA. This includes net savings of $49.4 billion ($61.8 billion in savings to Medicare and $7.7 billion in savings for other federal programs, such as DoD, FEHB, and subsides for ACA Marketplace coverage, offset by $20.1 billion in additional Medicaid spending) and higher federal revenues of $34.2 billion.

Limits on Cost Sharing for Insulin Products. CBO estimates additional federal spending of $1.4 billion ($0.9 billion for Medicare and $0.5 billion in other federal spending) and a reduction in federal revenues of $4.6 billion over 10 years associated with the insulin cost-sharing limits in the BBBA.

Vaccines. CBO estimates that this provision would increase federal spending by $3.3 billion over 10 years (2022-2031).

Repealing the Trump Administration's Drug Rebate Rule. Because the rebate rule was finalized (although not implemented), its cost has been incorporated in CBO's baseline for federal spending. Therefore, repealing the rebate rule is expected to generate savings. CBO estimates savings of $142.6 billion from the repeal of the Trump Administration's rebate rule between 2026 (when the BBBA provision takes effect) and 2031. In addition, CBO estimated savings of $50.8 billion between 2023 and 2026 for the three-year delay of this rule included in the Infrastructure Investment and Jobs Act.

4. Medicare Part D Benefit Redesign

BACKGROUND

Medicare Part D currently provides catastrophic coverage for high out-of-pocket drug costs, but there is no limit on the total amount that beneficiaries pay out-of-pocket each year. Medicare Part D enrollees with drug costs high enough to exceed the catastrophic coverage threshold are required to pay 5% of their total drug costs unless they qualify for Part D Low-Income Subsidies (LIS). Medicare pays 80% of total costs above the catastrophic threshold and plans pay 15%. Medicare's reinsurance payments to Part D plans now account for close to half of total Part D spending (45%), up from 14% in 2006.

Under the current structure of Part D, there are multiple phases, including a deductible, an initial coverage phase, a coverage gap phase, and the catastrophic phase. When enrollees reach the coverage gap benefit phase, they pay 25% of drug costs for both brand-name and generic drugs; plan sponsors pay 5% for brands and 75% for generics; and drug manufacturers provide a 70% price discount on brands (there is no discount on generics). Under the current benefit design, beneficiaries can face different cost sharing amounts for the same medication depending on which phase of the benefit they are in, and can face significant out-of-pocket costs for high-priced drugs because of coinsurance requirements and no hard out-of-pocket cap.

PROVISION DESCRIPTION

Sections 139201 and 139202 of the Build Back Better Act amend the design of the Part D benefit by adding a hard cap on out-of-pocket spending set at $2,000 in 2024, increasing each year based on the rate of increase in per capita Part D costs. It also lowers beneficiaries' share of total drug costs below the spending cap from 25% to 23%. It also lowers Medicare's share of total costs above the spending cap ("reinsurance") from 80% to 20% for brand-name drugs and to 40% for generic drugs; increases plans' share of costs from 15% to 60% for both brands and generics; and adds a 20% manufacturer price discount on brand-name drugs. Manufacturers would also be required to provide a 10% discount on brand-name drugs in the initial coverage phase (below the annual out-of-pocket spending threshold), instead of a 70% price discount.

The legislation also increases Medicare's premium subsidy for the cost of standard drug coverage to 76.5% (from 74.5% under current law) and reduces the beneficiary's share of the cost to 23.5% (from 25.5%). The legislation also allows beneficiaries the option of smoothing out their out-of-pocket costs over the year rather than face high out-of-pocket costs in any given month.

Effective Date: The Part D redesign and premium subsidy changes would take effect in 2024. The provision to smooth out-of-pocket costs would take effect in 2025.

PEOPLE AFFECTED

Medicare beneficiaries in Part D plans with relatively high out-of-pocket drug costs are likely to see substantial out-of-pocket cost savings from this provision. While most Part D enrollees have not had out-of-pocket costs high enough to exceed the catastrophic coverage threshold in a single year, the likelihood of a Medicare beneficiary incurring drug costs above the catastrophic threshold increases over a longer time span.

Our analysis shows that in 2019, nearly 1.5 million Medicare Part D enrollees had out-of-pocket spending above the catastrophic coverage threshold. Looking over a five-year period (2015-2019), the number of Part D enrollees with out-of-pocket spending above the catastrophic threshold in at least one year increases to 2.7 million, and over a 10-year period (2010-2019), the number of enrollees increases to 3.6 million.

Based on our analysis, 1.2 million Part D enrollees in 2019 incurred annual out-of-pocket costs for their medications above $2,000 in 2019, averaging $3,216 per person. Based on their average out-of-pocket spending, these enrollees would have saved $1,216, or 38% of their annual costs, on average, if a $2,000 cap had been in place in 2019. Part D enrollees with higher-than-average out-of-pocket costs could save substantial amounts with a $2,000 out-of-pocket spending cap. For example, the top 10% of beneficiaries (122,000 enrollees) with average out-of-pocket costs for their medications above $2,000 in 2019 – who spent at least $5,348 – would have saved $3,348 (63%) in out-of-pocket costs with a $2,000 cap.

BUDGETARY IMPACT

CBO estimates the benefit redesign and smoothing provisions of the BBBA would reduce federal spending by $1.5 billion over 10 years (2022-2031), which consists of $1.6 billion in lower spending associated with Part D benefit redesign and $0.1 billion in higher spending associated with the provision to smooth out-of-pocket costs.

5. Medicaid Coverage Gap

BACKGROUND

There are currently 12 states that have not adopted the ACA provision to expand Medicaid to adults with incomes through 138% of poverty. The result is a coverage gap for individuals whose below-poverty-level income is too high to qualify for Medicaid in their state, but too low to be eligible for premium subsidies in the ACA Marketplace.

PROVISION DESCRIPTION

Section 137304 of the Build Back Better Act would allow people living in states that have not expanded Medicaid to purchase subsidized coverage on the ACA Marketplace for 2022 through 2025. The federal government would fully subsidize the premium for a benchmark plan. People would also be eligible for cost sharing subsidies that would reduce their out-of-pocket costs to 1% of overall covered health expenses on average.

Section 30608 includes adjustments to uncompensated care (UCC) pools and disproportionate share hospital (DSH) payments for non-expansion states. These states would not be able draw down federal matching funds for UCC amounts for individuals who could otherwise qualify for Medicaid expansion, and their DSH allotments would be reduced by 12.5% starting in 2023.

Section 30609 would increase the federal match rate for states that have adopted the ACA Medicaid expansion from 90% to 93% from 2023 through 2025, designed to discourage states from dropping current expansion coverage.

PEOPLE AFFECTED

We estimate that 2.2 million uninsured people with incomes under poverty fall in the “coverage gap”. Most in the coverage gap are concentrated in four states (TX, FL, GA

and NC) where eligibility levels for parents in Medicaid are low, and there is no coverage pathway for adults without dependent children. Half of those in the coverage gap are working and six in 10 are people of color.

CBO estimates that provisions to address the coverage gap would result in 1.7 million fewer uninsured people.

BUDGETARY IMPACT

CBO estimates that the net federal cost of extending Marketplace coverage to certain low-income people would increase federal spending by $57 billion over the next decade (this reflects $43.8 billion in federal costs and a loss of federal revenues of $13.2 billion).

CBO estimates provisions to limit DSH and uncompensated care pool funding for non-expansion states would reduce federal costs by $18.3 billion over 5 years and $34.5 billion over the next 10 years and federal costs would increase by $10.4 billion due to the increase in the match rate for current expansion states from 90% to 93% for expansion states for 2023 through 2025.

6. Maternity Care and Postpartum Coverage

BACKGROUND

Medicaid currently covers almost half of births in the U.S. Federal law requires that pregnancy-related Medicaid coverage last through 60 days postpartum. After that period, some may qualify for Medicaid through another pathway, but others may not qualify, particularly in non-expansion states. In an effort to improve maternal health and coverage stability and to help address racial disparities in maternal health, a provision in the American Rescue Plan Act (ARPA) of 2021 gives states a new option to extend Medicaid postpartum coverage to 12 months. This new option takes effect on April 1, 2022 and is available to states for five years.

PROVISION DESCRIPTION

Section 30721 of the Build Back Better Act would require states to extend Medicaid postpartum coverage from 60 days to 12 months, ensuring continuity of Medicaid coverage for postpartum individuals in all states. This requirement would take effect in the first fiscal quarter beginning one year after enactment and also applies to state CHIP programs that cover pregnant individuals.

Section 30722 would create a new option for states to coordinate care for Medicaid-enrolled pregnant and post-partum individuals through a maternal health home model. States that take up this option would receive a 15% increase in FMAP for care delivered through maternal health homes for the first two years. States that are interested in pursuing this new option can receive planning grants prior to implementation.

Sections 31031 through 31048 of the Build Back Better Act provide federal grants to bolster other aspects of maternal health care. The funds would be used to address a wide range of issues, such as addressing social determinants of maternal health; diversifying the perinatal nursing workforce, expanding care for maternal mental health and substance use, and supporting research and programs that promote maternal health equity.

PEOPLE AFFECTED

Largely in response to the new federal option, at least 26 states have taken steps to extend Medicaid postpartum coverage. Pregnant people in non-expansion states could see the biggest change as they are more likely than those in expansion states to become uninsured after the 60-day postpartum coverage period. For example, in Alabama, the Medicaid eligibility level for pregnant individuals is 146% FPL, but only 18% FPL (approximately $4,000/year for a family of three) for parents.

Some states have piloted maternal health homes and seen positive impacts on health outcomes. The federal grant provisions related to maternal health could affect care for all persons giving birth, but the focus of these proposals is on reducing racial and ethnic inequities. There were approximately 3.7 million births in 2019, and nearly half were to women of color. There are approximately 700-800 pregnancy-related deaths annually, with the rate 2-3 times higher among Black and American Indian and Alaska Native women compared to White women. Additionally, there are stark racial and ethnic disparities in other maternal and health outcomes, including preterm birth and infant mortality.

BUDGETARY IMPACT

CBO estimates that requiring 12 month postpartum coverage in Medicaid and CHIP would have a net federal cost of $1.2 billion over 10 years (new costs of $2.2 billion offset by new revenues of $1.0 billion. CBO estimates that the option to create a maternal health home would increase federal spending by $1.0 billion over 10 years.

CBO estimates that federal outlays for the grant sections in the Build Back Better Act related to maternal health care outside of the postpartum extension and maternal health homes are $1.1 billion.

7. Other Medicaid and Children’s Health Insurance (CHIP) Changes

BACKGROUND

Under current law, states have the option to provide 12-months of continuous coverage for children. Under this option, states allow a child to remain enrolled for a full year unless the child ages out of coverage, moves out of state, voluntarily withdraws, or does not make premium payments. As such, 12-month continuous eligibility eliminates coverage gaps due to fluctuations in income over the course of the year.

To help support states and promote stability of coverage during the COVID-19 pandemic, the Families First Coronavirus Response Act (FFCRA) provides a 6.2 percentage point increase in the federal share of certain Medicaid spending, provided that states meet maintenance of eligibility (MOE) requirements that include ensuring continuous coverage for current enrollees.

Under current law, Medicaid is the base of coverage for low-income children. CHIP complements Medicaid by covering uninsured children in families with incomes above Medicaid eligibility levels. Unlike Medicaid, federal funding for CHIP is capped and provided as annual allotments to states. CHIP funding is authorized through September 30, 2027. While CHIP generally has bipartisan support, during the last reauthorization funding lapsed before Congress reauthorized funding.

PROVISION DESCRIPTION

Section 30741 of the Build Back Better Act would require states to extend 12-month continuous coverage for children on Medicaid and CHIP.

Section 30741 of the Build Back Better Act would phase out the FFCRA enhanced federal funding to states. States would continue to receive the 6.2 percentage point increase through March 31, 2022, followed by a 3.0 percentage point increase from April 1, 2022 through June 30, 2022, and a 1.5 percentage point increase from July 1, 2022 through September 30, 2022.

Section 30741 also would modify the FFCRA MOE requirement for continuous coverage. From April 1 through September 30, 2022, states could continue receiving the enhanced federal matching funds if they only terminate coverage for individuals who are determined no longer eligible for Medicaid and have been enrolled at least 12 consecutive months. The legislation includes other rules for states about conducting eligibility redeterminations and when states can terminate coverage.

Section 30801 of the Build Back Better Act would permanently extend the CHIP program.

PEOPLE AFFECTED

As of May 2021, there were 39 million children enrolled in Medicaid and CHIP (nearly half of all enrollees). As of January 2020, 34 states provide 12-month continuous eligibility to at least some children in either Medicaid or CHIP. A recent MACPAC report found that the overall mean length of coverage for children in 2018 was 11.7 months, and also that rates of churn (in which children dis-enroll and reenroll within a short period of time) were lower in states that had adopted the 12-month continuous coverage option and in states that did not conduct periodic data checks. Another recent report shows that children with gaps in coverage during a year are more likely to be children of color with lower incomes.

As of May 2021, there were 6.9 million people (mostly children) enrolled in CHIP.

BUDGETARY IMPACT

CBO estimates that Section 30741 would reduce federal costs by a net $3.5 billion over 10 years. This 10 year number reflects $17.1 billion in federal savings in FY 2022 that is likely related to the provisions to end the enhanced fiscal relief and the continuous coverage requirements and then federal costs starting in FY 2024. CBO estimates that permanently extending the CHIP program would reduce federal costs by $1.2 billion over 10 years.

8. Other Medicaid Financing and Benefit Changes

BACKGROUND

Unlike in the 50 states and D.C., annual federal funding for Medicaid in the U.S. Territories is subject to a statutory cap and fixed matching rate. The funding caps and match rates have been increased by Congress in response to emergencies over time.

Vaccines are an optional benefit for certain adult populations, including low-income parent/caretakers, pregnant women, and persons who are eligible based on old age or a disability. For adults enrolled under the ACA's Medicaid expansion and other populations for whom the state elects to provide an "alternative benefit plan," their benefits are subject to certain requirements in the ACA, including coverage of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) with no cost sharing.

Under the Families First Coronavirus Response Act, coverage of testing and treatment for COVID-19, including vaccines, is required with no cost sharing in order for states to access temporary enhanced federal funding for Medicaid which is tied to the public health emergency. The American Rescue Plan Act (ARPA) clarified that coverage of COVID-19 vaccines and their administration, without cost sharing, is required for nearly all Medicaid enrollees, through the last day of the 1st calendar quarter beginning at least 1 year after the public health emergency ends. The ARPA also provides 100% federal financing for this coverage.

PROVISION DESCRIPTION

Section 30731 of the Build Back Better Act would increase the Medicaid cap amount and match rate for the territories. The FMAP would be permanently adjusted to 83% for the territories beginning in FY 2022, except that Puerto Rico's match rate would be 76% in FY 2022 before increasing to 83% in FY 2023 and subsequent years. The legislation would also require a payment floor for certain physician services in Puerto Rico with a penalty for failure to establish the floor.

Section 30751 of the Build Back Better Act would establish a 3.1 percentage point FMAP reduction from October 1, 2022 through December 31, 2025 for states that adopt eligibility standards, methodologies, or procedures that are more restrictive than those

in place as of October 1, 2021 (except the penalty would not apply to coverage of non-pregnant, non-disabled adults with income above 133% FPL after December 31, 2022, if the state certifies that it has a budget deficit).

Section 139405 of the Build Back Better Act would require state Medicaid programs to cover all approved vaccines recommended by ACIP and vaccine administration, without cost sharing, for categorically and medically needy adults. States that provide adult vaccine coverage without cost sharing as of the date of enactment would receive a 1 percentage point FMAP increase for 8 quarters.

PEOPLE AFFECTED

In June 2019 there were approximately 1.3 million Medicaid enrollees in the territories (with 1.2 million in Puerto Rico).

From February 2020 through May 2021 Medicaid and CHIP enrollment has increased by 11.5 million or 16.2% due to the economic effects of the pandemic and MOE requirements.

All states provide some vaccine coverage for adults enrolled in Medicaid who are not covered as part of the ACA's Medicaid expansion, but as of 2019, only about half of states covered all ACIP-recommended vaccines.

BUDGETARY IMPACT

CBO estimates that the changes in Medicaid financing for the Territories would increase federal spending by $9.5 billion over 10 years.

CBO estimates that the provision to impose a penalty in the match rate if states implement eligibility or enrollment restrictions through 2025 would increase federal costs by $7.0 billion.

CBO estimates that extending vaccines to adults on Medicaid would increase federal spending by $2.8 billion over 10 years.https://www.kff.org/health-costs/issue-brief/potential-costs-and-impact-of-health-provisions-in-the-build-back-better-act/ - top

9. Medicaid Home and Community Based Services and the Direct Care Workforce

BACKGROUND

Medicaid is currently the primary payer for long-term services and supports (LTSS), including home and community-based services (HCBS), that help seniors and people with disabilities with daily self-care and independent living needs. There is currently a great deal of state variation as most HCBS eligibility pathways and benefits are optional for states.

PROVISION DESCRIPTION

Sections 30711-30713 of the Build Back Better Act would create the HCBS Improvement Program, which would provide a permanent 6 percentage point increase in federal Medicaid matching funds for HCBS. To qualify for the enhanced funds, states would have to maintain existing HCBS eligibility, benefits, and payment rates and have an approved plan to expand HCBS access, strengthen the direct care workforce, and monitor HCBS quality. The bill includes some provisions to support family caregivers. In addition, the Act would include funding ($130 million) for state planning grants and enhanced funding for administrative costs for certain activities (80% instead of 50%).

Section 30714 of the Build Back Better Act would require states to report HCBS quality measures to HHS, beginning 2 years after the Secretary publishes HCBS quality measures as part of the Medicaid/CHIP core measures for children and adults. The bill provides states with an enhanced 80% federal matching rate for adopting and reporting these measures.

Sections 30715 and 30716 of the Build Back Better Act would make the ACA HCBS spousal impoverishment protections and the Money Follows the Person (MFP) program permanent.

Sections 22301 and 22302 of the Build Back Better Act would provide $1 billion in grants to states, community-based organizations, educational institutions, and other entities by the Department of Labor Secretary to develop and implement strategies for direct service workforce recruitment, retention, and/or education and training.

Section 25005 of the Build Back Better Act would provide $20 million for HHS and the Administration on Community Living to establish a national technical assistance center for supporting the direct care workforce and family caregivers.

Section 25006 of the Build Back Better Act would provide $40 million for the HHS Secretary to award to states, nonprofits, educational institutions, and other entities to address the behavioral health needs of unpaid caregivers of older individuals and older relative caregivers.

PEOPLE AFFECTED

The majority of HCBS are provided by waivers, which served over 2.5 million enrollees in 2018. There is substantial unmet need for HCBS, which is expected to increase with the growth in the aging population in the coming years. Nearly 820,000 people in 41 states were on a Medicaid HCBS waiver waiting list in 2018. Though waiting lists alone are an incomplete measure, they are one proxy for unmet need for HCBS. Additionally, a shortage of direct care workers predated and has been intensified by the COVID-19 pandemic, characterized by low wages and limited opportunities for career advancement. The direct care workforce is disproportionately female and Black.

A KFF survey found that, as of 2018, 14 states expected that allowing the ACA spousal impoverishment provision to expire would affect Medicaid HCBS enrollees, for example by making fewer individuals eligible for waiver services.

Over 101,000 seniors and people with disabilities across 44 states and DC moved from nursing homes to the community using MFP funds from 2008-2019. A federal evaluation of MFP showed about 5,000 new participants in each six month period from December 2013 through December 2016, indicating a continuing need for the program.

BUDGETARY IMPACT

CBO estimates that all of the Medicaid-related HCBS provisions together will increase federal spending by about $150 billion in the 10-year budget window. The new HCBS Improvement Program (Section 30712) accounts for most of this spending ($146.5 billion).

CBO scores the Department of Labor direct care workforce provisions according to the amount of spending authorized for each in the bill: $1 billion for grants to support the direct care workforce (Section 22302), $20 million for a technical assistance center for supporting direct care and caregiving (Section 25005), and $40 million for funding to support unpaid caregivers (Section 25006).

10. Paid Family and Medical Leave

BACKGROUND

The U.S. is the only industrialized nation without a minimum standard of paid family or medical leave. Although six states and DC have paid family and medical leave laws in effect, and some employers voluntarily offer these benefits, this has resulted in a patchwork of policies with varying degrees of generosity and leaves many workers without a financial safety net when they need to take time off work to care for themselves or their families.

PROVISION DESCRIPTION

Section 130001 of the Build Back Better Act would guarantee four weeks per year of paid family and medical leave to all workers in the U.S. who need time off work to welcome a new child, recover from a serious illness, or care for a seriously ill family member. Annual earnings up to $15,080 would be replaced at approximately 90% of average weekly earnings, plus about 73% of average weekly earnings for annual wages between $15,080 and $32,248, capping out at 53% of average weekly earnings for annual wages between $32,248 and $62,000. While all workers taking qualified leave would be eligible for at least some wage replacement, the progressive benefits formula means that the share of pay replaced while on qualified leave is highest for workers with lower wages. The original Act called for 12 weeks of paid leave for similar qualified reasons, plus three days of bereavement leave, and benefits began at 85% of average

weekly earnings for annual wages up to $15,080 and were capped at 5% of average weekly earnings for annual wages up to $250,000.

PEOPLE AFFECTED

According to the Bureau of Labor Statistics (BLS), approximately one in four (23%) workers has access to paid family leave through their employer. Data on the share of workers with access to paid medical leave for their own longer, serious illness are limited, although BLS also reports that 40% of workers have access to short-term disability insurance.

It is estimated that 53 million adults are caregivers for a dependent child or adult and 61% of them are women. Sixty percent (60%) of caregivers reported having to take a leave of absence leave from work or cut their hours in order to care for a family member. Workers who take leave do so for different reasons: Half (51%) reported taking leave due to their own serious illness, one-quarter (25%) for reasons related to pregnancy, childbirth, or bonding with a new child, and one-fifth (19%) to care for a seriously ill family member. In total, four in ten (42%) reported receiving their full pay while on leave, one-quarter (24%) received partial pay, and one-third (34%) received no pay.

BUDGETARY IMPACT

CBO estimates that the federal cost of these provisions would be about $205.5 billion over the 2022-2031 period. The estimate accounts for funding the paid leave benefits and administration, grants for the state administration option for states that already have a comprehensive paid leave law, and partial reimbursements for employers that provide equally comprehensive paid leave as a benefit to all their workers. The CBO estimate is modestly offset by application fees paid by employers participating in the reimbursement option for employer-sponsored paid leave benefits.

11. Consumer Assistance, Enrollment Assistance, and Outreach

BACKGROUND

Consumer Assistance in Health Insurance – The Affordable Care Act (ACA) established a new system of state health insurance ombudsman programs, also called Consumer Assistance Programs, or CAPs. These programs are required to conduct public education about health insurance consumer protections and help people resolve problems with their health plans, including filing appeals for denied claims. By law, private health plans, including employer-sponsored plans, are required to include contact information for CAPs on all explanation-of-benefit statements (EOB) with notice that CAPs can help consumers file appeals.

To help inform oversight, CAPs are also required to report data to the Secretary of HHS on consumer experiences and problems. The ACA permanently authorized CAPs and

appropriated seed funding of $30 million in 2010. Forty state CAPs were established that year; since then, Congress has not appropriated CAP funding.

Enrollment Assistance and Outreach in the Marketplace – The Affordable Care Act also requires marketplaces to establish Navigator programs that help consumers apply for and enroll in coverage through the marketplace. And it requires marketplaces to conduct public education and outreach about the availability of coverage and financial assistance. As noted above, the Build Back Better Act would create new eligibility for marketplace coverage and financial assistance for low-income adults in states that have not expanded Medicaid.

PROVISION DESCRIPTION

Section 30603 appropriates $100 million for state consumer assistance programs (CAPs) over the 4-year period, 2022-2025.

Section 30601(d) appropriates $105 million to conduct public education and outreach in non-expansion states so people will learn about new coverage and subsidy options. $15 million is appropriated for 2022 and $30 million for each of 2023-2025. In addition, this section requires the Secretary to obligate no less than $70 million of marketplace user-fee revenues for additional Navigator funding to support enrollment assistance for the new coverage-gap population (at least $10 million in FY 2022 and at least $20 million in each of FY 2023-2025).

PEOPLE AFFECTED

CAP Funding – More than 175 million Americans are covered by private health insurance plans today. Consumers generally find health insurance confusing and have limited understanding of even basic health insurance terms and concepts. Four-in-ten have difficulty understanding what their health plan will cover or how much they will have to pay out-of-pocket for needed care; when faced with unaffordable bills, only one-in-ten even try to get providers to lower their price. When claims are denied, consumers rarely appeal. These are the kinds of problems CAPs could help address with expanded funding. Most of the state CAPs established in 2010 continue to operate today, though at reduced capacity without federal financial support; programs rely on state funding (many CAPs are housed in state Insurance Departments or Attorney General offices) and philanthropic support today. With recent enactment of the federal No Surprises Act, as well as amendments to the Mental Health Parity and Addiction Equity Act (MHPAEA), CAPS can help consumers understand and navigate new federal health insurance protections and inform oversight by federal and state agencies.

Marketplace Enrollment Assistance and Outreach – After years of cuts in funding for Navigator enrollment assistance and outreach, the Biden Administration took steps this year to restore federal marketplace funding for these activities. During the 2021 COVID special enrollment opportunity, when expanded subsidies enacted by ARPA first became available, more than 2.2 million people newly signed up for marketplace

coverage. However, KFF found only 1 in 4 people who are uninsured or buy their own health insurance checked to see if they would qualify for affordable coverage. This finding is consistent with earlier KFF surveys that find 3 in 4 uninsured don't look for health coverage because they assume it is not affordable. Investments in public education, outreach, and enrollment assistance can help inform the 2.2 million uninsured adults in the coverage gap of new affordable health coverage options through the marketplace.

BUDGETARY IMPACT

New appropriations for Consumer Assistance Programs would cost $100 million over 5 years.

New appropriations for marketplace outreach would cost $105 million over 5 years. Additional funding for Navigator enrollment assistance in coverage gap states would not come from new appropriations; these resources will come from user fee revenue collected by the marketplace.

Issue 10: Biden's Inflation Reduction Act as passed on healthcare

The Biden administration only managed to pass part of its healthcare reform vision. Below, we provide the healthcare reform section of Biden's 2022 Inflation Reduction Act.

See how closely – and how differently – this resembles Biden's original vision.

Prescription Drug Pricing Reform

PART 1—Lowering Prices Through Drug Price Negotiation

SEC. 11001. Providing for lower prices for certain high-priced single source drugs.

(a) Program To lower prices for certain high-Priced single source drugs.—Title XI of the Social Security Act is amended by adding after section 1184 (42 U.S.C. 1320e–3) the following new part:

"PART E—Price Negotiation Program to Lower Prices for Certain High-Priced Single Source Drugs

"SEC. 1191. Establishment of program.

"(a) In general.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the 'program'). Under the program, with respect to each price applicability period, the Secretary shall—

"(1) publish a list of selected drugs in accordance with section 1192;

"(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

"(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194;

"(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1195 and 1196.

"(b) Definitions relating to timing.—For purposes of this part:

"(1) INITIAL PRICE APPLICABILITY YEAR.—The term 'initial price applicability year' means a year (beginning with 2026).

"(2) PRICE APPLICABILITY PERIOD.—The term 'price applicability period' means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

“(3) SELECTED DRUG PUBLICATION DATE.—The term ‘selected drug publication date’ means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

“(4) NEGOTIATION PERIOD.—The term ‘negotiation period’ means, with respect to an initial price applicability year with respect to a selected drug, the period—

“(A) beginning on the sooner of—

“(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

“(ii) February 28 following the selected drug publication date with respect to such selected drug; and

“(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

“(c) Other definitions.—For purposes of this part:

“(1) MANUFACTURER.—The term ‘manufacturer’ has the meaning given that term in section 1847A(c)(6)(A).

“(2) MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL.—The term ‘maximum fair price eligible individual’ means, with respect to a selected drug—

“(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

“(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug.

“(3) MAXIMUM FAIR PRICE.—The term ‘maximum fair price’ means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price negotiated pursuant to section 1194, and updated pursuant to section 1195(b), as applicable, for such drug and year.

“(4) REFERENCE PRODUCT.—The term ‘reference product’ has the meaning given such term in section 351(i) of the Public Health Service Act.

“(5) TOTAL EXPENDITURES.—The term ‘total expenditures’ includes, in the case of expenditures with respect to part D of title XVIII, the total gross covered prescription drug costs (as defined in section 1860D–15(b)(3)). The term ‘total expenditures’ excludes, in the case of expenditures with respect to part B of such title, expenditures

for a drug or biological product that are bundled or packaged into the payment for another service.

“(6) UNIT.—The term ‘unit’ means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

“(d) Timing for initial price applicability year 2026.—Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the following rules shall apply for purposes of implementing the program:

“(1) Subsection (b)(3) shall be applied by substituting ‘September 1, 2023’ for ‘, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year’.

“(2) Subsection (b)(4) shall be applied—

“(A) in subparagraph (A)(ii), by substituting ‘October 1, 2023’ for ‘February 28 following the selected drug publication date with respect to such selected drug’; and

“(B) in subparagraph (B), by substituting ‘August 1, 2024’ for ‘November 1 of the year that begins 2 years prior to the initial price applicability year’.

“(3) Section 1192 shall be applied—

“(A) in subsection (b)(1)(A), by substituting ‘during the period beginning on June 1, 2022, and ending on May 31, 2023’ for ‘during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available’; and

“(B) in subsection (d)(1)(A), by substituting ‘during the period beginning on June 1, 2022, and ending on May 31, 2023’ for ‘during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year’.

“(4) Section 1193(a) shall be applied by substituting ‘October 1, 2023’ for ‘February 28 following the selected drug publication date with respect to such selected drug’.

“(5) Section 1194(b)(2) shall be applied—

“(A) in subparagraph (A), by substituting ‘October 2, 2023’ for ‘March 1 of the year of the selected drug publication date, with respect to the selected drug’;

“(B) in subparagraph (B), by substituting ‘February 1, 2024’ for ‘the June 1 following the selected drug publication date’; and

“(C) in subparagraph (E), by substituting ‘August 1, 2024’ for ‘the first day of November following the selected drug publication date, with respect to the initial price applicability year ’.

“(6) Section 1195(a)(1) shall be applied by substituting ‘September 1, 2024’ for ‘November 30 of the year that is 2 years prior to such initial price applicability year’.

“SEC. 1192. Selection of negotiation-eligible drugs as selected drugs.

“(a) In general.—Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

“(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

“(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

“(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

“(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1194(f)(5), each drug published on the list pursuant to the previous sentence shall be subject to the negotiation process under section 1194 for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

“(b) Selection of drugs.—

“(1) IN GENERAL.—In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

“(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of

such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

“(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

“(2) HIGH SPEND PART D DRUGS FOR 2026 AND 2027.—With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to ‘negotiation-eligible drugs described in subsection (d)(1)’ were a reference to ‘negotiation-eligible drugs described in subsection (d)(1)(A)’ and as if the reference to ‘total expenditures for such drugs under parts B and D of title XVIII’ were a reference to ‘total expenditures for such drugs under part D of title XVIII’.

“(c) Selected drug.—

“(1) IN GENERAL.—For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a ‘selected drug’ with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

“(A) is approved or licensed (as applicable)—

“(i) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

“(ii) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

“(B) is marketed pursuant to such approval or licensure.

“(2) CLARIFICATION.—A negotiation-eligible drug—

“(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

“(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1194 with respect to such negotiation period and shall continue to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

“(d) Negotiation-Eligible drug.—

“(1) IN GENERAL.—For purposes of this part, subject to paragraph (2), the term ‘negotiation-eligible drug’ means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

“(A) PART D HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

“(B) PART B HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

“(2) EXCEPTION FOR SMALL BIOTECH DRUGS.—

“(A) IN GENERAL.—Subject to subparagraph (C), the term ‘negotiation-eligible drug’ shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

“(i) PART D DRUGS.—The total expenditures for the qualifying single source drug under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

“(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1860D–2(e)) during such year; and

“(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1860D–14A during such year.

“(ii) PART B DRUGS.—The total expenditures for the qualifying single source drug under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

“(I) are equal to or less than 1 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

“(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

“(B) CLARIFICATIONS RELATING TO MANUFACTURERS.—

“(i) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

“(ii) LIMITATION.—A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii), effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

“(C) DRUGS NOT INCLUDED AS SMALL BIOTECH DRUGS.—A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

“(3) CLARIFICATIONS AND DETERMINATIONS.—

“(A) PREVIOUSLY SELECTED DRUGS AND SMALL BIOTECH DRUGS EXCLUDED.—In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

“(i) drugs that are already selected drugs; and

“(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

“(B) USE OF DATA.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

“(e) Qualifying single source drug.—

“(1) IN GENERAL.—For purposes of this part, the term ‘qualifying single source drug’ means, with respect to an initial price applicability year, subject to paragraphs (2) and (3), a covered part D drug (as defined in section 1860D–2(e)) that is described in any of the following or a drug or biological product for which payment may be made under part B of title XVIII that is described in any of the following:

“(A) DRUG PRODUCTS.—A drug—

“(i) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval;

“(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

“(iii) that is not the listed drug for any drug that is approved and marketed under section 505(j) of such Act.

“(B) BIOLOGICAL PRODUCTS.—A biological product—

“(i) that is licensed under section 351(a) of the Public Health Service Act and is marketed under section 351 of such Act;

“(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

“(iii) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of such Act.

“(2) TREATMENT OF AUTHORIZED GENERIC DRUGS.—

“(A) IN GENERAL.—In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 505(j) of the Federal Food, Drug, and Cosmetic Act) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

“(B) AUTHORIZED GENERIC DRUG DEFINED.—For purposes of this paragraph, the term ‘authorized generic drug’ means—

“(i) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act); and

“(ii) in the case of a biological product, a product that—

“(I) has been licensed under section 351(a) of such Act; and

“(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

“(3) EXCLUSIONS.—In this part, the term ‘qualifying single source drug’ does not include any of the following:

“(A) CERTAIN ORPHAN DRUGS.—A drug that is designated as a drug for only one rare disease or condition under section 526 of the Federal Food, Drug, and Cosmetic

Act and for which the only approved indication (or indications) is for such disease or condition.

“(B) LOW SPEND MEDICARE DRUGS.—A drug or biological product with respect to which the total expenditures under parts B and D of title XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

“(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

“(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

“(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

“(C) PLASMA-DERIVED PRODUCTS.—A biological product that is derived from human whole blood or plasma.

“SEC. 1193. Manufacturer agreements.

“(a) In general.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

“(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manufacturer in order for the manufacturer to provide access to such price—

“(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(2) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

“(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

“(2) the Secretary and the manufacturer shall, in accordance with section 1194, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

“(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(2) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

“(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

“(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

“(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(2), at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

“(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

“(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f)) with respect to such drug—

“(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the drug for the applicable year or period; and

“(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

“(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

“(b) Agreement in effect until drug is no longer a selected drug.—An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1192(c).

“(c) Confidentiality of information.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

“(d) Nonduplication with 340B ceiling price.—Under an agreement entered into under this section, the manufacturer of a selected drug—

“(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

“(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

“SEC. 1194. Negotiation and renegotiation process.

“(a) In general.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the period for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer—

“(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

“(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1193(a)(2) if such drug is a renegotiation-eligible drug under such subsection.

“(b) Negotiation process requirements.—

“(1) METHODOLOGY AND PROCESS.—The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

“(2) SPECIFIC ELEMENTS OF NEGOTIATION PROCESS.—As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

“(A) SUBMISSION OF INFORMATION.—Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1193(a)(4), the information described in such section.

“(B) INITIAL OFFER BY SECRETARY.—Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary’s proposal for the maximum fair price of the drug and a concise justification based on the factors described in section 1194(e) that were used in developing such offer.

“(C) RESPONSE TO INITIAL OFFER.—

“(i) IN GENERAL.—Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

“(ii) COUNTEROFFER REQUIREMENTS.—If a manufacturer proposes a counteroffer, such counteroffer—

“(I) shall be in writing; and

“(II) shall be justified based on the factors described in subsection (e).

“(D) RESPONSE TO COUNTEROFFER.—After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

“(E) DEADLINE.—All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

“(F) LIMITATIONS ON OFFER AMOUNT.—In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug,

and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

“(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

“(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

“(c) Ceiling for maximum fair price.—

“(1) GENERAL CEILING.—

“(A) IN GENERAL.—The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

“(B) SUBPARAGRAPH (B) AMOUNT.—An amount equal to the following:

“(i) COVERED PART D DRUG.—In the case of a covered part D drug (as defined in section 1860D–2(e)), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA–PD plan (as determined under paragraph (2)).

“(ii) PART B DRUG OR BIOLOGICAL.—In the case of a drug or biological product for which payment may be made under part B of title XVIII, the payment amount under section 1847A(b)(4) for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

“(C) SUBPARAGRAPH (C) AMOUNT.—An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

“(i) INITIAL PRICE APPLICABILITY YEAR 2026.—In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

“(ii) INITIAL PRICE APPLICABILITY YEAR 2027 AND SUBSEQUENT YEARS.—In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

“(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

“(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

“(2) PLAN SPECIFIC ENROLLMENT WEIGHTED AMOUNT.—For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

“(A) the negotiated price of the drug under such plan under part D of title XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

“(B) a fraction—

“(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

“(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA–PD plan in such year.

“(3) APPLICABLE PERCENT DESCRIBED.—For purposes of this subsection, the applicable percent described in this paragraph is the following:

“(A) SHORT-MONOPOLY DRUGS AND VACCINES.—With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

“(B) EXTENDED-MONOPOLY DRUGS.—With respect to an extended-monopoly drug, 65 percent.

“(C) LONG-MONOPOLY DRUGS.—With respect to a long-monopoly drug, 40 percent.

“(4) EXTENDED-MONOPOLY DRUG DEFINED.—

“(A) IN GENERAL.—In this part, subject to subparagraph (B), the term ‘extended-monopoly drug’ means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic

Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

“(B) EXCLUSIONS.—The term ‘extended-monopoly drug’ shall not include any of the following:

“(i) A vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

“(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

“(C) CLARIFICATION.—Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the selected drug meets the definition of a long-monopoly drug.

“(5) LONG-MONOPOLY DRUG DEFINED.—

“(A) IN GENERAL.—In this part, subject to subparagraph (B), the term ‘long-monopoly drug’ means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

“(B) EXCLUSION.—The term ‘long-monopoly drug’ shall not include a vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

“(6) AVERAGE NON-FEDERAL AVERAGE MANUFACTURER PRICE.—In this part, the term ‘average non-Federal average manufacturer price’ means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the 4 calendar quarters of the year involved.

“(d) Temporary floor for small biotech drugs.—In the case of a selected drug that is a qualifying single source drug described in section 1192(d)(2) and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

“(e) Factors.—For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

“(1) MANUFACTURER-SPECIFIC DATA.—The following data, with respect to such selected drug, as submitted by the manufacturer:

“(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

“(B) Current unit costs of production and distribution of the drug.

“(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

“(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug.

“(E) Market data and revenue and sales volume data for the drug in the United States.

“(2) EVIDENCE ABOUT ALTERNATIVE TREATMENTS.—The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

“(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

“(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

“(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

“(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

“(f) Renegotiation process.—

“(1) IN GENERAL.—In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

“(2) RENEGOTIATION-ELIGIBLE DRUG DEFINED.—In this section, the term ‘renegotiation-eligible drug’ means a selected drug that is any of the following:

“(A) ADDITION OF NEW INDICATION.—A selected drug for which a new indication is added to the drug.

“(B) CHANGE OF STATUS TO AN EXTENDED-MONOPOLY DRUG.—A selected drug that—

“(i) is not an extended-monopoly or a long-monopoly drug; and

“(ii) for which there is a change in status to that of an extended-monopoly drug.

“(C) CHANGE OF STATUS TO A LONG-MONOPOLY DRUG.—A selected drug that—

“(i) is not a long-monopoly drug; and

“(ii) for which there is a change in status to that of a long-monopoly drug.

“(D) MATERIAL CHANGES.—A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

“(3) SELECTION OF DRUGS FOR RENEGOTIATION.—For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

“(A) ALL EXTENDED-MONOPOLY NEGOTIATION-ELIGIBLE DRUGS.—The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

“(B) ALL LONG-MONOPOLY NEGOTIATION-ELIGIBLE DRUGS.—The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

“(C) REMAINING DRUGS.—Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

“(4) RENEGOTIATION PROCESS.—

“(A) IN GENERAL.—The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

“(B) CONSISTENT WITH NEGOTIATION PROCESS.—The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

“(5) CLARIFICATION.—A renegotiation-eligible drug for which the Secretary makes a determination described in section 1192(c)(1) before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

“(g) Clarification.—The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1) shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph (A) or (B), as applicable.

“SEC. 1195. Publication of maximum fair prices.

“(a) In general.—With respect to an initial price applicability year and a selected drug with respect to such year—

“(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

“(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1193(c), the explanation for the maximum fair price with respect to the factors as applied under section 1194(e) for such drug described in paragraph (1).

“(b) Updates.—

“(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1193, not later than November 30 of the year that is 2 years prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—

“(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

“(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

“(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

“SEC. 1196. Administrative duties and compliance monitoring.

“(a) Administrative duties.—For purposes of section 1191(a)(4), the administrative duties described in this section are the following:

“(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

“(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

“(B) any other discounts.

“(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

“(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

“(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title; and

“(B) maximum fair price eligible individuals who are enrolled under part B of such title, including who are enrolled in an MA plan under part C of such title.

“(4) The establishment of a negotiation process and renegotiation process in accordance with section 1194.

“(5) The establishment of a process for manufacturers to submit information described in section 1194(b)(2)(A).

“(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

“(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1860D-14A and the date on which any subsequent agreement under such program is entered into;

“(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1860D-14C and the date on which any subsequent agreement under such program is entered into; and

“(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1927(b) and the date on which any subsequent rebate agreement described in such section is entered into.

“(7) The establishment of procedures for purposes of applying section 1192(d)(2)(B).

“(b) Compliance monitoring.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1193 and establish a mechanism through which violations of such terms shall be reported.

“SEC. 1197. Civil monetary penalties.

“(a) Violations relating to offering of maximum fair price.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

“(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(2) and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

“(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

“(b) Violations of certain terms of agreement.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement

imposed pursuant to section 1193(a)(5), including the requirement to submit information pursuant to section 1193(a)(4), shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

“(c) False information.—Any manufacturer that knowingly provides false information pursuant to section 1196(a)(7) shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

“(d) Application.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“SEC. 1198. Limitation on administrative and judicial review.

“There shall be no administrative or judicial review of any of the following:

“(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1191(c)(6).

“(2) The selection of drugs under section 1192(b), the determination of negotiation-eligible drugs under section 1192(d), and the determination of qualifying single source drugs under section 1192(e).

“(3) The determination of a maximum fair price under subsection (b) or (f) of section 1194.

“(4) The determination of renegotiation-eligible drugs under section 1194(f)(2) and the selection of renegotiation-eligible drugs under section 1194(f)(3).”.

(b) Application of maximum fair prices and conforming amendments.—

(1) UNDER MEDICARE.—

(A) APPLICATION TO PAYMENTS UNDER PART B.—Section 1847A(b)(1)(B) of the Social Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is amended by inserting “or in the case of such a drug or biological product that is a selected drug (as referred to in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), 106 percent of the maximum fair price (as defined in section 1191(c)(3)) applicable for such drug and a year during such period” after “paragraph (4)”.

(B) APPLICATION UNDER MA OF COST-SHARING FOR PART B DRUGS BASED OFF OF NEGOTIATED PRICE.—Section 1852(a)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)(B)(iv)) is amended—

(i) by redesignating subclause (VII) as subclause (VIII); and

(ii) by inserting after subclause (VI) the following subclause:

“(VII) A drug or biological product that is a selected drug (as referred to in section 1192(c)).”.

(C) EXCEPTION TO PART D NON-INTERFERENCE.—Section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)) is amended—

(i) in paragraph (1), by striking “and” at the end;

(ii) in paragraph (2), by striking “or institute a price structure for the reimbursement of covered part D drugs.” and inserting “, except as provided under section 1860D–4(b)(3)(I); and”; and

(iii) by adding at the end the following new paragraph:

“(3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of title XI.”.

(D) APPLICATION AS NEGOTIATED PRICE UNDER PART D.—Section 1860D–2(d)(1) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)) is amended—

(i) in subparagraph (B), by inserting “, subject to subparagraph (D),” after “negotiated prices”; and

(ii) by adding at the end the following new subparagraph:

“(D) APPLICATION OF MAXIMUM FAIR PRICE FOR SELECTED DRUGS.—In applying this section, in the case of a covered part D drug that is a selected drug (as referred to in section 1192(c)), with respect to a price applicability period (as defined in section 1191(b)(2)), the negotiated prices used for payment (as described in this subsection) shall be no greater than the maximum fair price (as defined in section 1191(c)(3)) for such drug and for each year during such period plus any dispensing fees for such drug.”.

(E) COVERAGE OF SELECTED DRUGS.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended by adding at the end the following new subparagraph:

“(I) REQUIRED INCLUSION OF SELECTED DRUGS.—

“(i) IN GENERAL.—For 2026 and each subsequent year, the PDP sponsor offering a prescription drug plan shall include each covered part D drug that is a selected drug under section 1192 for which a maximum fair price (as defined in section 1191(c)(3)) is in effect with respect to the year.

“(ii) CLARIFICATION.—Nothing in clause (i) shall be construed as prohibiting a PDP sponsor from removing such a selected drug from a formulary if such removal would be permitted under section 423.120(b)(5)(iv) of title 42, Code of Federal Regulations (or any successor regulation).”.

(F) INFORMATION FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS REQUIRED.—

(i) PRESCRIPTION DRUG PLANS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

“(8) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary for purposes of carrying out section 1194.”.

(ii) MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

“(E) PROVISION OF INFORMATION RELATED TO MAXIMUM FAIR PRICES.—Section 1860D–12(b)(8).”.

(G) CONDITIONS FOR COVERAGE.—

(i) MEDICARE PART D.—Section 1860D–43(c) of the Social Security Act (42 U.S.C. 1395w–153(c)) is amended—

(I) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively;

(II) by striking “agreements.—Subsection” and inserting the following: “agreements.—

“(1) IN GENERAL.—Subject to paragraph (2), subsection”; and

(III) by adding at the end the following new paragraph:

“(2) EXCEPTION.—Paragraph (1)(A) shall not apply to a covered part D drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.”.

(ii) MEDICAID AND MEDICARE PART B.—Section 1927(a)(3) of the Social Security Act (42 U.S.C. 1396r–8(a)(3)) is amended by adding at the end the following new sentence: “The preceding sentence shall not apply to a single source drug or innovator multiple source drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal Revenue Code of 1986 with respect to the manufacturer.”.

(H) DISCLOSURE OF INFORMATION UNDER MEDICARE PART D.—

(i) CONTRACT REQUIREMENTS.—Section 1860D–12(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1395w–112(b)(3)(D)(i)) is amended by inserting “, or carrying out part E of title XI” after “appropriate)”.

(ii) SUBSIDIES.—Section 1860D–15(f)(2)(A)(i) of the Social Security Act (42 U.S.C. 1395w–115(f)(2)(A)(i)) is amended by inserting “or part E of title XI” after “this section”.

(2) DRUG PRICE NEGOTIATION PROGRAM PRICES INCLUDED IN BEST PRICE.—Section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)) is amended—

(A) in clause (i)(VI), by striking “any prices charged” and inserting “subject to clause (ii)(V), any prices charged”; and

(B) in clause (ii)—

(i) in subclause (III), by striking “; and” at the end;

(ii) in subclause (IV), by striking the period at the end and inserting “; and”; and

(iii) by adding at the end the following new subclause:

“(V) in the case of a rebate period and a covered outpatient drug that is a selected drug (as referred to in section 1192(c)) during such rebate period, shall be inclusive of the maximum fair price (as defined in section 1191(c)(3)) for such drug with respect to such period.”.

(3) MAXIMUM FAIR PRICES EXCLUDED FROM AVERAGE MANUFACTURER PRICE.—Section 1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)(B)(i)) is amended—

(A) in subclause (IV) by striking “; and” at the end;

(B) in subclause (V) by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subclause:

“(VI) any reduction in price paid during the rebate period to the manufacturer for a drug by reason of application of part E of title XI.”.

(c) Implementation for 2026 through 2028.—The Secretary of Health and Human Services shall implement this section, including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.

SEC. 11002. Special rule to delay selection and negotiation of biologics for biosimilar market entry.

(a) In general.—Part E of title XI of the Social Security Act, as added by section 11001, is amended—

(1) in section 1192—

(A) in subsection (a), in the flush matter following paragraph (4), by inserting “and subsection (b)(3)” after “the previous sentence”;

(B) in subsection (b)—

(i) in paragraph (1), by adding at the end the following new subparagraph:

“(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under

subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).”; and

(ii) by adding at the end the following new paragraph:

“(3) INCLUSION OF DELAYED BIOLOGICAL PRODUCTS.—Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).”; and

(C) by adding at the end the following new subsection:

“(f) Special rule To delay selection and negotiation of biologics for biosimilar market entry.—

“(1) APPLICATION.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1194(c)(4)) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2) shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 351(k) of the Public Health Service Act before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year.

“(B) REQUEST REQUIRED.—

“(i) IN GENERAL.—The Secretary shall not provide for a delay under—

“(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

“(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in subsection (a) would have been included as a selected drug on such list but for paragraph (2)(A).

“(ii) INFORMATION AND DOCUMENTS.—

“(I) IN GENERAL.—A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

“(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and

“(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

“(II) ADDITIONAL INFORMATION AND DOCUMENTS.—After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

“(III) ITEMS DESCRIBED.—The items described in this clause are the following:

“(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 351(k).

“(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

“(C) AGGREGATION RULE.—

“(i) IN GENERAL.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

“(ii) PARTNERSHIP DEFINED.—In clause (i), the term ‘partnership’ means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

“(2) RULES DESCRIBED.—The rules described in this paragraph are the following:

“(A) DELAYED SELECTION AND NEGOTIATION FOR 1 YEAR.—If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of

the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

“(B) IF NOT LICENSED AND MARKETED DURING THE INITIAL DELAY.—

“(i) IN GENERAL.—If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 351(k) of the Public Health Service Act, the Secretary shall, at the request of such manufacturer—

“(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be licensed and marketed under such section 351(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

“(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

“(ii) SELECTION AND NEGOTIATION.—If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

“(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

“(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

“(iii) SECOND 1-YEAR DELAY.—If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause (i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

“(C) IF NOT LICENSED AND MARKETED DURING THE YEAR TWO DELAY.—If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

“(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

“(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

“(D) LIMITATIONS ON DELAYS.—

“(i) LIMITED TO 2 YEARS.—In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

“(ii) EXCLUSION OF BIOLOGICAL PRODUCTS THAT TRANSITIONED TO A LONG-MONOPOLY DRUG DURING THE DELAY.—In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1194(c)(5)) if such biological product had been a selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

“(iii) EXCLUSION OF BIOLOGICAL PRODUCTS IF MORE THAN 1 YEAR SINCE LICENSURE.—In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the

biosimilar biological product has been licensed under section 351(k) of the Public Health Service Act and marketing has not commenced for such biosimilar biological product.

“(iv) CERTAIN MANUFACTURERS OF BIOSIMILAR BIOLOGICAL PRODUCTS EXCLUDED.—In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

“(I) is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or

“(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

“(aa) requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B); or

“(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

“(3) HIGH LIKELIHOOD.—For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

“(A) an application for licensure under section 351(k) of the Public Health Service Act for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

“(B) information from items described in sub clauses (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

“(4) REBATE.—

“(A) IN GENERAL.—For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and entered into an agreement under section 1193 with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

“(B) AMOUNT.—Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

“(i) in the case of a biological product that is a covered part D drug (as defined in section 1860D–2(e)), that is the sum of the products of—

“(I) 75 percent of the amount by which—

“(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1927 (or, if not reported by such manufacturer under section 1927, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1193(a)) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

“(bb) in the initial price applicability year that would have applied but for a delay under—

“(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

“(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1195(b)(1)(A); and

“(II) the number of units dispensed under part D of title XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

“(ii) in the case of a biological product for which payment may be made under part B of title XVIII, that is the sum of the products of—

“(I) 80 percent of the amount by which—

“(aa) the payment amount for such biological product under section 1847A(b), with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

“(bb) in the initial price applicability year that would have applied but for a delay under—

“(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

“(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1195(b)(1)(A); and

“(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

“(C) SPECIAL RULE FOR DELAYED BIOLOGICAL PRODUCTS THAT ARE LONG-MONOPOLY DRUGS.—

“(i) IN GENERAL.—In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-

monopoly drug (as defined in section 1194(c)(5)) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause (ii) shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

“(ii) AMOUNT DESCRIBED.—The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

“(D) REBATE DEPOSITS.—Amounts paid as rebates under this paragraph shall be deposited into—

“(i) in the case payment is made for such biological product under part B of title XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1841; and

“(ii) in the case such biological product is a covered part D drug (as defined in section 1860D–2(e)), the Medicare Prescription Drug Account under section 1860D–16 in such Trust Fund.

“(5) DEFINITIONS OF BIOSIMILAR BIOLOGICAL PRODUCT.—In this subsection, the term ‘biosimilar biological product’ has the meaning given such term in section 1847A(c)(6).”;

(2) in section 1193(a)(4)—

(A) in the matter preceding subparagraph (A), by inserting “, and for section 1192(f),” after “section 1194(f))”;

(B) in subparagraph (A), by striking “and” at the end;

(C) by adding at the end the following new subparagraph:

“(C) information that the Secretary requires to carry out section 1192(f), including rebates under paragraph (4) of such section; and”;

(3) in section 1196(a)(7), by striking “section 1192(d)(2)(B)” and inserting “subsections (d)(2)(B) and (f)(1)(C) of section 1192”;

(4) in section 1197—

(A) by redesignating subsections (b), (c), and (d) as subsections (c), (d), and (e), respectively; and

(B) by inserting after subsection (a) the following new subsection:

“(b) Violations relating to providing rebates.—Any manufacturer that fails to comply with the rebate requirements under section 1192(f)(4) shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.”; and

(5) in section 1198(b)(2), by inserting “the application of section 1192(f),” after “section 1192(e)”.

(b) Conforming amendments for disclosure of certain information.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by striking “or to carry out section 1847B” and inserting “or to carry out section 1847B or section 1192(f), including rebates under paragraph (4) of such section”.

(c) Implementation for 2026 through 2028.—The Secretary of Health and Human Services shall implement this section, including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.

SEC. 11003. Excise tax imposed on drug manufacturers during noncompliance periods.

(a) In general.—Subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following new chapter:

“CHAPTER 50A—DESIGNATED DRUGS

“Sec. 5000D. Designated drugs during noncompliance periods.

“SEC. 5000D. Designated drugs during noncompliance periods.

“(a) In general.—There is hereby imposed on the sale by the manufacturer, producer, or importer of any designated drug during a day described in subsection (b) a tax in an amount such that the applicable percentage is equal to the ratio of—

“(1) such tax, divided by

“(2) the sum of such tax and the price for which so sold.

“(b) Noncompliance periods.—A day is described in this subsection with respect to a designated drug if it is a day during one of the following periods:

“(1) The period beginning on the March 1st (or, in the case of initial price applicability year 2026, the October 2nd) immediately following the date on which such drug is included on the list published under section 1192(a) of the Social Security Act and ending on the earlier of—

“(A) the first date on which the manufacturer of such designated drug has in place an agreement described in section 1193(a) of such Act with respect to such drug, or

“(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

“(2) The period beginning on the November 2nd immediately following the March 1st described in paragraph (1) (or, in the case of initial price applicability year 2026, the August 2nd immediately following the October 2nd described in such paragraph) and ending on the earlier of—

“(A) the first date on which the manufacturer of such designated drug and the Secretary of Health and Human Services have agreed to a maximum fair price under an agreement described in section 1193(a) of the Social Security Act, or

“(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

“(3) In the case of any designated drug which is a selected drug (as defined in section 1192(c) of the Social Security Act) that the Secretary of Health and Human Services has selected for renegotiation under section 1194(f) of such Act, the period beginning on the November 2nd of the year that begins 2 years prior to the first initial price applicability year of the price applicability period for which the maximum fair price established pursuant to such renegotiation applies and ending on the earlier of—

“(A) the first date on which the manufacturer of such designated drug has agreed to a renegotiated maximum fair price under such agreement, or

“(B) the date that the Secretary of Health and Human Services has made a determination described in section 1192(c)(1) of such Act with respect to such designated drug.

“(4) With respect to information that is required to be submitted to the Secretary of Health and Human Services under an agreement described in section 1193(a) of the Social Security Act, the period beginning on the date on which such Secretary certifies that such information is overdue and ending on the date that such information is so submitted.

“(c) Suspension of tax.—

“(1) IN GENERAL.—A day shall not be taken into account as a day during a period described in subsection (b) if such day is also a day during the period—

“(A) beginning on the first date on which—

“(i) the notice of terminations of all applicable agreements of the manufacturer have been received by the Secretary of Health and Human Services, and

“(ii) none of the drugs of the manufacturer of the designated drug are covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act, and

“(B) ending on the last day of February following the earlier of—

“(i) the first day after the date described in subparagraph (A) on which the manufacturer enters into any subsequent applicable agreement, or

“(ii) the first date any drug of the manufacturer of the designated drug is covered by an agreement under section 1860D-14A or 1860D-14C of the Social Security Act.

“(2) APPLICABLE AGREEMENT.—For purposes of this subsection, the term ‘applicable agreement’ means the following:

“(A) An agreement under—

“(i) the Medicare coverage gap discount program under section 1860D-14A of the Social Security Act, or

“(ii) the manufacturer discount program under section 1860D-14C of such Act.

“(B) A rebate agreement described in section 1927(b) of such Act.

“(d) Applicable percentage.—For purposes of this section, the term ‘applicable percentage’ means—

“(1) in the case of sales of a designated drug during the first 90 days described in subsection (b) with respect to such drug, 65 percent,

“(2) in the case of sales of such drug during the 91st day through the 180th day described in subsection (b) with respect to such drug, 75 percent,

“(3) in the case of sales of such drug during the 181st day through the 270th day described in subsection (b) with respect to such drug, 85 percent, and

“(4) in the case of sales of such drug during any subsequent day, 95 percent.

“(e) Definitions.—For purposes of this section—

“(1) DESIGNATED DRUG.—The term ‘designated drug’ means any negotiation-eligible drug (as defined in section 1192(d) of the Social Security Act) included on the list published under section 1192(a) of such Act which is manufactured or produced in the United States or entered into the United States for consumption, use, or warehousing.

“(2) UNITED STATES.—The term ‘United States’ has the meaning given such term by section 4612(a)(4).

“(3) OTHER TERMS.—The terms ‘initial price applicability year’, ‘price applicability period’, and ‘maximum fair price’ have the meaning given such terms in section 1191 of the Social Security Act.

“(f) Special rules.—

“(1) COORDINATION WITH RULES FOR POSSESSIONS OF THE UNITED STATES.—Rules similar to the rules of paragraphs (2) and (4) of section 4132(c) shall apply for purposes of this section.

“(2) ANTI-ABUSE RULE.—In the case of a sale which was timed for the purpose of avoiding the tax imposed by this section, the Secretary may treat such sale as occurring during a day described in subsection (b).

“(g) Exports.—Rules similar to the rules of section 4662(e) (other than section 4662(e)(2)(A)(ii)(II)) shall apply for purposes of this chapter.

“(h) Regulations.—The Secretary shall prescribe such regulations and other guidance as may be necessary to carry out this section.”.

(b) No deduction for excise tax payments.—Section 275(a)(6) of the Internal Revenue Code of 1986 is amended by inserting “50A,” after “46,”.

(c) Clerical amendment.—The table of chapters for subtitle D of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

“CHAPTER 50A—DESIGNATED DRUGS”.

(d) Effective date.—The amendments made by this section shall apply to sales after the date of the enactment of this Act.

SEC. 11004. Funding.

In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $3,000,000,000 for fiscal year 2022, to remain available until expended, to carry out the provisions of, including the amendments made by, this part.

PART 2—Prescription Drug Inflation Rebates

SEC. 11101. Medicare part B rebate by manufacturers.

(a) In general.—Section 1847A of the Social Security Act (42 U.S.C. 1395w–3a) is amended by redesignating subsection (i) as subsection (j) and by inserting after subsection (h) the following subsection:

“(i) Rebate by manufacturers for single source drugs and biologicals with prices increasing faster than inflation.—

“(1) REQUIREMENTS.—

“(A) SECRETARIAL PROVISION OF INFORMATION.—Not later than 6 months after the end of each calendar quarter beginning on or after January 1, 2023, the Secretary shall, for each part B rebatable drug, report to each manufacturer of such part B rebatable drug the following for such calendar quarter:

“(i) Information on the total number of units of the billing and payment code described in subparagraph (A)(i) of paragraph (3) with respect to such drug and calendar quarter.

“(ii) Information on the amount (if any) of the excess average sales price increase described in subparagraph (A)(ii) of such paragraph for such drug and calendar quarter.

“(iii) The rebate amount specified under such paragraph for such part B rebatable drug and calendar quarter.

“(B) MANUFACTURER REQUIREMENT.—For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a part B rebatable drug shall, for such drug, not later than 30 days after the date of receipt from the Secretary of the information described in subparagraph (A) for such calendar quarter, provide to the Secretary a rebate that is equal to the amount specified in paragraph (3) for such drug for such calendar quarter.

“(C) TRANSITION RULE FOR REPORTING.—The Secretary may, for each part B rebatable drug, delay the timeframe for reporting the information described in subparagraph (A) for calendar quarters beginning in 2023 and 2024 until not later than September 30, 2025.

“(2) PART B REBATABLE DRUG DEFINED.—

“(A) IN GENERAL.—In this subsection, the term ‘part B rebatable drug’ means a single source drug or biological (as defined in subparagraph (D) of subsection (c)(6)), including a biosimilar biological product (as defined in subparagraph (H) of such subsection) but excluding a qualifying biosimilar biological product (as defined in subsection (b)(8)(B)(iii)), for which payment is made under this part, except such term shall not include such a drug or biological—

“(i) if, as determined by the Secretary, the average total allowed charges for such drug or biological under this part for a year per individual that uses such a drug or biological are less than, subject to subparagraph (B), $100; or

“(ii) that is a vaccine described in subparagraph (A) or (B) of section 1861(s)(10).

“(B) INCREASE.—The dollar amount applied under subparagraph (A)(i)—

“(i) for 2024, shall be the dollar amount specified under such subparagraph for 2023, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

“(ii) for a subsequent year, shall be the dollar amount specified in this clause (or clause (i)) for the previous year (without application of subparagraph (C)), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year.

“(C) ROUNDING.—Any dollar amount determined under subparagraph (B) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

“(3) REBATE AMOUNT.—

“(A) IN GENERAL.—For purposes of paragraph (1), the amount specified in this paragraph for a part B rebatable drug assigned to a billing and payment code for a calendar quarter is, subject to subparagraphs (B) and (G) and paragraph (4), the estimated amount equal to the product of—

“(i) the total number of units determined under subparagraph (B) for the billing and payment code of such drug; and

“(ii) the amount (if any) by which—

“(I) the amount equal to—

“(aa) in the case of a part B rebatable drug described in paragraph (1)(B) of subsection (b), 106 percent of the amount determined under paragraph (4) of such section for such drug during the calendar quarter; or

“(bb) in the case of a part B rebatable drug described in paragraph (1)(C) of such subsection, the payment amount under such paragraph for such drug during the calendar quarter; exceeds

“(II) the inflation-adjusted payment amount determined under subparagraph (C) for such part B rebatable drug during the calendar quarter.

“(B) TOTAL NUMBER OF UNITS.—For purposes of subparagraph (A)(i), the total number of units for the billing and payment code with respect to a part B rebatable drug furnished during a calendar quarter described in subparagraph (A) is equal to—

“(i) the number of units for the billing and payment code of such drug furnished during such calendar quarter, minus

“(ii) the number of units for such billing and payment code of such drug furnished during such calendar quarter—

“(I) with respect to which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act or a rebate under section 1927; or

“(II) that are packaged into the payment amount for an item or service and are not separately payable.

“(C) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this subparagraph for a part B rebatable drug for a calendar quarter is—

“(i) the payment amount for the billing and payment code for such drug in the payment amount benchmark quarter (as defined in subparagraph (D)); increased by

“(ii) the percentage by which the rebate period CPI–U (as defined in subparagraph (F)) for the calendar quarter exceeds the benchmark period CPI–U (as defined in subparagraph (E)).

“(D) PAYMENT AMOUNT BENCHMARK QUARTER.—The term ‘payment amount benchmark quarter’ means the calendar quarter beginning July 1, 2021.

“(E) BENCHMARK PERIOD CPI–U.—The term ‘benchmark period CPI–U’ means the consumer price index for all urban consumers (United States city average) for January 2021.

“(F) REBATE PERIOD CPI–U.—The term ‘rebate period CPI–U’ means, with respect to a calendar quarter described in subparagraph (C), the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for the first month of the calendar quarter that is two calendar quarters prior to such described calendar quarter.

“(G) REDUCTION OR WAIVER FOR SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part B rebatable drug and a calendar quarter—

“(i) in the case of a part B rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the calendar quarter; or

“(ii) in the case of a biosimilar biological product, when the Secretary determines there is a severe supply chain disruption during the calendar quarter, such as that caused by a natural disaster or other unique or unexpected event.

“(4) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

“(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020, clause (i) of paragraph (3)(C) shall be applied as if the term ‘payment amount benchmark quarter’ were defined under paragraph (3)(D) as the third full calendar quarter after the day on which the drug was first marketed and clause (ii) of paragraph (3)(C) shall be applied as if the term ‘benchmark period CPI–U’ were defined under paragraph (3)(E) as if the reference to ‘January 2021’ under such paragraph were a reference to ‘the first month of the first full calendar quarter after the day on which the drug was first marketed’.

“(B) TIMELINE FOR PROVISION OF REBATES FOR SUBSEQUENTLY APPROVED DRUGS.—In the case of a part B rebatable drug first approved or licensed by the Food and Drug Administration after December 1, 2020, paragraph (1)(B) shall be applied as if the reference to ‘January 1, 2023’ under such paragraph were a reference to ‘the later of the 6th full calendar quarter after the day on which the drug was first marketed or January 1, 2023’.

“(C) SELECTED DRUGS.—In the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)) with respect to a price applicability period (as defined in section 1191(b)(2)), in the case such drug is no longer considered to be a selected drug under section 1192(c), for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect to such drug, clause (i) of paragraph (3)(C) shall be applied as if the term ‘payment amount benchmark quarter’ were defined under paragraph (3)(D) as the calendar quarter beginning January 1 of the last year during such price applicability period with respect to such selected drug and clause (ii) of paragraph (3)(C) shall be applied as if the term ‘benchmark period CPI–U’ were defined under paragraph (3)(E) as if the reference to ‘January 2021’ under such paragraph were a reference to ‘the July of the year preceding such last year’.

“(5) APPLICATION TO BENEFICIARY COINSURANCE.—In the case of a part B rebatable drug furnished on or after April 1, 2023, if the payment amount described in paragraph (3)(A)(ii)(I) (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c)), the payment amount described in subsection (b)(1)(B) for such drug) for a calendar quarter exceeds the inflation adjusted payment for such quarter—

“(A) in computing the amount of any coinsurance applicable under this part to an individual to whom such drug is furnished, the computation of such coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount determined under paragraph (3)(C) for such part B rebatable drug; and

“(B) the amount of such coinsurance for such calendar quarter, as computed under subparagraph (A), shall be applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply under subparagraphs (B) or (C) of subsection (b)(1).

“(6) REBATE DEPOSITS.—Amounts paid as rebates under paragraph (1)(B) shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

“(7) CIVIL MONEY PENALTY.—If a manufacturer of a part B rebatable drug has failed to comply with the requirements under paragraph (1)(B) for such drug for a calendar quarter, the manufacturer shall be subject to, in accordance with a process established by the Secretary pursuant to regulations, a civil money penalty in an amount equal to at

least 125 percent of the amount specified in paragraph (3) for such drug for such calendar quarter. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(8) LIMITATION ON ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review of any of the following:

“(A) The determination of units under this subsection.

“(B) The determination of whether a drug is a part B rebatable drug under this subsection.

“(C) The calculation of the rebate amount under this subsection.

“(D) The computation of coinsurance under paragraph (5) of this subsection.

“(E) The computation of amounts paid under section 1833(a)(1)(EE).”.

(b) Amounts payable; cost-Sharing.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) in subsection (a)(1)—

(A) in subparagraph (G), by inserting “, subject to subsection (i)(9),” after “the amounts paid”;

(B) in subparagraph (S), by striking “with respect to” and inserting “subject to subparagraph (EE), with respect to”;

(C) by striking “and (DD)” and inserting “(DD)”; and

(D) by inserting before the semicolon at the end the following: “, and (EE) with respect to a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) furnished on or after April 1, 2023, for which the payment amount for a calendar quarter under paragraph (3)(A)(ii)(I) of such section (or, in the case of a part B rebatable drug that is a selected drug (as defined in section 1192(c) for which, the payment amount described in section 1847A(b)(1)(B)) for such drug for such quarter exceeds the inflation-adjusted payment under paragraph (3)(A)(ii)(II) of such section for such quarter, the amounts paid shall be equal to the percent of the payment amount under paragraph (3)(A)(ii)(I) of such section or section 1847A(b)(1)(B), as applicable, that equals the difference between (i) 100 percent, and (ii) the percent applied under section 1847A(i)(5)(B)”;

(2) in subsection (i), by adding at the end the following new paragraph:

“(9) In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i)) for which payment under this subsection is not packaged into a payment for a service furnished on or after April 1, 2023, under the revised payment system under this

subsection, in lieu of calculation of coinsurance and the amount of payment otherwise applicable under this subsection, the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection."; and

(3) in subsection (t)(8), by adding at the end the following new subparagraph:

"(F) PART B REBATABLE DRUGS.—In the case of a part B rebatable drug (as defined in paragraph (2) of section 1847A(i), except if such drug does not have a copayment amount as a result of application of subparagraph (E)) for which payment under this part is not packaged into a payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under this subsection is the same as the amount for a calendar quarter under paragraph (3)(A)(ii)(I) of section 1847A(i), under the system under this subsection, in lieu of calculation of the copayment amount and the amount of payment otherwise applicable under this subsection (other than the application of the limitation described in subparagraph (C)), the provisions of section 1847A(i)(5) and paragraph (1)(EE) of subsection (a), shall, as determined appropriate by the Secretary, apply under this subsection in the same manner as such provisions of section 1847A(i)(5) and subsection (a) apply under such section and subsection.".

(c) Conforming amendments.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended by inserting "subsection (i) or" before "section 1927".

(2) EXCLUDING PART B DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by inserting "or section 1847A(i)" after "this section".

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)) is amended by inserting "and the rebate" after "the payment amount".

(4) EXCLUDING PART B DRUG INFLATION REBATES FROM AVERAGE MANUFACTURER PRICE.—Section 1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)(B)(i)), as amended by section 11001(b)(3), is amended—

(A) in subclause (V), by striking "and" at the end;

(B) in subclause (VI), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new subclause:

"(VII) rebates paid by manufacturers under section 1847A(i); and".

(d) Funding.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $80,000,000 for fiscal year 2022, including $12,500,000 to carry out the provisions of, including the amendments made by, this section in fiscal year 2022, and $7,500,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2023 through 2031, to remain available until expended.

SEC. 11102. Medicare part D rebate by manufacturers.

(a) In general.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1395w–114a) the following new section:

“SEC. 1860D–14B. Manufacturer rebate for certain drugs with prices increasing faster than inflation.

“(a) Requirements.—

“(1) SECRETARIAL PROVISION OF INFORMATION.—Not later than 9 months after the end of each applicable period (as defined in subsection (g)(7)), subject to paragraph (3), the Secretary shall, for each part D rebatable drug, report to each manufacturer of such part D rebatable drug the following for such period:

“(A) The amount (if any) of the excess annual manufacturer price increase described in subsection (b)(1)(A)(ii) for each dosage form and strength with respect to such drug and period.

“(B) The rebate amount specified under subsection (b) for each dosage form and strength with respect to such drug and period.

“(2) MANUFACTURER REQUIREMENTS.—For each applicable period, the manufacturer of a part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in paragraph (1) for such period, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (b) for such dosage form and strength with respect to such drug for such period.

“(3) TRANSITION RULE FOR REPORTING.—The Secretary may, for each rebatable covered part D drug, delay the timeframe for reporting the information and rebate amount described in subparagraphs (A) and (B) of such paragraph for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

“(b) Rebate amount.—

“(1) IN GENERAL.—

“(A) CALCULATION.—For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable period is, subject to subparagraph (C), paragraph (5)(B), and paragraph (6), the estimated amount equal to the product of—

“(i) subject to subparagraph (B) of this paragraph, the total number of units of such dosage form and strength for each rebatable covered part D drug dispensed under this part during the applicable period; and

“(ii) the amount (if any) by which—

“(I) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the period; exceeds

“(II) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and strength with respect to such part D rebatable drug for the period.

“(B) EXCLUDED UNITS.—For purposes of subparagraph (A)(i), beginning with plan year 2026, the Secretary shall exclude from the total number of units for a dosage form and strength with respect to a part D rebatable drug, with respect to an applicable period, units of each dosage form and strength of such part D rebatable drug for which the manufacturer provides a discount under the program under section 340B of the Public Health Service Act.

“(C) REDUCTION OR WAIVER FOR SHORTAGES AND SEVERE SUPPLY CHAIN DISRUPTIONS.—The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part D rebatable drug and an applicable period—

“(i) in the case of a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act at any point during the applicable period;

“(ii) in the case of a generic part D rebatable drug (described in subsection (g)(1)(C)(ii)) or a biosimilar (defined as a biological product licensed under section 351(k) of the Public Health Service Act), when the Secretary determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and

“(iii) in the case of a generic Part D rebatable drug (as so described), if the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.

“(2) DETERMINATION OF ANNUAL MANUFACTURER PRICE.—The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable period, is the sum of the products of—

“(A) the average manufacturer price (as defined in subsection (g)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such period; and

“(B) the ratio of—

“(i) the total number of units of such dosage form and strength reported under section 1927 with respect to each such calendar quarter of such period; to

“(ii) the total number of units of such dosage form and strength reported under section 1927 with respect to such period, as determined by the Secretary.

“(3) DETERMINATION OF INFLATION-ADJUSTED PAYMENT AMOUNT.—The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D rebatable drug for an applicable period, subject to paragraph (5), is—

“(A) the benchmark period manufacturer price determined under paragraph (4) for such dosage form and strength with respect to such drug and period; increased by

“(B) the percentage by which the applicable period CPI–U (as defined in subsection (g)(5)) for the period exceeds the benchmark period CPI–U (as defined in subsection (g)(4)).

“(4) DETERMINATION OF BENCHMARK PERIOD MANUFACTURER PRICE.—The benchmark period manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable period, is the sum of the products of—

“(A) the average manufacturer price (as defined in subsection (g)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark period (as defined in subsection (g)(3)); and

“(B) the ratio of—

“(i) the total number of units reported under section 1927 of such dosage form and strength with respect to each such calendar quarter of such payment amount benchmark period; to

“(ii) the total number of units reported under section 1927 of such dosage form and strength with respect to such payment amount benchmark period.

“(5) SPECIAL TREATMENT OF CERTAIN DRUGS AND EXEMPTION.—

“(A) SUBSEQUENTLY APPROVED DRUGS.—In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after October 1, 2021, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term ‘payment amount benchmark period’ were defined under subsection (g)(3) as the first calendar

year beginning after the day on which the drug was first marketed and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (g)(4) as if the reference to 'January 2021' under such subsection were a reference to 'January of the first year beginning after the date on which the drug was first marketed'.

"(B) TREATMENT OF NEW FORMULATIONS.—

"(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the rebate amount under paragraph (1) and the inflation adjusted payment amount under paragraph (3) with respect to such part D rebatable drug and an applicable period, consistent with the formula applied under subsection (c)(2)(C) of section 1927 for determining a rebate obligation for a rebate period under such section.

"(ii) LINE EXTENSION DEFINED.—In this subparagraph, the term 'line extension' means, with respect to a part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

"(C) SELECTED DRUGS.—In the case of a part D rebatable drug that is a selected drug (as defined in section 1192(c)) with respect to a price applicability period (as defined in section 1191(b)(2)), in the case such drug is no longer considered to be a selected drug under section 1192(c), for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect to such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term 'payment amount benchmark period' were defined under subsection (g)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term 'benchmark period CPI–U' were defined under subsection (g)(4) as if the reference to 'January 2021' under such subsection were a reference to 'January of the last year beginning during such price applicability period with respect to such drug'.

"(6) RECONCILIATION IN CASE OF REVISED INFORMATION.—The Secretary shall provide for a method and process under which, in the case where a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan submits revisions to the number of units of a rebatable covered part D drug dispensed, the Secretary determines, pursuant to such revisions, adjustments, if any, to the calculation of the amount specified in this subsection for a dosage form and strength with respect to such part D rebatable drug and an applicable period and reconciles any overpayments or underpayments in amounts paid as rebates under this subsection. Any identified underpayment shall be rectified by the manufacturer not later than 30 days after the date of receipt from the Secretary of information on such underpayment.

“(c) Rebate deposits.—Amounts paid as rebates under subsection (b) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1841.

“(d) Information.—For purposes of carrying out this section, the Secretary shall use information submitted by—

“(1) manufacturers under section 1927(b)(3);

“(2) States under section 1927(b)(2)(A); and

“(3) PDP sponsors of prescription drug plans and MA organization offering MA–PD plans under this part.

“(e) Civil money penalty.—If a manufacturer of a part D rebatable drug has failed to comply with the requirement under subsection (a)(2) with respect to such drug for an applicable period, the manufacturer shall be subject to a civil money penalty in an amount equal to 125 percent of the amount specified in subsection (b) for such drug for such period. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(f) Limitation on administrative or judicial review.—There shall be no administrative or judicial review of any of the following:

“(1) The determination of units under this section.

“(2) The determination of whether a drug is a part D rebatable drug under this section.

“(3) The calculation of the rebate amount under this section.

“(g) Definitions.—In this section:

“(1) PART D REBATABLE DRUG.—

“(A) IN GENERAL.—Except as provided in subparagraph (B), the term ‘part D rebatable drug’ means, with respect to an applicable period, a drug or biological described in subparagraph (C) that is a covered part D drug (as such term is defined under section 1860D–2(e)).

“(B) EXCLUSION.—

“(i) IN GENERAL.—Such term shall, with respect to an applicable period, not include a drug or biological if the average annual total cost under this part for such period per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to clause (ii), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

“(ii) INCREASE.—The dollar amount applied under clause (i)—

“(I) for the applicable period beginning October 1, 2023, shall be the dollar amount specified under such clause for the applicable period beginning October 1, 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with October of 2023; and

“(II) for a subsequent applicable period, shall be the dollar amount specified in this clause for the previous applicable period, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with October of the previous period.

Any dollar amount specified under this clause that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

“(C) DRUG OR BIOLOGICAL DESCRIBED.—A drug or biological described in this subparagraph is a drug or biological that, as of the first day of the applicable period involved, is—

“(i) a drug approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act;

“(ii) a drug approved under an abbreviated new drug application under section 505(j) of the Federal Food, Drug, and Cosmetic Act, in the case where—

“(I) the reference listed drug approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, including any ‘authorized generic drug’ (as that term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act), is not being marketed, as identified in the Food and Drug Administration’s National Drug Code Directory;

“(II) there is no other drug approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act that is rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of ‘Approved Drug Products with Therapeutic Equivalence Evaluations’) and that is being marketed, as identified in the Food and Drug Administration’s National Drug Code Directory;

“(III) the manufacturer is not a ‘first applicant’ during the ‘180-day exclusivity period’, as those terms are defined in section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act; and

“(IV) the manufacturer is not a ‘first approved applicant’ for a competitive generic therapy, as that term is defined in section 505(j)(5)(B)(v) of the Federal Food, Drug, and Cosmetic Act; or

“(iii) a biological licensed under section 351 of the Public Health Service Act.

“(2) UNIT.—The term ‘unit’ means, with respect to a part D rebatable drug, the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug, as reported under section 1927.

“(3) PAYMENT AMOUNT BENCHMARK PERIOD.—The term ‘payment amount benchmark period’ means the period beginning January 1, 2021, and ending in the month immediately prior to October 1, 2021.

“(4) BENCHMARK PERIOD CPI–U.—The term ‘benchmark period CPI–U’ means the consumer price index for all urban consumers (United States city average) for January 2021.

“(5) APPLICABLE PERIOD CPI–U.—The term ‘applicable period CPI–U’ means, with respect to an applicable period, the consumer price index for all urban consumers (United States city average) for the first month of such applicable period.

“(6) AVERAGE MANUFACTURER PRICE.—The term ‘average manufacturer price’ has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1927(k)(1), with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1927.

“(7) APPLICABLE PERIOD.—The term ‘applicable period’ means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

“(h) Implementation for 2022, 2023, and 2024.—The Secretary shall implement this section for 2022, 2023, and 2024 by program instruction or other forms of program guidance.”.

(b) Conforming amendments.—

(1) TO PART B ASP CALCULATION.—Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)), as amended by section 11101(c)(1), is amended by striking “subsection (i) or section 1927” and inserting “subsection (i), section 1927, or section 1860D–14B”.

(2) EXCLUDING PART D DRUG INFLATION REBATE FROM BEST PRICE.—Section 1927(c)(1)(C)(ii)(I) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by section 11101(c)(2), is amended by striking “or section 1847A(i)” and inserting “, section 1847A(i), or section 1860D–14B”.

(3) COORDINATION WITH MEDICAID REBATE INFORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)(i)), as amended by sections 11002(b) and 11101(c)(3), is amended by striking “or section 1192(f), including rebates under paragraph (4) of such section” and inserting “, section 1192(f), including rebates under paragraph (4) of such section, or section 1860D–14B”.

(4) EXCLUDING PART D DRUG INFLATION REBATES FROM AVERAGE MANUFACTURER PRICE.—Section 1927(k)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(k)(1)(B)(i)), as amended by section 11001(b)(3) and section 11101(c)(4), is amended by adding at the end the following new subclause:

(A) in subclause (VI), by striking “and” at the end;

(B) in subclause (VII), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new subclause:

“(VIII) rebates paid by manufacturers under section 1860D–14B.”.

(c) Funding.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $80,000,000 for fiscal year 2022, including $12,500,000 to carry out the provisions of, including the amendments made by, this section in fiscal year 2022, and $7,500,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2023 through 2031, to remain available until expended.

PART 3—Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

SEC. 11201. Medicare part D benefit redesign.

(a) Benefit structure redesign.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting “for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year” after “paragraph (3)”;

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting “for a year preceding 2025, ” after “paragraph (4),”; and

(ii) in clause (ii)(III), by striking “and each subsequent year” and inserting “through 2024”; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2025, ” after “paragraph (4),”; and

(II) in subclause (I)(bb), by striking “a year after 2018” and inserting “each of years 2019 through 2024”; and

(ii) in clause (ii)(V), by striking “2019 and each subsequent year” and inserting “each of years 2019 through 2024”;

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting “for a year preceding 2025,” after “and (4),”; and

(B) in clause (ii), by striking “for a subsequent year” and inserting “for each of years 2007 through 2024”; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and moving the margin of each such redesignated item 2 ems to the right;

(II) in the matter preceding item (aa), as redesignated by subclause (I), by striking “is equal to the greater of—” and inserting “is equal to—

“(I) for a year preceding 2024, the greater of—”;

(III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting “; and”; and

(IV) by adding at the end the following:

“(II) for 2024 and each succeeding year, $0.”; and

(ii) in clause (ii)—

(I) by striking “clause (i)(I)” and inserting “clause (i)(I)(aa)”; and

(II) by adding at the end the following new sentence: “The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1860D–14(a)(1)(D)(iii).”;

(B) in subparagraph (B)—

(i) in clause (i)—

(I) in subclause (V), by striking “or” at the end;

(II) in subclause (VI)—

(aa) by striking “for a subsequent year” and inserting “for each of years 2021 through 2024”; and

(bb) by striking the period at the end and inserting a semicolon; and

(III) by adding at the end the following new subclauses:

“(VII) for 2025, is equal to $2,000; or

“(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.”; and

(ii) in clause (ii), by striking “clause (i)(II)” and inserting “clause (i)”;

(C) in subparagraph (C)—

(i) in clause (i), by striking “and for amounts” and inserting “and, for a year preceding 2025, for amounts”; and

(ii) in clause (iii)—

(I) by redesignating subclauses (I) through (IV) as items (aa) through (dd) and indenting appropriately;

(II) by striking “if such costs are borne or paid” and inserting “if such costs—

“(I) are borne or paid—”; and

(III) in item (dd), by striking the period at the end and inserting “; or”; and

(IV) by adding at the end the following new subclause:

“(II) for 2025 and subsequent years, are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage (as defined in subsection (a)(3)) or any payments by a manufacturer under the manufacturer discount program under section 1860D–14C.”; and

(D) in subparagraph (E), by striking “In applying” and inserting “For each of years 2011 through 2024, in applying”.

(b) Reinsurance payment amount.—Section 1860D–15(b) of the Social Security Act (42 U.S.C. 1395w–115(b)) is amended—

(1) in paragraph (1)—

(A) by striking “equal to 80 percent” and inserting “equal to—

“(A) for a year preceding 2025, 80 percent”;

(B) in subparagraph (A), as added by subparagraph (A), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(B) for 2025 and each subsequent year, the sum of—

“(i) with respect to applicable drugs (as defined in section 1860D–14C(g)(2)), an amount equal to 20 percent of such allowable reinsurance costs attributable to that portion of

gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B); and

“(ii) with respect to covered part D drugs that are not applicable drugs (as so defined), an amount equal to 40 percent of such allowable reinsurance costs attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B).”;

(2) in paragraph (2)—

(A) by striking “COSTS.—For purposes” and inserting “Costs.—

“(A) IN GENERAL.—Subject to subparagraph (B), for purposes”; and

(B) by adding at the end the following new subparagraph:

“(B) INCLUSION OF MANUFACTURER DISCOUNTS ON APPLICABLE DRUGS.—For purposes of applying subparagraph (A), the term ‘allowable reinsurance costs’ shall include the portion of the negotiated price (as defined in section 1860D–14C(g)(6)) of an applicable drug (as defined in section 1860D–14C(g)(2)) that was paid by a manufacturer under the manufacturer discount program under section 1860D–14C.”; and

(3) in paragraph (3)—

(A) in the first sentence, by striking “For purposes” and inserting “Subject to paragraph (2)(B), for purposes”; and

(B) in the second sentence, by inserting “(or, with respect to 2025 and subsequent years, in the case of an applicable drug, as defined in section 1860D–14C(g)(2), by a manufacturer)” after “by the individual or under the plan”.

(c) Manufacturer discount program.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 through 42 U.S.C. 1395w–153), as amended by section 11102, is amended by inserting after section 1860D–14B the following new sections:

“SEC. 1860D–14C. Manufacturer discount program.

“(a) Establishment.—The Secretary shall establish a manufacturer discount program (in this section referred to as the ‘program’). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c).

“(b) Terms of agreement.—

“(1) IN GENERAL.—

“(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries on or after January 1, 2025.

“(B) CLARIFICATION.—Nothing in this section shall be construed as affecting—

“(i) the application of a coinsurance of 25 percent of the negotiated price, as applied under paragraph (2)(A) of section 1860D–2(b), for costs described in such paragraph; or

“(ii) the application of the copayment amount described in paragraph (4)(A) of such section, with respect to costs described in such paragraph.

“(C) TIMING OF AGREEMENT.—

“(i) SPECIAL RULE FOR 2025.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2025, and ending on December 31, 2025, the manufacturer shall enter into such agreement not later than March 1, 2024.

“(ii) 2026 AND SUBSEQUENT YEARS.—In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2026 or a subsequent plan year, the manufacturer shall enter into such agreement not later than a calendar quarter or semi-annual deadline established by the Secretary.

“(2) PROVISION OF APPROPRIATE DATA.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

“(3) COMPLIANCE WITH REQUIREMENTS FOR ADMINISTRATION OF PROGRAM.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary, as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

“(4) LENGTH OF AGREEMENT.—

“(A) IN GENERAL.—An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

“(B) TERMINATION.—

“(i) BY THE SECRETARY.—The Secretary shall provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The

Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

“(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

“(I) if the termination occurs before January 31 of a plan year, as of the day after the end of the plan year; and

“(II) if the termination occurs on or after January 31 of a plan year, as of the day after the end of the succeeding plan year.

“(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

“(5) EFFECTIVE DATE OF AGREEMENT.—An agreement under this section shall take effect at the start of a calendar quarter or another date specified by the Secretary.

“(c) Duties described.—The duties described in this subsection are the following:

“(1) ADMINISTRATION OF PROGRAM.—Administering the program, including—

“(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

“(B) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

“(i) the negotiated price of the applicable drug; and

“(ii) the discounted price of the applicable drug;

“(C) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as specified by the Secretary; and

“(D) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, prescription drug plans and MA–PD plans, and the Secretary.

“(2) MONITORING COMPLIANCE.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

“(3) COLLECTION OF DATA FROM PRESCRIPTION DRUG PLANS AND MA–PD PLANS.—The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

“(d) Administration.—

“(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c).

“(2) LIMITATION.—In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

“(e) Civil money penalty.—

“(1) IN GENERAL.—A manufacturer that fails to provide discounted prices for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with an agreement in effect under this section shall be subject to a civil money penalty for each such failure in an amount the Secretary determines is equal to the sum of—

“(A) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

“(B) 25 percent of such amount.

“(2) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

“(f) Clarification regarding availability of other covered part D drugs.—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

“(g) Definitions.—In this section:

“(1) APPLICABLE BENEFICIARY.—The term ‘applicable beneficiary’ means an individual who, on the date of dispensing a covered part D drug—

“(A) is enrolled in a prescription drug plan or an MA–PD plan;

“(B) is not enrolled in a qualified retiree prescription drug plan; and

“(C) has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that exceed the annual deductible specified in section 1860D–2(b)(1).

“(2) APPLICABLE DRUG.—The term ‘applicable drug’, with respect to an applicable beneficiary—

“(A) means a covered part D drug—

“(i) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act; and

“(ii) (I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

“(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

“(III) is provided through an exception or appeal; and

“(B) does not include a selected drug (as referred to under section 1192(c)) during a price applicability period (as defined in section 1191(b)(2)) with respect to such drug.

“(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term ‘applicable number of calendar days’ means—

“(A) with respect to claims for reimbursement submitted electronically, 14 days; and

“(B) with respect to claims for reimbursement submitted otherwise, 30 days.

“(4) DISCOUNTED PRICE.—

“(A) IN GENERAL.—The term ‘discounted price’ means, subject to subparagraphs (B) and (C), with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary—

“(i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, 90 percent of the negotiated price of such drug; and

“(ii) who has incurred such costs, as so determined, in the year that are equal to or exceed such threshold for the year, 80 percent of the negotiated price of such drug.

“(B) PHASE-IN FOR CERTAIN DRUGS DISPENSED TO LIS BENEFICIARIES.—

“(i) IN GENERAL.—In the case of an applicable drug of a specified manufacturer (as defined in clause (ii)) that is marketed as of the date of enactment of this subparagraph and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3)), the term ‘discounted price’ means the specified LIS

percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

“(ii) SPECIFIED MANUFACTURER.—

“(I) IN GENERAL.—In this subparagraph, subject to subclause (II), the term ‘specified manufacturer’ means a manufacturer of an applicable drug for which, in 2021—

“(aa) the manufacturer had a coverage gap discount agreement under section 1860D–14A;

“(bb) the total expenditures for all of the specified drugs of the manufacturer covered by such agreement or agreements for such year and covered under this part during such year represented less than 1.0 percent of the total expenditures under this part for all covered Part D drugs during such year; and

“(cc) the total expenditures for all of the specified drugs of the manufacturer that are single source drugs and biological products for which payment may be made under part B during such year represented less than 1.0 percent of the total expenditures under part B for all drugs or biological products for which payment may be made under such part during such year.

“(II) SPECIFIED DRUGS.—

“(aa) IN GENERAL.—For purposes of this clause, the term ‘specified drug’ means, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

“(bb) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

“(III) LIMITATION.—The term ‘specified manufacturer’ shall not include a manufacturer described in subclause (I) if such manufacturer is acquired after 2021 by another manufacturer that is not a specified manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

“(iii) SPECIFIED LIS PERCENT.—In this subparagraph, the ‘specified LIS percent’ means, with respect to a year—

“(I) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

“(aa) for 2025, 99 percent;

“(bb) for 2026, 98 percent;

“(cc) for 2027, 95 percent;

“(dd) for 2028, 92 percent; and

“(ee) for 2029 and each subsequent year, 90 percent; and

“(II) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

“(aa) for 2025, 99 percent;

“(bb) for 2026, 98 percent;

“(cc) for 2027, 95 percent;

“(dd) for 2028, 92 percent;

“(ee) for 2029, 90 percent;

“(ff) for 2030, 85 percent; and

“(gg) for 2031 and each subsequent year, 80 percent.

“(C) PHASE-IN FOR SPECIFIED SMALL MANUFACTURERS.—

“(i) IN GENERAL.—In the case of an applicable drug of a specified small manufacturer (as defined in clause (ii)) that is marketed as of the date of enactment of this subparagraph and dispensed for an applicable beneficiary, the term ‘discounted price’ means the specified small manufacturer percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

“(ii) SPECIFIED SMALL MANUFACTURER.—

“(I) IN GENERAL.—In this subparagraph, subject to subclause (III), the term ‘specified small manufacturer’ means a manufacturer of an applicable drug for which, in 2021—

“(aa) the manufacturer is a specified manufacturer (as defined in subparagraph (B)(ii)); and

“(bb) the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section 1860D–14A of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered

by such agreement or agreements for such year and covered under this part during such year.

“(II) SPECIFIED SMALL MANUFACTURER DRUGS.—

“(aa) IN GENERAL.—For purposes of this clause, the term ‘specified small manufacturer drugs’ means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

“(bb) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

“(III) LIMITATION.—The term ‘specified small manufacturer’ shall not include a manufacturer described in subclause (I) if such manufacturer is acquired after 2021 by another manufacturer that is not a specified small manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

“(iii) SPECIFIED SMALL MANUFACTURER PERCENT.—In this subparagraph, the term ‘specified small manufacturer percent’ means, with respect to a year—

“(I) for an applicable drug dispensed for an applicable beneficiary who has not incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

“(aa) for 2025, 99 percent;

“(bb) for 2026, 98 percent;

“(cc) for 2027, 95 percent;

“(dd) for 2028, 92 percent; and

“(ee) for 2029 and each subsequent year, 90 percent; and

“(II) for an applicable drug dispensed for an applicable beneficiary who has incurred costs, as determined in accordance with section 1860D–2(b)(4)(C), for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year—

“(aa) for 2025, 99 percent;

“(bb) for 2026, 98 percent;

“(cc) for 2027, 95 percent;

“(dd) for 2028, 92 percent;

“(ee) for 2029, 90 percent;

“(ff) for 2030, 85 percent; and

“(gg) for 2031 and each subsequent year, 80 percent.

“(D) TOTAL EXPENDITURES.—For purposes of this paragraph, the term ‘total expenditures’ includes, in the case of expenditures with respect to part D, the total gross covered prescription drug costs as defined in section 1860D–15(b)(3). The term ‘total expenditures’ excludes, in the case of expenditures with respect to part B, expenditures for a drug or biological that are bundled or packaged into the payment for another service.

“(E) SPECIAL CASE FOR CERTAIN CLAIMS.—

“(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls above such annual deductible.

“(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

“(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

“(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

“(5) MANUFACTURER.—The term ‘manufacturer’ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

“(6) NEGOTIATED PRICE.—The term ‘negotiated price’ has the meaning given such term for purposes of section 1860D–2(d)(1)(B), and, with respect to an applicable drug,

such negotiated price shall include any dispensing fee and, if applicable, any vaccine administration fee for the applicable drug.

“(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term ‘qualified retiree prescription drug plan’ has the meaning given such term in section 1860D–22(a)(2).

“SEC. 1860D–14D. Selected drug subsidy program.

“With respect to covered part D drugs that would be applicable drugs (as defined in section 1860D–14C(g)(2)) but for the application of subparagraph (B) of such section, the Secretary shall provide a process whereby, in the case of an applicable beneficiary (as defined in section 1860D–14C(g)(1)) who, with respect to a year, is enrolled in a prescription drug plan or is enrolled in an MA–PD plan, has not incurred costs that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i), and is dispensed such a drug, the Secretary (periodically and on a timely basis) provides the PDP sponsor or the MA organization offering the plan, a subsidy with respect to such drug that is equal to 10 percent of the negotiated price (as defined in section 1860D–14C(g)(6)) of such drug.”.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the Social Security Act (42 U.S.C. 1395w–114a) is amended—

(A) in subsection (a), in the first sentence, by striking “The Secretary” and inserting “Subject to subsection (h), the Secretary”; and

(B) by adding at the end the following new subsection:

“(h) Sunset of program.—

“(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2025, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

“(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply on and after January 1, 2025, with respect to applicable drugs dispensed prior to such date.”.

(3) SELECTED DRUG SUBSIDY PAYMENTS FROM MEDICARE PRESCRIPTION DRUG ACCOUNT.—Section 1860D–16(b)(1) of the Social Security Act (42 U.S.C. 1395w–116(b)(1)) is amended—

(A) in subparagraph (C), by striking “and” at the end;

(B) in subparagraph (D), by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new subparagraph:

“(E) payments under section 1860D–14D (relating to selected drug subsidy payments).”.

(d) Medicare part D premium stabilization.—

(1) 2024 THROUGH 2029.—Section 1860D–13 of the Social Security Act (42 U.S.C. 1395w–113) is amended—

(A) in subsection (a)—

(i) in paragraph (1)(A), by inserting “or (8) (as applicable)” after “paragraph (2)”;

(ii) in paragraph (2), in the matter preceding subparagraph (A), by striking “The base” and inserting “Subject to paragraph (8), the base”;

(iii) in paragraph (7)—

(I) in subparagraph (B)(ii), by inserting “or (8) (as applicable)” after “paragraph (2)”; and

(II) in subparagraph (E)(i), by inserting “or (8) (as applicable)” after “paragraph (2)”; and

(iv) by adding at the end the following new paragraph:

“(8) PREMIUM STABILIZATION.—

“(A) IN GENERAL.—The base beneficiary premium under this paragraph for a prescription drug plan for a month in 2024 through 2029 shall be computed as follows:

“(i) 2024.—The base beneficiary premium for a month in 2024 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under paragraph (2) for a month in 2023 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2024 that would have applied if this paragraph had not been enacted.

“(ii) 2025.—The base beneficiary premium for a month in 2025 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under clause (i) for a month in 2024 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2025 that would have applied if this paragraph had not been enacted.

“(iii) 2026.—The base beneficiary premium for a month in 2026 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under clause (ii) for a month in 2025 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2026 that would have applied if this paragraph had not been enacted.

“(iv) 2027.—The base beneficiary premium for a month in 2027 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under clause (iii) for a month in 2026 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2027 that would have applied if this paragraph had not been enacted.

“(v) 2028.—The base beneficiary premium for a month in 2028 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under clause (iv) for a month in 2027 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2028 that would have applied if this paragraph had not been enacted.

“(vi) 2029.—The base beneficiary premium for a month in 2029 shall be equal to the lesser of—

“(I) the base beneficiary premium computed under clause (v) for a month in 2028 increased by 6 percent; or

“(II) the base beneficiary premium computed under paragraph (2) for a month in 2029 that would have applied if this paragraph had not been enacted.

“(B) CLARIFICATION REGARDING 2030 AND SUBSEQUENT YEARS.—The base beneficiary premium for a month in 2030 or a subsequent year shall be computed under paragraph (2) without regard to this paragraph.”; and

(B) in subsection (b)(3)(A)(ii), by striking “subsection (a)(2)” and inserting “paragraph (2) or (8) of subsection (a) (as applicable)”.

(2) ADJUSTMENT TO BENEFICIARY PREMIUM PERCENTAGE FOR 2030 AND SUBSEQUENT YEARS.—Section 1860D–13(a) of the Social Security Act (42 U.S.C. 1395w–113(a)), as amended by paragraph (1), is amended—

(A) in paragraph (3)(A), by inserting “(or, for 2030 and each subsequent year, the percent specified under paragraph (9))” after “25.5 percent”; and

(B) by adding at the end the following new paragraph:

“(9) PERCENT SPECIFIED.—

“(A) IN GENERAL.—Subject to subparagraph (B), for purposes of paragraph (3)(A), the percent specified under this paragraph for 2030 and each subsequent year is the percent that the Secretary determines is necessary to ensure that the base beneficiary premium computed under paragraph (2) for a month in 2030 is equal to the lesser of—

“(i) the base beneficiary premium computed under paragraph (8)(A)(vi) for a month in 2029 increased by 6 percent; or

“(ii) the base beneficiary premium computed under paragraph (2) for a month in 2030 that would have applied if this paragraph had not been enacted.

“(B) FLOOR.—The percent specified under subparagraph (A) may not be less than 20 percent.”.

(3) CONFORMING AMENDMENTS.—

(A) Section 1854(b)(2)(B) of the Social Security Act 42 U.S.C. 1395w–24(b)(2)(B)) is amended by striking “section 1860D–13(a)(2)” and inserting “paragraph (2) or (8) (as applicable) of section 1860D–13(a)”.

(B) Section 1860D–11(g)(6) of the Social Security Act (42 U.S.C. 1395w–111(g)(6)) is amended by inserting “(or, for 2030 and each subsequent year, the percent specified under section 1860D–13(a)(9))” after “25.5 percent”.

(C) Section 1860D–13(a)(7)(B)(i) of the Social Security Act (42 U.S.C. 1395w–113(a)(7)(B)(i)) is amended—

(i) in subclause (I), by inserting “(or, for 2030 and each subsequent year, the percent specified under paragraph (9))” after “25.5 percent”; and

(ii) in subclause (II), by inserting “(or, for 2030 and each subsequent year, the percent specified under paragraph (9))” after “25.5 percent”.

(D) Section 1860D–15(a) of the Social Security Act (42 U.S.C. 1395w–115(a)) is amended—

(i) in the matter preceding paragraph (1), by inserting “(or, for each of 2024 through 2029, the percent applicable as a result of the application of section 1860D–13(a)(8), or, for 2030 and each subsequent year, 100 percent minus the percent specified under section 1860D–13(a)(9))” after “74.5 percent”; and

(ii) in paragraph (1)(B), by striking “paragraph (2) of section 1860D–13(a)” and inserting “paragraph (2) or (8) of section 1860D–13(a) (as applicable)”.

(e) Conforming amendments.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking “, or an increase in the initial” and inserting “or, for a year preceding 2025, an increase in the initial”;

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking “at initial coverage limit”; and

(ii) by inserting “for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year” after “subsection (b)(3) for the year” each place it appears; and

(C) in subsection (d)(1)(A), by striking “or an initial” and inserting “or, for a year preceding 2025, an initial”.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is amended by striking “the initial” and inserting “for a year preceding 2025, the initial”.

(3) Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (C), by striking “The continuation” and inserting “For a year preceding 2025, the continuation”;

(ii) in subparagraph (D)(iii), by striking “1860D–2(b)(4)(A)(i)(I)” and inserting “1860D–2(b)(4)(A)(i)(I)(aa)”; and

(iii) in subparagraph (E), by striking “The elimination” and inserting “For a year preceding 2024, the elimination”; and

(B) in paragraph (2)(E), by striking “1860D–2(b)(4)(A)(i)(I)” and inserting “1860D–2(b)(4)(A)(i)(I)(aa)”.

(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended by striking “section 1860D–2(b)(4)(B)(i)” and inserting “section 1860D–2(b)(4)(C)(i)”.

(5) Section 1860D–22(a)(2)(A) of the Social Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is amended—

(A) by striking “the value of any discount” and inserting the following: “the value of—

“(i) for years prior to 2025, any discount”;

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new clause:

“(ii) for 2025 and each subsequent year, any discount provided pursuant to section 1860D–14C.”.

(6) Section 1860D–41(a)(6) of the Social Security Act (42 U.S.C. 1395w–151(a)(6)) is amended—

(A) by inserting “for a year before 2025” after “1860D–2(b)(3)”; and

(B) by inserting “for such year” before the period.

(7) Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

(A) in subsection (a)—

(i) by striking paragraph (1) and inserting the following:

“(1) participate in—

“(A) for 2011 through 2024, the Medicare coverage gap discount program under section 1860D–14A; and

“(B) for 2025 and each subsequent year, the manufacturer discount program under section 1860D–14C;”;

(ii) by striking paragraph (2) and inserting the following:

“(2) have entered into and have in effect—

“(A) for 2011 through 2024, an agreement described in subsection (b) of section 1860D–14A with the Secretary; and

“(B) for 2025 and each subsequent year, an agreement described in subsection (b) of section 1860D–14C with the Secretary; and”; and

(iii) in paragraph (3), by striking “such section” and inserting “section 1860D–14A”; and

(B) by striking subsection (b) and inserting the following:

“(b) Effective date.—Paragraphs (1)(A), (2)(A), and (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2025, and paragraphs (1)(B) and (2)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2025.”.

(8) Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (c)(1)(C)(i)(VI), by inserting before the period at the end the following: “or under the manufacturer discount program under section 1860D–14C”; and

(B) in subsection (k)(1)(B)(i)(V), by inserting before the period at the end the following: “or under section 1860D–14C”.

(f) Implementation for 2024 through 2026.—The Secretary shall implement this section, including the amendments made by this section, for 2024, 2025, and 2026 by program instruction or other forms of program guidance.

(g) Funding.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not

otherwise appropriated, $341,000,000 for fiscal year 2022, including $20,000,000 and $65,000,000 to carry out the provisions of, including the amendments made by, this section in fiscal years 2022 and 2023, respectively, and $32,000,000 to carry out the provisions of, including the amendments made by, this section in each of fiscal years 2024 through 2031, to remain available until expended.

SEC. 11202. Maximum monthly cap on cost-sharing payments under prescription drug plans and MA–PD plans.

(a) In general.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), by striking “and (D)” and inserting “, (D), and (E)”; and

(B) by adding at the end the following new subparagraph:

“(E) MAXIMUM MONTHLY CAP ON COST-SHARING PAYMENTS.—

“(i) IN GENERAL.—For plan years beginning on or after January 1, 2025, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1860D–14(a)), the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped in accordance with this subparagraph.

“(ii) DETERMINATION OF MAXIMUM MONTHLY CAP.—For each month in the plan year for which an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

“(iii) BENEFICIARY MONTHLY PAYMENTS.—With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

“(iv) MAXIMUM MONTHLY CAP DEFINED.—In this subparagraph, the term ‘maximum monthly cap’ means, with respect to an enrollee—

“(I) for the first month for which the enrollee has made an election pursuant to clause (i), an amount determined by calculating—

“(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

“(bb) the number of months remaining in the plan year; and

“(II) for a subsequent month, an amount determined by calculating—

“(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by

“(bb) the number of months remaining in the plan year.

“(v) ADDITIONAL REQUIREMENTS.—The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

“(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1804(a).

“(II) TIMING OF ELECTION.—An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

“(aa) prior to the beginning of the plan year; or

“(bb) in any month during the plan year.

“(III) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

“(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

“(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

“(cc) shall include information on such option in enrollee educational materials;

“(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

“(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

“(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

“(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

“(IV) FAILURE TO PAY AMOUNT BILLED.—If an enrollee fails to pay the amount billed for a month as required under this subparagraph—

“(aa) the election of the enrollee pursuant to clause (i) shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B); and

“(bb) the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.

“(V) CLARIFICATION REGARDING PAST DUE AMOUNTS.—Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

“(VI) TREATMENT OF UNSETTLED BALANCES.—Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.”; and

(2) in paragraph (4)—

(A) in subparagraph (C), by striking “subparagraph (E)” and inserting “subparagraph (E) or subparagraph (F)”; and

(B) by adding at the end the following new subparagraph:

“(F) INCLUSION OF COSTS PAID UNDER MAXIMUM MONTHLY CAP OPTION.—In applying subparagraph (A), with respect to an enrollee who has made an election pursuant to clause (i) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the option provided under such paragraph.”.

(b) Application to alternative prescription drug coverage.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

“(4) SAME MAXIMUM MONTHLY CAP ON COST-SHARING.—The maximum monthly cap on cost-sharing payments shall apply to coverage with respect to an enrollee who has made an election pursuant to clause (i) of subsection (b)(2)(E) under the option provided under such subsection.”.

(c) Implementation for 2025.—The Secretary shall implement this section, including the amendments made by this section, for 2025 by program instruction or other forms of program guidance.

(d) Funding.—In addition to amounts otherwise available, there are appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $10,000,000 for fiscal year 2023, to remain available until expended, to carry out the provisions of, including the amendments made by, this section.

PART 4—Continued Delay of Implementation of Prescription Drug Rebate Rule

SEC. 11301. Extension of moratorium on implementation of rule relating to eliminating the anti-kickback statute safe harbor protection for prescription drug rebates.

The Secretary of Health and Human Services shall not, prior to January 1, 2032, implement, administer, or enforce the provisions of the final rule published by the Office of the Inspector General of the Department of Health and Human Services on November 30, 2020, and titled “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees ” (85 Fed. Reg. 76666).

PART 5—Miscellaneous

SEC. 11401. Coverage of adult vaccines recommended by the Advisory Committee on Immunization Practices under Medicare part D.

(a) Ensuring treatment of cost-sharing and deductible is consistent with treatment of vaccines under medicare part b.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by sections 11201 and 11202, is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A), by striking “The coverage” and inserting “Subject to paragraph (8), the coverage”;

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting “and paragraph (8)” after “and (E)”;

(ii) in subparagraph (C)(i), in the matter preceding subclause (I), by striking “paragraph (4)” and inserting “paragraphs (4) and (8)”; and

(iii) in subparagraph (D)(i), in the matter preceding subclause (I), by striking “paragraph (4)” and inserting “paragraphs (4) and (8)”;

(C) in paragraph (3)(A), in the matter preceding clause (i), by striking “and (4)” and inserting “(4), and (8)”;

(D) in paragraph (4)(A)(i), by striking “The coverage” and inserting “Subject to paragraph (8), the coverage”; and

(E) by adding at the end the following new paragraph:

“(8) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES CONSISTENT WITH TREATMENT OF VACCINES UNDER PART B.—

“(A) IN GENERAL.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in subparagraph (B))—

“(i) the deductible under paragraph (1) shall not apply; and

“(ii) there shall be no coinsurance or other cost-sharing under this part with respect to such vaccine.

“(B) ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For purposes of this paragraph, the term ‘adult vaccine recommended by the Advisory Committee on Immunization Practices’ means a covered part D drug that is a vaccine licensed under section 351 of the Public Health Service Act for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.”; and

(2) in subsection (c), by adding at the end the following new paragraph:

“(5) TREATMENT OF COST-SHARING FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—The coverage is in accordance with subsection (b)(8).”.

(b) Conforming amendments to cost-sharing for low-income individuals.—Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by section 11201, is amended—

(1) in paragraph (1)(D), in each of clauses (ii) and (iii), by striking “In the case” and inserting “Subject to paragraph (6), in the case”;

(2) in paragraph (2)—

(A) in subparagraph (B), by striking “A reduction” and inserting “Subject to section 1860D–2(b)(8), a reduction”;

(B) in subparagraph (D), by striking “The substitution” and inserting “Subject to paragraph (6), the substitution”; and

(C) in subparagraph (E), by striking “subsection (c)” and inserting “paragraph (6) of this subsection and subsection (c)”; and

(3) by adding at the end the following new paragraph:

“(6) NO APPLICATION OF COST-SHARING OR DEDUCTIBLE FOR ADULT VACCINES RECOMMENDED BY THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in section 1860D–2(b)(8)(B))—

“(A) the deductible under section 1860D–2(b)(1) shall not apply; and

“(B) there shall be no cost-sharing under this section with respect to such vaccine.”.

(c) Temporary retrospective subsidy.—

(1) IN GENERAL.—Section 1860D–15 of the Social Security Act (42 U.S.C. 1395w–115) is amended by adding at the end the following new subsection:

“(h) Temporary retrospective subsidy for reduction in cost-sharing and deductible for adult vaccines recommended by the advisory committee on immunization practices during 2023.—

“(1) IN GENERAL.—In addition to amounts otherwise payable under this section to a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan, for plan year 2023, the Secretary shall provide the PDP sponsor or MA organization offering the plan subsidies in an amount equal to the aggregate reduction in cost-sharing and deductible by reason of the application of section 1860D–2(b)(8) for individuals under the plan during the year.

“(2) TIMING.—The Secretary shall provide a subsidy under paragraph (1), as applicable, not later than 18 months following the end of the applicable plan year.”.

(2) TREATMENT AS INCURRED COSTS.—Section 1860D–2(b)(4)(C)(iii)(I) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)(C)(iii)(I)), as amended by section 11201(a)(3)(C), is amended—

(A) in item (cc), by striking “or” at the end; and

(B) by adding at the end the following new item:

“(dd) under section 1860D–15(h); or”.

(d) Rule of construction.—Nothing in this section shall be construed as limiting coverage under part D of title XVIII of the Social Security Act for vaccines that are not recommended by the Advisory Committee on Immunization Practices.

(e) Implementation for 2023 through 2025.—The Secretary shall implement this section, including the amendments made by this section, for 2023, 2024, and 2025, by program instruction or other forms of program guidance.

SEC. 11402. Payment for biosimilar biological products during initial period.

Section 1847A(c)(4) of the Social Security Act (42 U.S.C. 1395w–3a(c)(4)) is amended—

(1) in each of subparagraphs (A) and (B), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively, and moving such subclauses 2 ems to the right;

(2) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii) and moving such clauses 2 ems to the right;

(3) by striking “unavailable.—In the case” and inserting “unavailable.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case”; and

(4) by adding at the end the following new subparagraph:

“(B) LIMITATION ON PAYMENT AMOUNT FOR BIOSIMILAR BIOLOGICAL PRODUCTS DURING INITIAL PERIOD.—In the case of a biosimilar biological product furnished on or after July 1, 2024, during the initial period described in subparagraph (A) with respect to the biosimilar biological product, the amount payable under this section for the biosimilar biological product is the lesser of the following:

“(i) The amount determined under clause (ii) of such subparagraph for the biosimilar biological product.

“(ii) The amount determined under subsection (b)(1)(B) for the reference biological product.”.

SEC. 11403. Temporary increase in Medicare part B payment for certain biosimilar biological products.

Section 1847A(b)(8) of the Social Security Act (42 U.S.C. 1395w–3a(b)(8)) is amended—

(1) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving the margin of each such redesignated clause 2 ems to the right;

(2) by striking “product.—The amount” and inserting the following: “product.—

“(A) IN GENERAL.—Subject to subparagraph (B), the amount”; and

(3) by adding at the end the following new subparagraph:

“(B) TEMPORARY PAYMENT INCREASE.—

“(i) IN GENERAL.—In the case of a qualifying biosimilar biological product that is furnished during the applicable 5-year period for such product, the amount specified in this paragraph for such product with respect to such period is the sum determined under subparagraph (A), except that clause (ii) of such subparagraph shall be applied by substituting ‘8 percent’ for ‘6 percent’.

“(ii) APPLICABLE 5-YEAR PERIOD.—For purposes of clause (i), the applicable 5-year period for a qualifying biosimilar biological product is—

“(I) in the case of such a product for which payment was made under this paragraph as of September 30, 2022, the 5-year period beginning on October 1, 2022; and

“(II) in the case of such a product for which payment is first made under this paragraph during a calendar quarter during the period beginning October 1, 2022, and ending December 31, 2027, the 5-year period beginning on the first day of such calendar quarter during which such payment is first made.

“(iii) QUALIFYING BIOSIMILAR BIOLOGICAL PRODUCT DEFINED.—For purposes of this subparagraph, the term ‘qualifying biosimilar biological product’ means a biosimilar biological product described in paragraph (1)(C) with respect to which—

“(I) in the case of a product described in clause (ii)(I), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product; and

“(II) in the case of a product described in clause (ii)(II), the average sales price under paragraph (8)(A)(i) for a calendar quarter during the 5-year period described in such clause is not more than the average sales price under paragraph (4)(A) for such quarter for the reference biological product.”.

SEC. 11404. Expanding eligibility for low-income subsidies under part D of the Medicare program.

Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by sections 11201 and 11401, is amended—

(1) in the subsection heading, by striking “individuals” and all that follows through “line” and inserting “certain individuals”;

(2) in paragraph (1)—

(A) by striking the paragraph heading and inserting “Individuals with certain low incomes”; and

(B) in the matter preceding subparagraph (A)—

(i) by inserting “(or, with respect to a plan year beginning on or after January 1, 2024, 150 percent)” after “135 percent”; and

(ii) by inserting “(or, with respect to a plan year beginning on or after January 1, 2024, paragraph (3)(E))” after “the resources requirement described in paragraph (3)(D)”; and

(3) in paragraph (2)—

(A) by striking the paragraph heading and inserting “Other low-income individuals”; and

(B) in the matter preceding subparagraph (A), by striking “In the case of a subsidy” and inserting “With respect to a plan year beginning before January 1, 2024, in the case of a subsidy”.

SEC. 11405. Improving access to adult vaccines under Medicaid and CHIP.

(a) Medicaid.—

(1) REQUIRING COVERAGE OF ADULT VACCINATIONS.—

(A) IN GENERAL.—Section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)) is amended in the matter preceding clause (i) by inserting “(13)(B),” after “(5),”.

(B) MEDICALLY NEEDY.—Section 1902(a)(10)(C)(iv) of such Act (42 U.S.C. 1396a(a)(10)(C)(iv)) is amended by inserting “, (13)(B),” after “(5)”.

(2) NO COST SHARING FOR VACCINATIONS.—

(A) GENERAL COST-SHARING LIMITATIONS.—Section 1916 of the Social Security Act (42 U.S.C. 1396o) is amended—

(i) in subsection (a)(2)—

(I) in subparagraph (G), by inserting a comma after “State plan”;

(II) in subparagraph (H), by striking “; or” and inserting a comma;

(III) in subparagraph (I), by striking “; and” and inserting “, or”; and

(IV) by adding at the end the following new subparagraph:

“(J) vaccines described in section 1905(a)(13)(B) and the administration of such vaccines; and”; and

(ii) in subsection (b)(2)—

(I) in subparagraph (G), by inserting a comma after “State plan”;

(II) in subparagraph (H), by striking “; or” and inserting a comma;

(III) in subparagraph (I), by striking “; and” and inserting “, or”; and

(IV) by adding at the end the following new subparagraph:

“(J) vaccines described in section 1905(a)(13)(B) and the administration of such vaccines; and”.

(B) APPLICATION TO ALTERNATIVE COST SHARING.—Section 1916A(b)(3)(B) of the Social Security Act (42 U.S.C. 1396o–1(b)(3)(B)) is amended by adding at the end the following new clause:

“(xiv) Vaccines described in section 1905(a)(13)(B) and the administration of such vaccines.”.

(3) INCREASED FMAP FOR ADULT VACCINES AND THEIR ADMINISTRATION.—Section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)) is amended—

(A) by striking “and (5)” and inserting “(5)”;

(B) by striking “services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines” and inserting “services described in subsection (a)(13)(A), and prohibits cost-sharing for such services”;

(C) by striking “medical assistance for such services and vaccines” and inserting “medical assistance for such services”; and

(D) by inserting “, and (6) during the first 8 fiscal quarters beginning on or after the effective date of this clause, in the case of a State which, as of the date of enactment of the Act titled ‘An Act to provide for reconciliation pursuant to title II of S. Con. Res. 14’, provides medical assistance for vaccines described in subsection (a)(13)(B) and their administration and prohibits cost-sharing for such vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y), shall be increased by 1 percentage point with respect to medical assistance for such vaccines and their administration” before the first period.

(b) CHIP.—

(1) REQUIRING COVERAGE OF ADULT VACCINATIONS.—Section 2103(c) of the Social Security Act (42 U.S.C. 1397cc(c)) is amended by adding at the end the following paragraph:

"(12) REQUIRED COVERAGE OF APPROVED, RECOMMENDED ADULT VACCINES AND THEIR ADMINISTRATION.—Regardless of the type of coverage elected by a State under subsection (a), if the State child health plan or a waiver of such plan provides child health assistance or pregnancy-related assistance (as defined in section 2112) to an individual who is 19 years of age or older, such assistance shall include coverage of vaccines described in section 1905(a)(13)(B) and their administration.".

(2) NO COST-SHARING FOR VACCINATIONS.—Section 2103(e)(2) of such Act (42 U.S.C. 1397cc(e)(2)) is amended by inserting "vaccines described in subsection (c)(12) (and the administration of such vaccines)," after "in vitro diagnostic products described in subsection (c)(10) (and administration of such products),".

(c) Effective date.—The amendments made by this section take effect on the 1st day of the 1st fiscal quarter that begins on or after the date that is 1 year after the date of enactment of this Act and shall apply to expenditures made under a State plan or waiver of such plan under title XIX of the Social Security Act (42 U.S.C. 1396 through 1396w–6) or under a State child health plan or waiver of such plan under title XXI of such Act (42 U.S.C. 1397aa through 1397mm) on or after such effective date.

SEC. 11406. Appropriate cost-sharing for covered insulin products under Medicare part D.

(a) In general.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by sections 11201, 11202, and 11401, is amended—

(1) in subsection (b)—

(A) in paragraph (1)(A), by striking "paragraph (8)" and inserting "paragraphs (8) and (9)";

(B) in paragraph (2)—

(i) in subparagraph (A), by striking "paragraph (8)" and inserting "paragraphs (8) and (9)";

(ii) in subparagraph (C)(i), in the matter preceding subclause (I), by striking "and (8)" and inserting ", (8), and (9)"; and

(iii) in subparagraph (D)(i), in the matter preceding subclause (I), by striking "and (8)" and inserting ", (8), and (9)";

(C) in paragraph (3)(A), in the matter preceding clause (i), by striking “and (8)” and inserting “(8), and (9)”;

(D) in paragraph (4)(A)(i), by striking “paragraph (8)” and inserting “paragraphs (8) and (9)”; and

(E) by adding at the end the following new paragraph:

“(9) TREATMENT OF COST-SHARING FOR COVERED INSULIN PRODUCTS.—

“(A) NO APPLICATION OF DEDUCTIBLE.—For plan year 2023 and subsequent plan years, the deductible under paragraph (1) shall not apply with respect to any covered insulin product.

“(B) APPLICATION OF COST-SHARING.—

“(i) PLAN YEARS 2023 AND 2024.—For plan years 2023 and 2024, the coverage provides benefits for any covered insulin product, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the out-of-pocket threshold under paragraph (4), with cost-sharing for a month’s supply that does not exceed the applicable copayment amount.

“(ii) PLAN YEAR 2025 AND SUBSEQUENT PLAN YEARS.—For a plan year beginning on or after January 1, 2025, the coverage provides benefits for any covered insulin product, prior to an individual reaching the out-of-pocket threshold under paragraph (4), with cost-sharing for a month’s supply that does not exceed the applicable copayment amount.

“(C) COVERED INSULIN PRODUCT.—In this paragraph, the term ‘covered insulin product’ means an insulin product that is a covered part D drug covered under the prescription drug plan or MA–PD plan that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

“(D) APPLICABLE COPAYMENT AMOUNT.—In this paragraph, the term ‘applicable copayment amount’ means, with respect to a covered insulin product under a prescription drug plan or an MA–PD plan dispensed—

“(i) during plan years 2023, 2024, and 2025, $35; and

“(ii) during plan year 2026 and each subsequent plan year, the lesser of—

“(I) $35;

“(II) an amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with part E of title XI; or

“(III) an amount equal to 25 percent of the negotiated price of the covered insulin product under the prescription drug plan or MA–PD plan.

“(E) SPECIAL RULE FOR FIRST 3 MONTHS OF 2023.—With respect to a month’s supply of a covered insulin product dispensed during the period beginning on January 1, 2023, and ending on March 31, 2023, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall reimburse an enrollee within 30 days for any cost-sharing paid by such enrollee that exceeds the cost-sharing applied by the prescription drug plan or MA–PD plan under subparagraph (B)(i) at the point-of-sale for such month’s supply.”; and

(2) in subsection (c), by adding at the end the following new paragraph:

“(6) TREATMENT OF COST-SHARING FOR COVERED INSULIN PRODUCTS.—The coverage is provided in accordance with subsection (b)(9).”.

(b) Conforming amendments to cost-sharing for low-income individuals.—Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)), as amended by sections 11201, 11401, and 11404, is amended—

(1) in paragraph (1)—

(A) in subparagraph (D)(iii), by adding at the end the following new sentence: “For plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence to a month’s supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”; and

(B) in subparagraph (E), by inserting the following before the period at the end: “or under section 1860D–2(b)(9) in the case of a covered insulin product (as defined in subparagraph (C) of such section)”; and

(2) in paragraph (2)—

(A) in subparagraph (B), by striking “section 1860D–2(b)(8)” and inserting “paragraphs (8) and (9) of section 1860D–2(b)”;

(B) in subparagraph (D), by adding at the end the following new sentence: “For plan year 2023, the amount of the coinsurance applicable under the preceding sentence to a month’s supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the

product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”; and

(C) in subparagraph (E), by adding at the end the following new sentence: “For plan year 2023, the amount of the copayment or coinsurance applicable under the preceding sentence to a month’s supply of a covered insulin product (as defined in section 1860D–2(b)(9)(C)) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”.

(c) Temporary retrospective subsidy.—Section 1860D–15(h) of the Social Security Act (42 U.S.C. 1395w–115(h)), as added by section 11401(c), is amended—

(1) in the subsection heading, by inserting “and insulin” after “practices”; and

(2) in paragraph (1), by striking “section 1860D–2(b)(8)” and inserting “paragraph (8) or (9) of section 1860D–2(b)”.

(d) Implementation for 2023 through 2025.—The Secretary shall implement this section for plan years 2023, 2024, and 2025 by program instruction or other forms of program guidance.

(e) Funding.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $1,500,000 for fiscal year 2022, to remain available until expended, to carry out the provisions of, including the amendments made by, this section.

SEC. 11407. Limitation on monthly coinsurance and adjustments to supplier payment under Medicare Part B for insulin furnished through durable medical equipment.

(a) Waiver of deductible.—The first sentence of section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(1) by striking “and (12)” and inserting “(12)”; and

(2) by inserting before the period the following: “, and (13) such deductible shall not apply with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n).”.

(b) Coinsurance.—

(1) IN GENERAL.—Section 1833(a)(1)(S) of the Social Security Act (42 U.S.C. 1395l(a)(1)(S)) is amended—

(A) by inserting “(i) except as provided in clause (ii),” after “(S)”; and

(B) by inserting after “or 1847B),” the following: “and (ii) with respect to insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n), the amounts paid shall be, subject to the fourth sentence of this subsection, 80 percent of the payment amount established under section 1847A (or section 1847B, if applicable) for such insulin,”.

(2) ADJUSTMENT TO SUPPLIER PAYMENTS; LIMITATION ON MONTHLY COINSURANCE.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended, in the flush matter at the end, by adding at the end the following new sentence: “The Secretary shall make such adjustments as may be necessary to the amounts paid as specified under paragraph (1)(S)(ii) for insulin furnished on or after July 1, 2023, through an item of durable medical equipment covered under section 1861(n), such that the amount of coinsurance payable by an individual enrolled under this part for a month’s supply of such insulin does not exceed $35.”.

(c) Implementation.—The Secretary of Health and Human Services shall implement this section for 2023 by program instruction or other forms of program guidance.

SEC. 11408. Safe harbor for absence of deductible for insulin.

(a) In general.—Paragraph (2) of section 223(c) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

“(G) SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR CERTAIN INSULIN PRODUCTS.—

“(i) IN GENERAL.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for selected insulin products.

“(ii) SELECTED INSULIN PRODUCTS.—For purposes of this subparagraph—

“(I) IN GENERAL.—The term ‘selected insulin products’ means any dosage form (such as vial, pump, or inhaler dosage forms) of any different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra long-acting, and premixed) of insulin.

“(II) INSULIN.—The term ‘insulin’ means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 (Public Law 111–148) and continues to be marketed pursuant to such licensure.”.

(b) Effective date.—The amendment made by this section shall apply to plan years beginning after December 31, 2022.

SEC. 12001. Improve affordability and reduce premium costs of health insurance for consumers.

(a) In general.—Clause (iii) of section 36B(b)(3)(A) of the Internal Revenue Code of 1986 is amended—

(1) by striking “in 2021 or 2022” and inserting “after December 31, 2020, and before January 1, 2026”, and

(2) by striking “2021 and 2022” in the heading and inserting “2021 through 2025”.

(b) Extension through 2025 of rule to allow credit to taxpayers whose household income exceeds 400 percent of the poverty line.—Section 36B(c)(1)(E) of the Internal Revenue Code of 1986 is amended—

(1) by striking “in 2021 or 2022” and inserting “after December 31, 2020, and before January 1, 2026”, and

(2) by striking “2021 and 2022” in the heading and inserting “2021 through 2025”.

(c) Effective date.—The amendments made by this section shall apply to taxable years beginning after December 31, 2022.

Issue 14: Overview of Health Insurance Reforms Since 2000

The US has enjoyed spurts of health insurance reforms for the past 60 years at least. Medicare and Medicaid, the first major public health insurance programs since World War II, passed Congress in the 1960s. Nixon's HMO Act of 1973 followed, presenting a major private sector reform about 6 years later. Both dramatically changed our health insurance landscape for years to come.

After 3 decade major healthcare reform lull, the W. Bush administration passed the Medicare Modernization Act in 2003 and the Obama administration the Affordable Care Act 7 years later. Both also dramatically changed our health insurance landscape for years to come.

But did either the MMA or Aca have the impacts their authors desired? Did either improve the health status of Americans? Did either cut medical costs? Did either dramatically expand coverage? This chapter will address those questions and propose some startling and perhaps unsettling answers. It will then suggest some changes to our healthcare system, already in the works, that *could* have the dramatic systemic impacts that the healthcare reformers had hoped to have.

The Two Major Healthcare Reforms Since 2000

The Medicare Modernization Act of 2003, passed by the George W. Bush administration, represented the ***market based*** reformers vision of an improved healthcare system. Among its key components, this legislation enhanced the so-called 'consumerism' movement in American health insurance by codifying Health Savings Accounts and Health Reimbursement Accounts into our income tax and health insurance systems.

- Health Savings Accounts (HSAs) allow insured folks to invest tax deductible money into special accounts called Health Savings Accounts that they own personally. This money grows tax free until needed, when it can be withdrawn tax free to spend on medical care. HSAs are the only triple tax free investments available under the IRS code; they're tax deductible when initiated, grow tax free and are not taxed when withdrawn for qualified medical expenses.
  HSAs have grown tremendously, totaling over $80 billion by 2022 with some individual accounts reaching $100,000 or more.

  Health Savings Accounts are closely tied into high deductible health plans, both legislatively and economically. Insured people could originally only invest an amount equal to their annual health insurance deductible into their HSA. Overtime, this requirement has changed; in 2021, the contribution limits were $3600 for an individual plan and $7200 for a family plan.

  Economically and philosophically, these accounts were designed to help medical care consumers think of medical payments as being made with their own money.

The Medicare Modernization Act authors hoped that this change in consumer attitude – from thinking of medical payments as someone else's money (the health insurance company's) to thinking of medical payments as their own money – would motivate patients to shop more wisely for medical care, compare prices and choose the least expensive care, in other words, act like purchasers of other consumer products. This consumer driven movement would, in turn, force medical providers to cut prices and therefore reduce healthcare spending by billions of dollars.

That, at least, was the theory.

- Health Reimbursement Accounts (HRAs) are funded by employers. These were designed, originally, to cushion the impact of high deductible plans on employees by covering all or part of the deductible. Operationally, the employee pays for a medical treatment, then submits a receipt to his / her employer for reimbursement. Overtime this became mechanically simpler, with employees paying for medical services with their HRA card.
  HRA payments are tax deductible to the employer and tax free to the employee.

  HSAs and HRAs have become integrated into our health insurance landscape since 2003 and have also become far more complicated and intricate than outlined here. My purpose in this chapter is simply to introduce them as components of the Medicare Modernization Act of 2003.

The Medicare Modernization Act also introduced Parts C and D of Medicare.

Medicare Part C, often called Medicare Advantage, operates like an old-fashioned HMO. These plans are offered by private insurance companies under Medicare's guidance and with Medicare's approval. Medicare pays a fixed amount to the companies that offer Medicare Advantage Plans. These companies must follow rules set by Medicare. However, each Medicare Advantage Plan can charge different out-of-pocket costs, have different rules for how to get services like specialist referrals or specific hospital and physician networks, and sometimes include additional benefits. That introduces additional consumerism into the marketplace; different Medicare beneficiaries can choose different Part C plans according to their own different insurance plan preferences.

The MMA authors hoped that competition among health insurers – the folks who actually offer various Part C plans – would force prices down. Part C subscribers would, again in theory, choose the lowest cost / most attractive insurance options. As these plans grew in popularity, the offering insurance companies could negotiate lower and lower prices with participating doctors and hospitals.

Again, in theory.

- Medicare Part D covers outpatient prescription drugs, previously not covered by Medicare.

Our purpose in this chapter is less to describe components of the Medicare Modernization Act or, later, the Affordable Care Act, but more to discuss their impacts on the American healthcare system. To that end, we'll move now to commentaries on the state of American healthcare post-MMA. I'll use summarizes from well known academics representing various disciplines – medicine, business, economics and public policy – to make my points.

In 2005 – two years after passage of the MMA – two Harvard Medical School professors, Jules Richmond and Rashi Fein representing for our purposes the medical school perspective, called our healthcare system a 'mess' in the title of their lengthy book on the state of American healthcare entitled 'The Healthcare Mess'. Interestingly Richmond was a former US Surgeon General and exceptionally well placed to understand the issues he discussed.

In 2010 – seven years after passage of the MMA – Regina Herzslinger, a well known Harvard Business School professor and, for our purposes representing the business school perspective, called our healthcare system 'insane'. That was at a Boston area lecture I attended, though my notes are somewhat confusing on this point; she may have called our system 'stupid'. The distinction doesn't matter.

Others from various academic disciplines offered similar commentaries.

Seven years after passing the Medicare Modernization Act and seeing an obvious need to correct some perceived fatal flaws in our healthcare system, the Obama administration passed the Affordable Care Act, a set of government based health insurance reforms. These differed markedly from the market based reforms encompassed in the 2003 Medicare Modernization Act. The ACA's primary goal was to expand insurance coverage, not to enhance consumer / patient power. Among the key ACA provisions, it

- Introduced income based subsidies for health insurance premiums, so lower income folks could afford to purchase private plans,
- Introduced health insurance exchanges or online marketplaces, where consumers could view all health insurance plans available in their area and comparison shop based on price and benefits,
- Introduced employer mandates, requiring employers to offer health insurance to their employees under various circumstances and conditions,
- Introduced an individual mandate, requiring everyone to have health insurance, again under various circumstances and conditions,
- Introduced community rating, so everyone in the same area paid the same amount for health insurance with some minor condition differences, like age and smoking status. This ended 'individual underwriting' where the insurance carrier priced policies differently based on a host of individual risk factors. Individual

underwriting made health insurance unaffordable to very sick people, a situation the Obama administration wanted to avoid.

- Eliminated annual or lifetime policy payment ‘caps’ or amounts of money a person could receive in insurance payments per year or per lifetime. Caps protected insurance carriers from extremely high payouts but, again according to ACA authors, did not serve severely sick patient interests as well.
- Medicaid expansion in which the Feds paid states to cover more low income people.

The commentators continued.

In 2014 – four years after passing the ACA and 11 after passing the Medicare Modernization Act, Ezekiel Emanuel, perhaps the primary author of the ACA and brother of President Obama’s Chief of Staff Rahm Emanuel, called our healthcare system “terribly complex, blatantly unjust, outrageously expensive, grossly inefficient and error prone”. Remember – this summary came from a supporter of healthcare reform.

In 2016 – six years after passing the ACA and 13 after passing the MMA, Jonathan Engle from Columbia University’s School of Public Heath called our system “uniquely dysfunctional”.

In 2020 – ten years after passing the ACA and 17 after passing the MMA, Angus Deaton and Anne Case, two Princeton economics professors, called our system a “calamity”. Deaton won the Nobel Prize for Economics in 2015 for his work in this field.

Other academics and healthcare commentators chimed in along the same general lines.

The summary of our selected healthcare commentaries above, described US healthcare system evolutions through 2 major reforms – the Medicare Modernization Act of 2003 and the Affordable Care Act of 2010 – as moving from a ‘mess’ to a ‘dysfunction calamity’. Not a ringing success by any means.

Interestingly, this fiasco (my word) is taxpayer subsidized since employer paid premiums are tax deductible to the employer and not taxable to the employee - the biggest tax break allowed by the IRS. This raises questions to me, at least, about the purpose of our healthcare system. Is it designed to get people healthy? Is it designed to be benefit sick people? Or is it primarily a jobs program designed to keep well educated, well compensated people happy? Read on and decide for yourself.

Success and failure defined and demonstrated

Let’s now define healthcare reform success and failure. Success in any business, economic, or public policy reform means better products at lower cost and with wider access. This applies to activities ranging from internet expansion to educational reforms, from air conditioning utilization to automobile safety and emission standards and from cell phone use to consumer product sales: better products at lower cost and

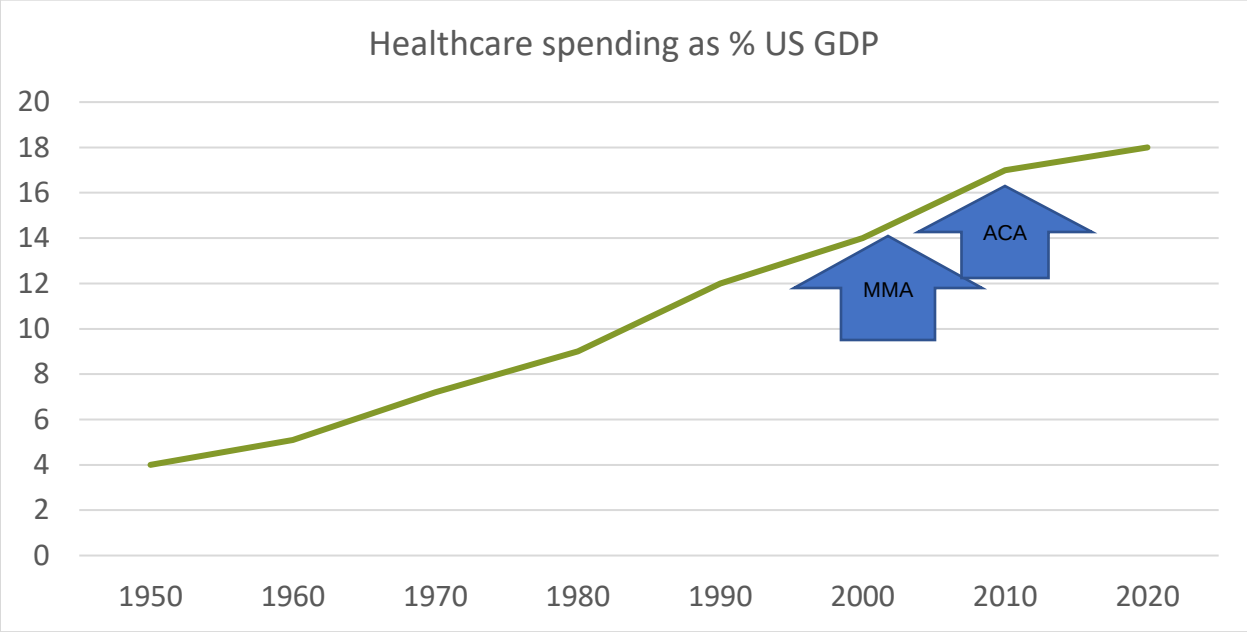
with wider access. By this definition, we can see internet success as an example – many more people have internet access today, at higher speeds, greater reliability and lower costs, than in 2003. Ditto cell phone use and automobile evolution and a host of other services and products.

> A quick note on car costs as an economic cost methodology example: we'll use the same approach to healthcare costs in a few pages.
>
> The average new car cost $24,770 in 2003, the average hourly wage then was $13 so the average person, working at the average wage, had to work 1905 hours to purchase a new car. (People generally financed new cars over time.)
>
> But in 2022, the average new car cost $47,150, the average hourly wage was $32 so the average person, working at the average wage, had to work only 1468 hours to purchase a new car. The 2022 new cars had a host of features that the 2003 cars lacked, including back up cameras, voice activated controls, onboard navigation, Wi-Fi and, increasingly, electric motors.
>
> Thus, despite the higher 2022 sticker price, the average 2022 new car, with all those additional safety and other features, cost less economically than the 2003 ones.

In healthcare, our reform definition means better health outcomes at lower costs for more people. Failure is the opposite: healthcare costs more, doesn't work any better than in the past and remains inaccessible to many.

How have we done on these metrics since 2003?

Healthcare spending as a percent of our total economy has risen since 1950 at about a constant rate. See the chart below. As healthcare spending grows, it consumes more and more of our economic resources. It inflates, in other words, more quickly than the economy as a whole. You can see that the Medicare Modernization Act had no impact on the rate of healthcare spending growth, while the Affordable Care Act has a minor impact. After both reforms, healthcare spending continues to grow faster than the overall economy and continues to consume more and more of our economic resources.



As a side note, ‘consume more and more of our economic resources’ means that we have fewer resources to invest in other parts of our economy as a percentage of our economy. Thus, as healthcare spending grows, other sectors – education, national defense, infrastructure development, etc. – have fewer resources available, again as a percentage of our total economy.

Phrased differently. this means that, as healthcare spending grows, we either spend less in these other sectors or borrow more to fund them fully.

Healthcare outcome improvements, though, do not demonstrate this same growth. See the chart below showing average life expectancy since 1950. I use life expectancy as the care quality metric since the fundamental function of a healthcare system is to keep people alive.

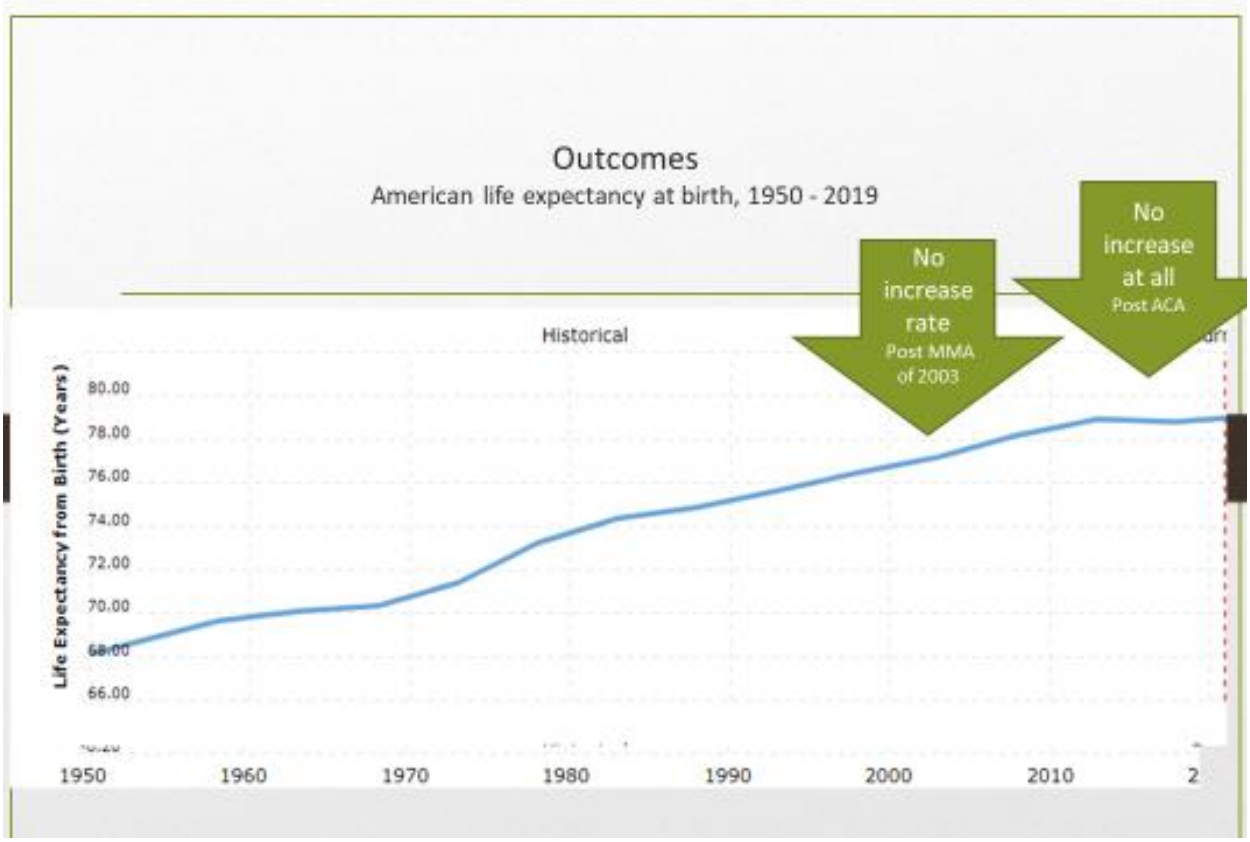
In economic / public policy terms, if our healthcare system keeps people alive longer, then it is arguably worth more funding; but if it does not, then I question whether the additional costs provide any value.

> Yes, I know that factors outside the healthcare system can impact longevity: wars, pollution, genetics, individual behaviors...a long list. But my point is that a healthcare system exists to keep people healthy and alive for longer. If a society identifies harms that limit longevity, then a good healthcare system will adapt and develop programs and treatments to ameliorate those harms. Take smoking, for example. Once identified as a cancer causing / life limiting agent, our healthcare system developed treatments – surgeries, early disease identification programs etc. – and preventive measures – patient education, smoking session programs,

medications to reduce smoker cravings, etc.- to combat smoking's negative effects. That's how a good healthcare system works.

A poor healthcare system limits the definition of 'healthcare' to functions it can perform well – knee surgeries and cataract removals for example - focuses on those, and claims that life extension is someone else's problem. A good healthcare system adapts and extends life. Is our healthcare system, post 2 reforms and by this definition, 'poor' or 'good'? See below.

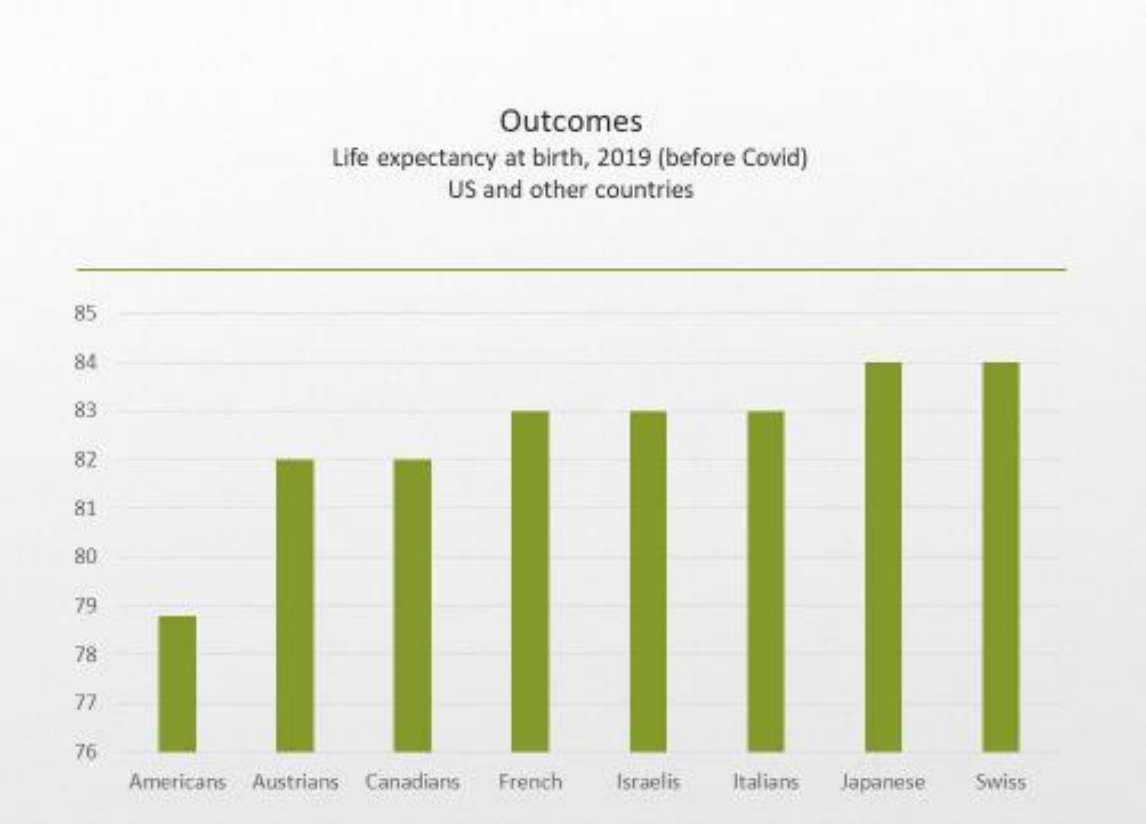
The chart below showing American average longevity at birth ends in 2019 on purpose: I did not want any Covid issues to interfere.



Four things to note here: first, the life expectancy annual increase is basically linear; we gained about as many life years in the 1950s as in the 1990s. Second, the biggest life expectancy gains occurred in the 1970s when we passed various public health measures like the Clean Water and Clean Air Acts. Third, the Medicare Modernization

Act had no impact on the rate of life expectancy growth; it was irrelevant. Fourth, interestingly and for some reason that I cannot explain, we saw no life expectancy growth post passage of the Affordable Care Act, again irrelevant.

In 2019, the last full year before Covid struck and all these metrics became murkier and more confusing, Americans lived less long than people in many (most?) other developed countries. See the chart below, generated **16 years** after passing the Medicare Modernization Act and **9** after passing the Affordable Care Act.



Neither the Medicare Modernization Act nor the Affordable Care Act impacted American's longevity. The underlying tends that existed when those healthcare reforms passed simply continued. The trillions of additional healthcare spending dollars encompassed in those legislations were irrelevant from a longevity perspective.

> Let's look at post-reform healthcare costs and outcomes as economists again, just like we looked at auto costs and quality a few pages ago. We'll use two different methodologies.
>
> First, the methodology we used in auto costs a few pages ago. In 2003, the US spent about $5,700 per capita on healthcare. The 2003 average hourly wage was about $13 so the average person, earning the average wage had to work 438 hours to pay for healthcare.

In 2019, the year before Covid hit, the US spent an average of about $11,500 per capita on healthcare. The 2019 the average hourly wage was about $15.35, so the average person, earning the average wage had to work 749 hours to pay for healthcare.

The analysis above shows that healthcare was much more expensive in 2022. It doesn't tell us if the more expensive healthcare system in 2019 worked better than the 2003 version like in the auto example above, where today's cars are better and safer than the 2003 versions.

So our second approach to thinking as economists will incorporate a productivity and quality indicator to measure healthcare system improvement (or lack thereof) over time. We'll divide average per capita healthcare spending per year by average longevity and compare that number in 2003 – the last year before passage of the Medicare Modernization Act - and 2019, the last year before Covid.

In 2003, again, the US spent about $5,700 per capita, we lived, on average, about 77 years, so our ratio of per capita spending to expected life years was 74. That doesn't mean anything in a vacuum but allows us to compare systemic quality and productivity over time.

In 2019, again, 16 years after passing the Medicare Modernization Act and 9 after passing the Affordable Care Act, we spent about $11,500 per capita and lived, on average, about 79 years. Our 2019 ratio of per capita spending to expected life years was 147, about 73 points higher than our 2003 indicator.

Could this increase be due to overall inflation? One online inflation calculator suggests that $1 in 2002 was equal to $1.42 in 2019.[196] Applying this factor, our healthcare efficiency metric of 74 in 2003 would reasonably be expected to rise to 105 in 2019 due to inflation, a rise of only 31. But it increased by 75. More than half the increase in our metric was something other than inflation.

What was it? My presumptive answer: healthcare system inefficiency, defined as outcomes per dollar spent. Leaving inflation out, we spent far more for each life year in 2019 than in 2003. I'll suggest 4 types of inefficiency or system value reductions.

- One type revolves around prices. Healthcare providers, pharmaceutical companies, medical device manufacturers etc. raised prices far more than at average overall inflation rates because they could – an indicator of market strength. We'll discuss market consolidation later in this chapter.

[196] CPI inflation calculator https://www.in2013dollars.com/us/inflation/2002?endYear=2019&amount=1

- A second type of inefficiency comes from patient coding. According to the HHS inspector general, “hospitals increasingly billed for inpatient stays at the most expensive level from FY2014 to FY2019…these stays are vulnerable to…upcoding.”[197] Upcoding means labelling a patient as sicker for financial and reimbursement purposes.
- A third type of inefficiency comes from the mix of medical services provided in 2019 vs. 2003. Providers in 2019 sometimes (often?) opted for more expensive treatments when less expensive ones existed, or new drugs that worked no better than older ones might dominate the marketplace, or new devices that worked no better than older ones.
- A fourth type of inefficiency might come from a changed patient population needing medical care. The 2019 folks might be older, sicker or more obese than the 2003 group.

There is good evidence that all 4 factors combined in 2019 to describe that increase in our healthcare efficiency metric. We’ll discuss some of this below. Regardless, though, of the exact cause, my underlying point here is that neither healthcare reform package – the 2003 Medicare Modernization Act nor the 2010 Affordable Care Act, nor both together – created a more efficient healthcare system that provided better outcomes at lower costs. Both reforms failed on that efficiency scale.

Let’s turn now to coverage expansion, one of the 3 goals of any economic reform program. Post-Medicare Modernization Act – the legislation that was supposed to reduce healthcare costs and thus stimulate higher coverage rates due to the lower costs of health insurance – our **national uninsured rate** did not decrease. But post-Affordable Care Act the national uninsured rate did decrease, from about 18 to 10% of our total non-elderly population, or from about 50 to 30 million people.

Wider health insurance coverage post-Affordable Care Act but no life expectancy gain. We’ll discuss why below, but this initial analysis raises an interesting question: should we grade healthcare reforms *only* on coverage rates? After all, coverage rates are something we can control fairly easily (nothing in healthcare is easy but expanding coverage is mainly a political issue while extending longevity includes medical, economic, social, genetic, educational, behavioral and other issues.)

Some people say ‘yes’, that the government’s role should only be to ensure coverage while the private sector – doctors, hospitals, pharmaceutical companies etc. - should focus on care quality and cost. The government’s role is only to promote access; the private sector’s is to promote quality. Thus ‘good healthcare reform’ by this definition, brings down the uninsured rate. Period.

[197] HHS Inspector General Data Brief, **February 2021** OEI-01-18-00380

I find this a strange argument. Extending it to the logical conclusion, it makes the Canadian or British healthcare systems better than ours. After all, they cover everyone while we only mange to insure about 90% of Americans. Few brokers, in my experience, and fewer politicians I suspect, would embrace that conclusion.

All this supports my skeptical position about healthcare reform, that Americans have no clear national vision of what a good healthcare system actually is. Yet each of us, working in the healthcare arena, claims to using our own, parochial one: a good healthcare system is one that pays me well. Odd but, unfortunately I suspect, true.

There is, though, one unequivocal, clear winner from healthcare reforms since 2000 – people declaring bankruptcy from medical expenses. Our national bankruptcy rate has fallen by about half since passage of the Affordable Care Act, from about 1.5 million to 750,000 annually. See the chart below. Many, if not most bankruptcies in the US are caused by medical bills.

Here are the approximate rates of personal bankruptcy annually as the ACA rolled out:

Year	# Bankruptcies	ACA rollout activity
2009	1.41 million	Pre-ACA
2010	1.54 million	ACA passed
2011	1.36 million	ACA rolls out
2012	1.18 million	
2013	1.04 million	
2014	.91 million	Full ACA implementation
2015	.82 million	
2016	.77 million	

While reducing the number of personal bankruptcies is clearly a good thing, I wonder if there might be alternative strategies available to accomplish this goal – other, that is, than revamping the entire US healthcare system. Nonetheless, I take this as a healthcare reform win, the only one I see.

Healthcare reform tools

Let’s now consider the tools available to healthcare reformers.

Market based reforms, like the Medicare Modernization Act, focus on so-called ‘bottom up’ or consumer driven incentives. These market based folks like to deregulate so the market, i.e. the interactions between medical care suppliers and medical care purchasers, takes place as efficiently as possible. Market based reformers dislike mandates and requirements, seeing these are obstacles coming between clinicians and patients. They dislike, in other words, things like insurance coverage requirements or minimum benefit packages that, in their eyes, raise prices unnecessarily. The marketplace, they argue, would differentiate ‘good’ from ‘bad’ insurance policies more efficiently.

> Classical economic theory holds that an unencumbered buyer with access to all available information, will choose the highest quality / lowest cost products available. The market based reform team tries to apply this economic principle to healthcare.

Market based reformers like competition, figuring that more competition will force medical care suppliers (providers, clinicians, physicians, pharmaceutical companies and insurers) to find better / less expensive ways to treat sick patients. This becomes, they hope, a virtuous circle in which each product improvement / price reduction move stimulates others in the same direction.

Market based reformers like association health plans, seeing them as competition to large insurance companies. They like price lists and reference pricing figuring that patients will use price as a choice consideration, purchase lower priced care and therefore exert downward pressure on medical prices.

> Reference pricing means that an employer or insurance policy will pay a stipulated amount for a specific treatment, say $5000 for knee surgery for example. If the patient wants the $6000 treatment, or prefers the $6000 surgeon, then he or she pays the additional $1000. In theory, reference price lists reflect the lowest priced medical providers in an area, thus stimulating other providers to lower their own prices to compete.

Market based reformers like Health Savings Accounts and HRAs, both of which put money into patient hands, on the theory that patients will spend their money more wisely than a huge, bureaucratic, bulky insurance carrier.

Government based reforms, on the other hand, use more top-down tools. This team likes regulations that force medical providers and carriers to act in certain ways. They don’t trust the market to work its magic in healthcare. These folks like mandates, for example, that require employers to provide health insurance to employees. They like the individual mandate that requires everyone to have health insurance, this to avoid so-called ‘insurance death spirals’ in which only sick people purchase insurance.

> Insurance death spirals occur when healthier people don’t purchase health insurance, but sicker people do. This drives up premiums, so ‘slightly sicker’

people stop purchasing and only the sickest remain on the insurance books. This makes premiums too expensive for most people, uninsured rates skyrocket and the system collapses.

Insurance operates on the law-of-large-numbers principle and needs lots of healthy people enrolled to counter the costs of sick people. That is why the Affordable Care Act instituted the individual mandate.

Government based reformers also like a required minimum set of benefits in any ACA compliant policies. They worry that carriers might lower their policy prices by leaving out important benefits. Policy holders, either unsophisticated purchasers or victims of unscrupulous sales tactics, might not learn of the benefit gaps until they get a bill, potentially a huge one. In other words, government based reformers see a minimum benefit requirement as consumer protection far less than inflationary. Our market based reform friends, discussed above, see the situation very differently.

The Affordable Care Act created health insurance exchanges, or online marketplaces where individuals could shop for health insurance. Exchanges list all available policy options from all available carriers in a region, encouraging consumers to compare prices and coverages before purchasing. By and large, exchange offered plans cover similar benefits but with different cost sharing.

Cost sharing means that the policy holder and insurance company each pay a portion of the premium and medical costs. Some policies might cost less but force the insured to pay more at the point of service; others might cost more but have a lower annual deductible.

Which team of healthcare reformers is right - the market based or government based folks? Which approach will reduce healthcare spending, extend life expectancy and provide universal insurance coverage? The unsatisfactory answer is that no one knows for sure, but both teams are convinced of their own infallibility with almost religious zeal. The Medicare Modernization Act passed the Senate in 2003 with 45 Republican votes and only 9 Democrats; the Affordable Care Act passed with 60 Democrats and no Republicans. Given that neither reform reduced costs, extended life expectancy or provided universal insurance coverage, I suspect that the real purpose of healthcare reform is to fight the good fight, raise money from political supporters and stay in office rather than actually to solve any of our myriad healthcare system problems.

But that’s just my own point of view.

Why reforms always fail to reduce costs, extend longevity and provide universal access?

I would argue that all our healthcare reforms since 2003 have ignored the 3 elephants in the room: obesity, industry consolidation and so-called ‘diseases of despair’ a new term to describe suicide, alcoholism and drug abuse. Any one of these 3 elephants would

have made true healthcare reform difficult; all three together make healthcare reform impossible and generate the dismal results we see today. Let's address each elephant in turn and do so in the classical economic terms of supply and demand. But in our case, we'll go in reverse order, demand and supply because this makes our story flow somewhat more logically.

Obesity on the demand side of our 'supply and demand' equation, suggests why Americans need so much medical care. High national obesity rates work in opposition to our 3 healthcare reform goals: obesity decreases life expectancy, increases healthcare costs and therefore exacerbates our uninsured problems.

As I researched the obesity data for this lecture, I found three examples of obesity costs that surprised even me, and I study this stuff for a living. First, as people become more obese, their need for knee surgery rises dramatically. For this analysis, remember that a normal or healthy Body Mass Index tops out at 25.

> Body Mass Index or BMI is our standard weight and obesity metric. It divides someone's weight in kilograms by their height in meters squared. You can find lots of online BMI calculators. A BMI between 18.5 and 24.9 is considered healthy. Below 18.5 is considered underweight, above 25 overweight. A BMI above 30 is labelled obese. The chart below shows BMI rates for a 6 foot tall person at different weights, simply as an example:
>
> - At 147.5 pounds, the 6 foot tall person has a BMI of 20
> - At 184 pounds, the 6 foot tall person has a BMI of 25
> - At 221 pounds, the 6 foot tall person has a BMI of 30
> - At 258 pounds, the 6 foot tall person has a BMI of 35
> - At 295 pounds, the 6 foot tall person has a BMI of 40

As the BMI increases, the need for knee surgery increases proportionally more. Here are estimates from the American Academy of Orthopedic Surgeons for the rate of total knee arthroscopy by BMI. Compared to a normal weight person,

- Someone with a BMI of 30 is 8.5 times more likely to need knee surgery;
- Someone with a BMI of 35 is 18.7 times more likely, and
- Someone with a BMI of 40 is 32.7 times more likely.

We'll label that example 'surprising cost impacts of obesity #1'.

Next, consider the need for bariatric surgery, or surgery to remove part of your stomach to reduce your weight. People generally opt for this procedure after diets and other lifestyle changes have failed. The US annually spends about $180 billion on bariatric surgery and related medical procedures, that approximation in 2020 dollars.

Compare that to our annual cancer treatment expenditures of around 200 billion or so. Almost as much. But note that virtually everyone in American who gets diagnosed with cancer gets treated. By contrast only about 1% of the eligible obese population has so

far had bariatric surgery. That's a huge population appropriate for and needing the procedure. We'll label this 'surprising cost impacts of obesity #2'.

And third, consider the additional Covid costs of obesity, including more severe symptoms, longer hospitalizations, more costly treatments and poorer outcomes. (This section was written in early 2022. Over time Covid treatments have evolved so some of this might be out-of-date when you read it.) According to Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy, as quoted in the Boston Globe on November 22, 2021 in an article The Obesity Pandemic Has Made Covid Much More Deadly, "64 percent of all the hospitalizations from COVID could have been prevented, if we had a metabolically healthy population, without the rates of obesity and diabetes and hypertension that we have now."

Let's try to calculate the obesity costs of Covid using Dr. Mozaffarian's estimate above. First, we'll assume the average hospital cost of treating a Covid patient at $100,000. Admittedly rough, this comes from the Becker's Hospital Review analysis by state.[198] To simplify, the average Massachusetts hospital costs of treating a complex Covid patient in 2020 – 2021 were $209,200; the average Massachusetts hospital cost of treating a non-complex patient were $62,900. Other states are basically in the same ballpark. $100,000 per patient is 'not obviously absurd' to quote one of my old grad school professor's mantra.

Meanwhile, the American Hospital Association estimates over 80 million Covid cases and 4.6 million hospitalizations.[199] Multiplying those 4.6 million hospitalizations times $100,000 per hospitalization comes to a whopping $460 billion. Dr. Mozaffarian's 64% of Covid hospitalizations attributable to obesity is almost $300 billion.

That's a huge cost! We'll label this 'surprising cost impact of obesity #3'.

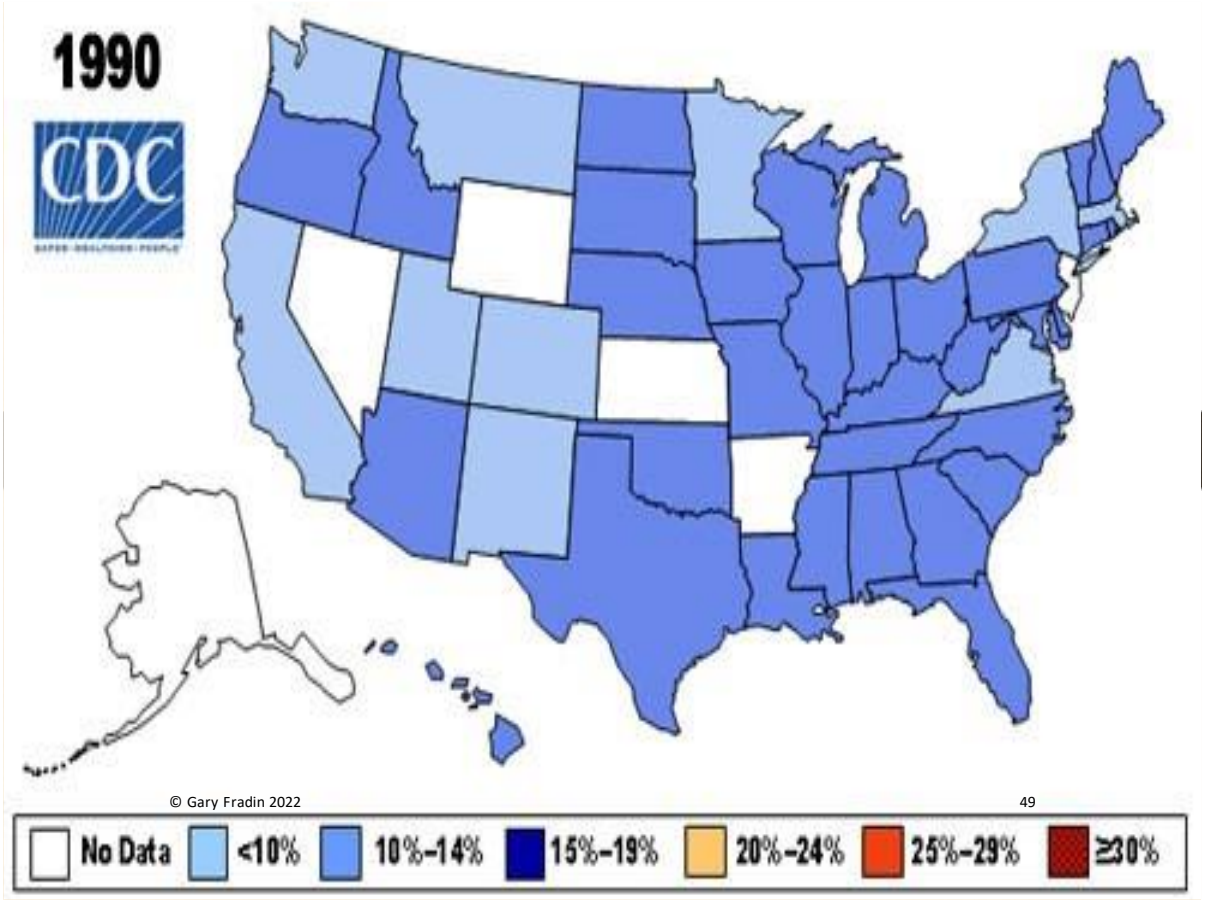
I hope I've made the basic point that obesity is a key driver of healthcare spending and adds a huge amount to our healthcare costs. Which raises the critical question of how well we have done on the obesity front since we reformed healthcare 2003. Presumably lower obesity would work toward our healthcare reform goals of better outcomes at lower costs for more people, which greater obesity would work in the opposite direction. In fact, I'll push this even further and suggest that healthcare reforms that fail to address or control obesity set themselves up for failure.

---

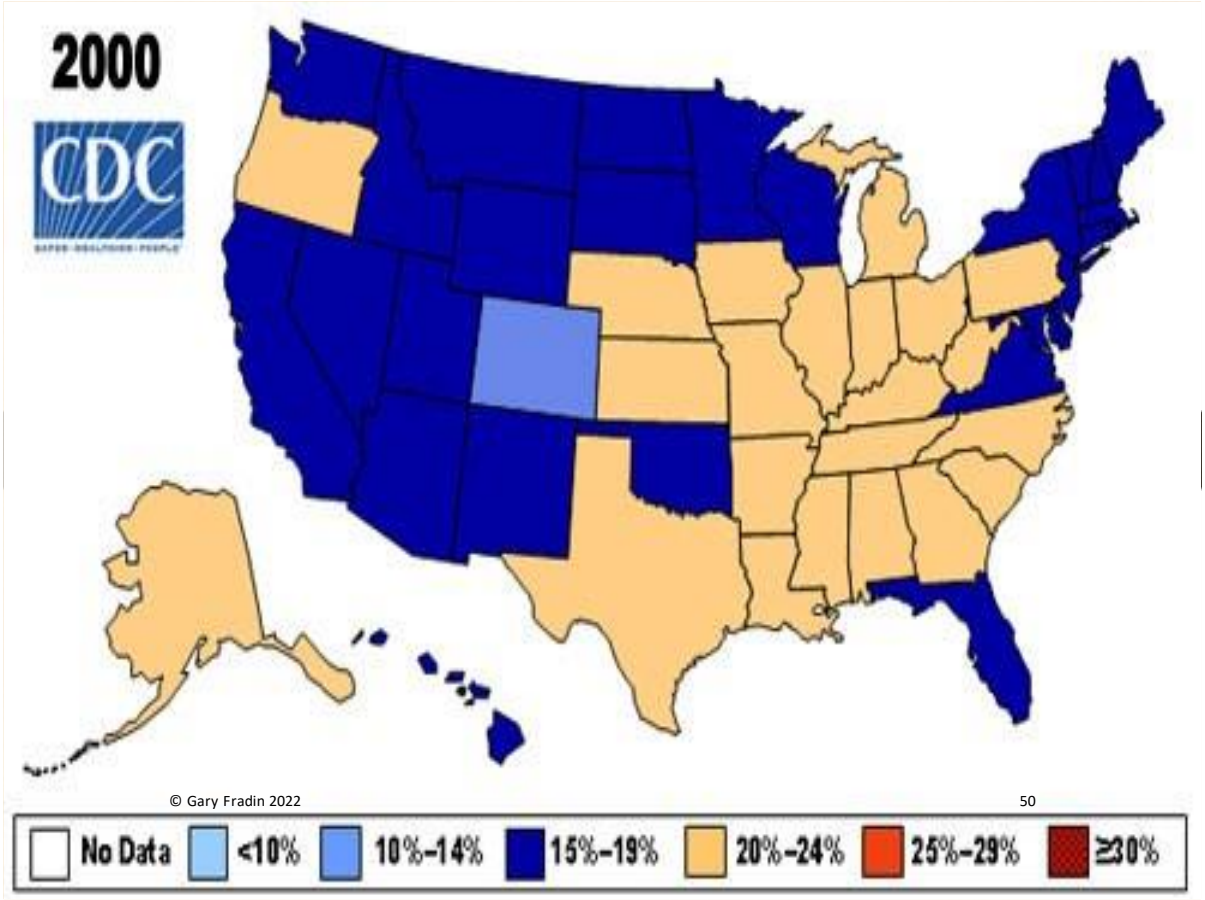
[198] Average charge for Covid 19 hospitalization by state, Alia Paavola, Becker's Hospital Review, October 20, 2021

[199] Rising growth in expenses and rising inflation fuel financial challenges for America's hospitals and hospital systems, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial#:~:text=Medical%20supply%20expenses%20grew%2020.6,%2C%20from%20pre%2Dpandemic%20levels.

Let’s see how we’ve done and use CDC charts as our guide. We’ll start in 1990, before our healthcare reform packages, to set a baseline. The chart below shows obesity by state in 1990. The 4 white states mean ‘no data’, the 19 light colored states have less than 10% of their populations obese, and the remaining darker states have 10 – 14% of their populations obese. Note also that the CDC’s grid at the bottom tops out at greater than 30% obese, a situation the CDC presumably figured unlikely to occur.

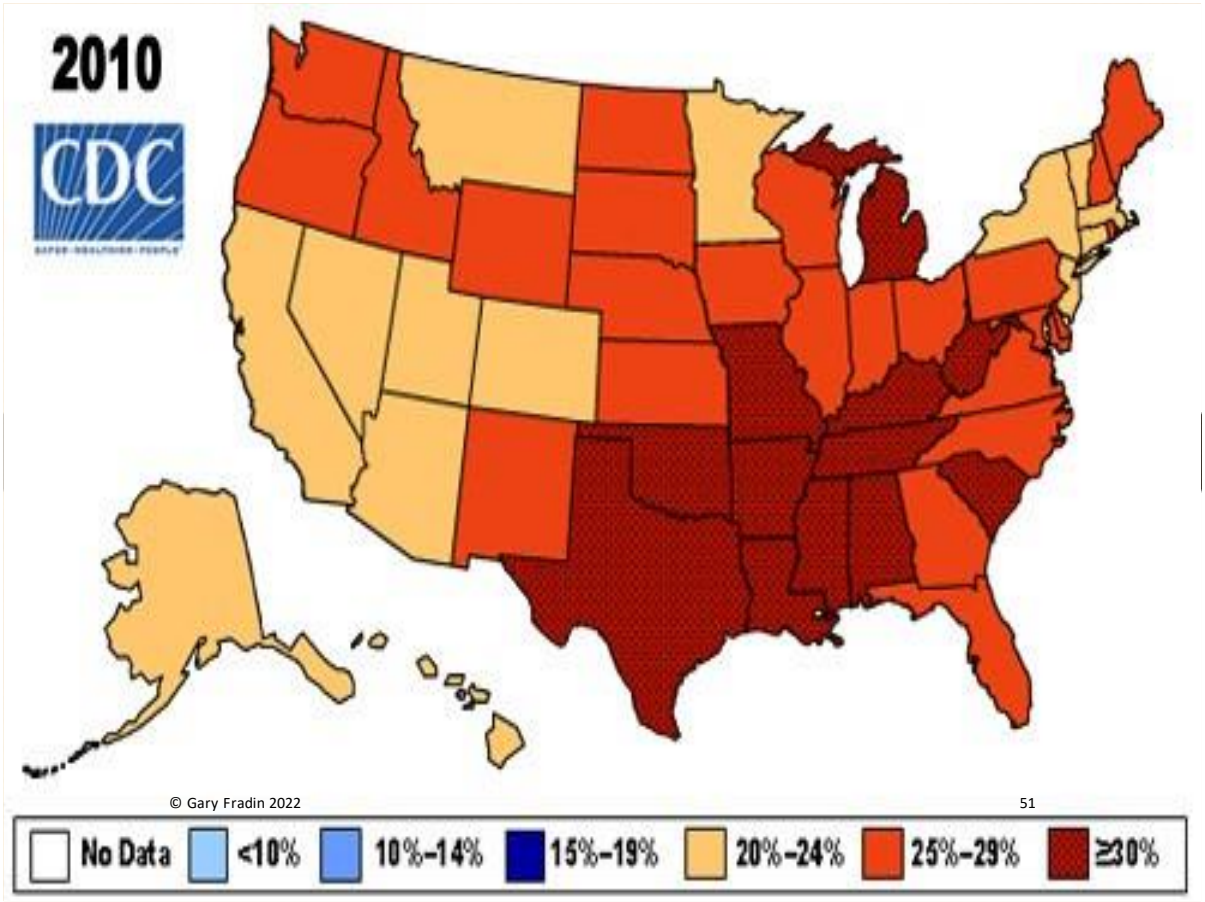


Then, 10 years later, our map changed. Same CDC methodology, same metrics, same format but a vastly different obesity map in only 10 years.



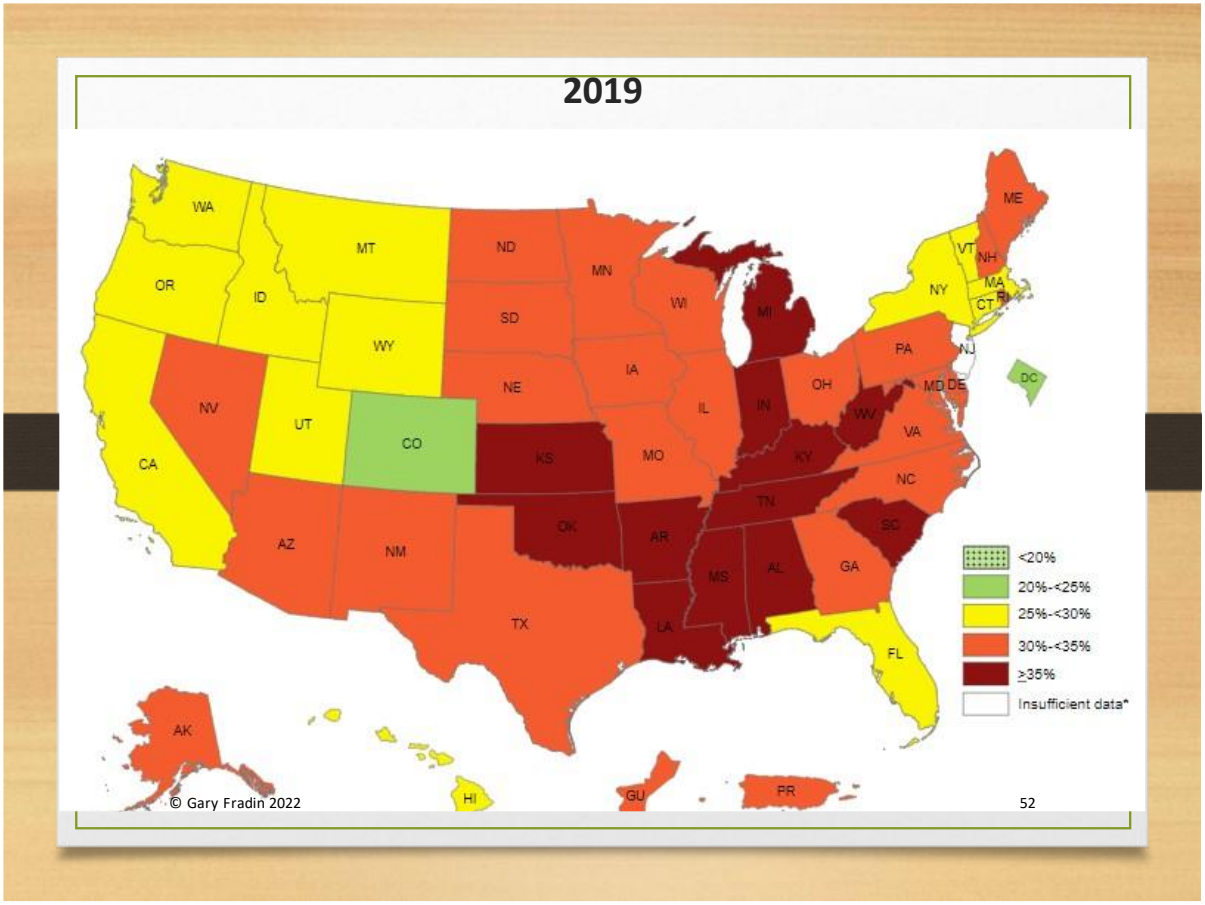
No state is less than 10% obese and only Colorado is less than 14% - the highest level of any state just 10 years before. Now, in 2000, over half the states are 20 – 24% obese, a level no one had reached in 1990.

We then passed the Medicare Modernization Act and the Affordable Care Act…and our map changed dramatically again.



Forget about being less than 20% obese, a level no state had approached just 20 years before. Now no state is less than 20% obese and 11 states had hit the CDC's top limit of 'greater than 30%' obese, a situation the CDC thought unlikely just 20 years previously.

This led the CDC to rethink their format and methodology. In 2019, again the last year before Covid hit, the CDC had a completely different map.



Only 2 states were less than 20% obese and only 14 less than 30% obese. All the others were greater than 30% obese and a handful exceeded 35%. That's exceptional growth since passage of the Medicare Modernization Act and Affordable Care Act, one that makes achievement of those reform goals overly difficult.

A different CDC study estimated that 42% of us were obese in 2018 and Dr. Mozaffarian, our old friend from the Tufts School of Nutrition, estimated at 1 in 4 teenagers were pre-diabetic.

How, I wonder, can we reduce healthcare spending, improve healthcare outcomes and insure more people with a national obesity rate of 42% and 25% of US teenagers suffering from pre-diabetes. My short answer: you can't.

Let's now move from obesity on the demand side of our 'supply and demand' analysis to the supply side and discuss industry consolidation in the healthcare arena. As a basic economic principle, if you have increasing demand for services – which we have from obesity – and fewer medical care suppliers, then you will see prices rise. Let's examine our post-reform history.

First, hospitals have merged to create large hospital systems. Though they had been merging fairly actively prior to passage of the Affordable Care Act – in Boston, for

example, Brigham and Women's merged with Mass General in 1994 – mergermania continued in the hospital sector. Between 2011 and 2017, i.e. post passage of the Affordable Care Act, some 1587 hospitals or about 25% of the US total, merged. These merged hospital systems became the largest (or 2nd largest depending on Amazon) employer in most states. This middle class or wealthier employee population represented votes at the state level to promote the hospital system's interests. The hospital's coffers represented lobbying dollars to promote the hospital system's interests. The merged hospital system spoke with one voice in negotiations with health insurers. And the hospital's wealth funded high priced lawyers to defend the hospital system's interests against aggressive state attorneys general who wished to curb hospital dominance.

The net result was higher medical prices with, according to a 202 analysis in the New England Journal of Medicine, no significant change in 30 day readmission or mortality rates, i.e. no care quality improvement.[200] The Inspector General at the US Department of Health and Human Services phrased this differently in 2021 saying "hospitals increasingly billed for inpatient stays at the most expensive level from FY 2014 through FY 2019" because "these stays are vulnerable to … upcoding".[201] (Upcoding means labelling the patient as sicker to get a higher insurance or Medicare payments.)

The net result: fewer hospitals, caused by the huge number of hospital mergers, used their market power to raise prices.

Hospitals not only merged together but also purchase physician groups to act as 'patient feeders', directing patients to specific hospitals. Between 2016 – 2019, hospitals purchased some 9000 physician practices, again constraining the supply of medical care providers in a region.

Then private equity groups entered the picture, purchasing about 22 physician practices between 2018 and 2019. Private equity purchasers had specific goals: either make a good return on their purchase investment or build an asset for future sale, or both. This motivated physicians to perform more procedures at higher prices. According to a 2022 American Medical Association study 'prices rose 26% in private equity-backed practices, while prices at similar practices without private equity investment grew by 12.9%'.[202]

[200] Beaulieu et al, Changes in Quality of Care After Hospital Mergers and Acquisitions, New England Journal of Medicine, 2020

[201] HHS Inspector General Data Brief, February 2021 OEI-01-18-00380

[202] Zhu, Private Equity Acquisitions of Physician Medical Groups, JAMA Network Research Letter, Feb 18, 2020

Merged hospitals, combined with acquired physician practices, reduced the number of independent, competitive, healthcare providers dramatically post-healthcare reform. (The actual number of physicians did not decrease, just the number of businesses competing.) Faced with less competition, these large, merged businesses did what any large business would do in similar circumstances: they raised prices. How, I wonder, do negotiations go between a hospital system that controls 75% of the beds in a region and most of the physicians, and an insurer who has a 15% market share?

So far, I've suggested that demand for healthcare services rose post-healthcare reform due to obesity (among other factors) and the supply of healthcare providers available to deal with that increased demand fell due to industry consolidation. Now let's switch focus and discuss the environment in which all this took place. We'll introduce a new term: 'diseases of despair' or alcoholism, drug abuse and suicide combined.

People who die from alcoholism, drug abuse or suicide are said to die 'deaths of despair'. Some numbers to set the scene:

- Alcohol is linked to 95,000 annual deaths according to the CDC. This is about double gunshot deaths.[203]
- 500,000 Americans have died from drug abuse since 1999 including 107,000 in 2021.[204]
- 48,000 annual suicides.[205]

Note that neither the Medicare Modernization Act of 2003 nor the Affordable Care Act of 2010 ameliorated this mortality trend. The following chart shows the net impacts of both healthcare reforms, the Medicare Modernization Act and Affordable Care Act on mortality rates between 2010 and 2017 among people aged 25 – 64. These are the folks who should finish their education, begin and develop their careers, get married, have kids, build community and pay taxes. In all states except California and Wyoming,

---

AMA 2022 study, Robeznieks, 'Physicians warned of the pitfalls behind private equity promises, Aug 1, 2022 https://www.ama-assn.org/practice-management/private-practices/physicians-warned-pitfalls-behind-private-equity-promises

[203] Forbes https://www.forbes.com/sites/joshuacohen/2018/07/19/diseases-of-despair-contribute-to-declining-u-s-life-expectancy/#277e57f0656b, Gunshot deaths https://www.cdc.gov/nchs/fastats/injury.htm

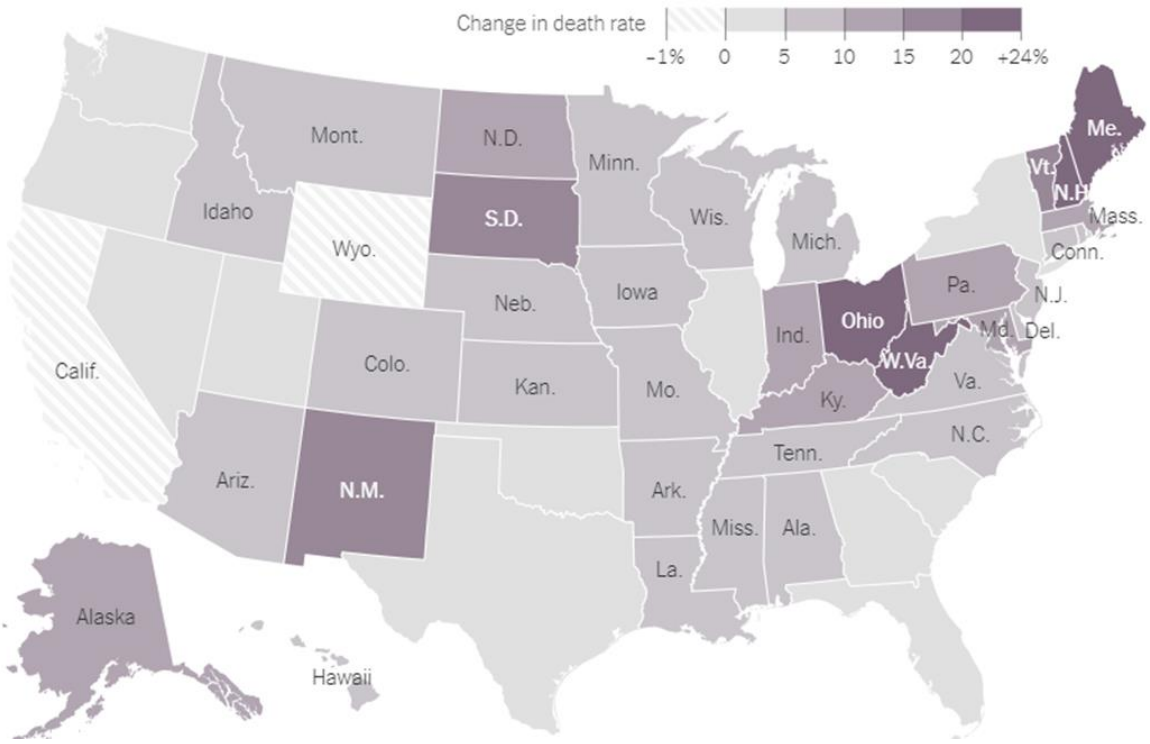
[204] CDC estimate https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html

[205] Reference for Figure 3 chart **SEP 05** 2019 United States Congress Joint Economic Committee "Long term trends in deaths of despair"

https://www.jec.senate.gov/public/index.cfm/republicans/2019/9/long-term-trends-in-deaths-of-despair

the death rate of this group has increased since passage of the ACA. In the darkest colored state, the death rate increase has been 20% or more.[206]

Death rate **increases** per state 2010 - 2017, people aged 25 – 64



I understand the components of healthcare reform and what they are supposed to do. Health insurance exchanges are designed to help people shop more easily for health insurance policies. Eliminating annual and lifetime caps allow patients to receive more medical care. Health Savings Accounts combined with annual deductibles and price lists can help people purchase lower cost commodities like MRIs, X rays and a few other relatively low cost products.

But I don't understand how expanding HSAs, increasing insurance options or publishing medical prices reduce obesity, because they don't.

I don't understand how any component of healthcare reform helps people navigate through our 'insane' (Harvard Business School's Regina Herzlinger's term) or 'uniquely dysfunctional' (Columbia School of Public Health's Jonathan Engle's term) healthcare system when 1 hospital system controls 70% of the physicians and beds in a region, because they don't.

[206] NY Times, It's Not Just Poor White People Driving a Decline in Life Expectancy, Kolata and Tavernise, Feb 18, 2021 https://www.nytimes.com/2019/11/26/health/life-expectancy-rate-usa.html

And I don't understand how any component of healthcare reform addresses deaths of despair because they don't.

In other words, I don't see any financial, political, insurance or payment format solution to our healthcare system problems. We've seen in the combination of Medicare Modernization Act and Affordable Care Act that incremental reforms don't work. And we know that dramatic, radical healthcare system reforms are politically impossible. The situation looks hopeless.

What might save us?

To answer this question, I propose a quick review of America's history of change, an analysis of how we have solved unsolvable problems in the past. By studying how we solved these problems in the past, we can see how we will likely solve our healthcare system problems in the future.

I am guided in this analysis by two thoughtful comments. The first comes from Herbert Stein, a well-known economist in the last century – Chairman of the Council of Economic Advisors to Presidents Nixon and Ford, for example – who famously observed that 'trends that can't continue, won't'. Something, in other words, always intercedes to avoid utter catastrophe. I suspect Stein is right about this.

The second comes from Mark Twain who equally famously observed that 'history doesn't repeat itself but it rhymes.' Historical examples, in other words, don't tell us exactly what will happen in the future but they suggest a direction.

Let's explore a non-healthcare problem from the late 1800s that could have destroyed civilization as we know it. The problem is horse refuse in major cities. We'll focus on New York since I have some data about this courtesy of the New York Times.[207]

Building technologies changed in the 1870s or so, with Andrew Carnegie's commercialization of steel. Buildings were no longer limited to 4 or 5 stories but could now reach 40, 50 or more. This led to more people living and working per acre.

At the same time, immigrants flooded to New York, increasing the city's population from 950,000 in 1870 to 3.4 million in 1900. More people jammed into tighter spaces meant more need for goods and services on, for example, Manhattan Island.

All these goods and services were transported by horse and buggy. In fact, according to the New York Times, there were more than 150,000 horses in New York in 1880. Each horse, according to their estimate, generated 22 pounds of manure per day. That's 1,650 tons! Plus, again the Times' estimate, 10,000 gallons on urine each day. Plus, again the Times' estimate, about 15,000 horses died each year on the streets – not a bad estimate assuming that each of the 150,000 horses lived an average of 10 years.

[207] Lee, When Horses Posed a Public Health Hazard, NY Times, June 9, 2008

All this – the manure, the urine and the horse carcasses – combined to pose a huge disease threat, potentially big enough to destroy cities as they then existed.

Let's now apply current healthcare reform thinking to the horse refuse problem. The market based approach to healthcare reform, a.k.a. the Medicare Modernization Act, would have proposed deregulating horse management, refuse collection and refuse dispersal. Market based thinkers like to deregulate. They probably also would have proposed tax breaks for companies that researched, implemented and demonstrated new and 'better' horse refuse control technologies and practices. Market based thinkers like tax breaks. They would have wanted to create an environment in which entrepreneurs and business builders would flourish, figuring that the market would solve the horse refuse problem more efficiently than any other approach.

By contrast, the government solution team, a.k.a. the Affordable Care Act thinkers, would have proposed a new government authority to oversee and manage horses. They likely would have wanted more regulations to control every aspect of horse management from feeding to housing to exercising and to refuse collection and dispersal. They would have wanted to license horse owners and users to ensure that the newest thinking and technologies applied to horse rearing. In short, the government solution team would have wanted to pass lots of rules to regulate as much about horses as possible.

I hope this brief historical example shows how both approaches – the market based and government solution – would have failed miserably to solve New York City's horse problem…just as they have failed to solve our healthcare system problems.

We know what ultimately solved the horse problem in New York – someone invented a car. The horse problem disappeared shortly thereafter. A new technology, unrelated to horse refuse, completely changed the paradigm and eliminated the manure problem.

Our question has changed. It's no longer 'what form of healthcare reform can we best solve our healthcare system problems?' Instead it has become 'what is the healthcare equivalent of cars?'. I have 4 ideas.

First, the combination of plant based proteins and new medications to address obesity. Things like Impossible Meats, Beyond Meat burgers and the like. Burger King introduced the Impossible Whopper in 2019 to positive reviews. Indeed, as part of my research for this chapter, I visited my local Burger King and ate one; it was delicious. As good as premium burgers and, arguable, healthier. We regularly eat these at home though, truth be told, I prefer the Beyond Burger taste – an individual preference.

Plant based meats act and taste like premium beef and, with their increased scale and 2022 inflation, have become less expensive. This portends a positive trend.

Combine this movement from animal to plant based protein new obesity drugs like semaglutide, trade name Wegovy, manufactured by Nova Nordisk. A high quality study

found that obese patients lost an average of 15% of their body weight over 68 weeks, making it twice as effective as older drugs. A similar new anti-obesity drug is Saxenda, also manufactured by Nova Nordisk.

This combination of plant based proteins and new anti-obesity medications could – emphasize 'could' – have a significant impact on our obesity rates. Stay tuned.

A second potential healthcare equivalent of cars is gene editing using CRISPR technologies. Full disclosure: as a non-scientist, I do not understand how DNA editing works. But as an occasional medical news article reader, I have seen reports about sickle cell and leukemia patients being ***cured*** by DNA editing.[208] 'Cured' means there is no evidence that the disease exists in the patient, different from 'remission'. That's tremendously exciting. DNA editing research and trials are continuing in many directions. Again, stay tuned.

A third potential healthcare equivalent of cars is mRNA technology, or messenger RNA. Again as a non-scientist, I don't know how this works. But mRNA technologies are the basis of the Pfizer and Moderna anti-Covid vaccinations that apparently worked quite well. Messenger RNA instructs the body to make specific new proteins. Still early days but a promising and exciting technology.

And a fourth potential healthcare equivalent of cars is the movement to home based healthcare and away from hospital care. Wall Street is betting that this movement will success. Consider these purchase prices from home based healthcare companies in 2021:

- Kindred at Home purchased by Humana, 2021 with **$8.1 billion** market value
- LHC Group Inc, market cap **$5.5 billion** Sept 2021
- Encompass Health, market cap **$7.9 billion**, Sept 2021
- LHC Group, purchased by UHC, 3/22 for **$5.4 billion**

Compare those prices to publicly traded hospital company market values, also in 2021: Tenet Health, 65 hospitals, $8 billion market value; Universal Health, 211 hospitals, $12 billion.

[208] Sickle Cell success – BBC report Feb 20, 2022 'Sickle Cell: 'The Revolutionary Gene Editing….' https://www.bbc.com/news/health-60348497

Leukemia cure, Boston Globe, 2/3/22 'Doctors: Cancer Patients Cured a Decade After Gene Therapy', Laura Ungar

Which, if any, of these potential healthcare equivalent of cars will succeed? I don’t know. Maybe all, maybe none.

Issue 15: Price transparency and CDH Plans

Dr. Clifton Meador, former dean of the University of Alabama Medical School, issued this caution about the role of financing and prices in American medicine: (references available offline)

> Solutions to the high costs of medical care are almost exclusively financial or payment based [but] the underlying causes are based on misdirected clinical and diagnostic thinking

In other words, Meador cautions us about using financial tools like price lists to address clinical problems.

Dr. Andy Lazris, geriatrician and author of Curing Medicare, agrees, decrying our medical care system that

> pushes the most aggressive care, often despite a paucity of evidence to support that approach …as little as 15% of what doctors do is backed up by valid evidence

Prices can vary dramatically for the same service throughout our healthcare system. 'Transparency' means 'making prices public so people can choose the most economical alternative'. Some say this increases systemic value.

I'm not so sure.

Some pricing examples

Here are some graphic examples of price differences within a relatively small geographic region for the same services. These prices come from the New Hampshire medical price website, nhhealthcost.org, downloaded in 2013 for arthroscopic knee surgery. I chose this website because it was public and easy to use.

Facility	**Total Cost**
Concord Ambulatory Surgery Center	$3,431
Franklin Regional Hospital	$5,118
Cheshire Medical Center	$6,644
Parkland Medical Center	$7,717
Weeks Medical Center	$9,873

Pretty wide variation for the same service. Here are some prices for a pelvic MRI, same website.

Facility	**Total Cost**
Derry Imaging Center	$1,486
St Joseph Hospital	$2,574
Exeter Hospital	$2,758
Speare Memorial Hospital	$3,381
Monadnock Community Hospital	$3,868

Impressive differences. The same situation occurs for dozens of tests and treatments throughout our healthcare system.

Why prices matter (a lot)

Paying too much for a test, medication or treatment *directly* affects two groups of people: individuals / families with high deductible health plans and self insured companies. Both, in an economic sense, function the same way – they spend their own money on medical care. Each dollar saved drops directly to their own bottom line.

Paying too much *indirectly* affects us all by raising overall costs and therefore health insurance premiums.

Thus, the argument goes, considering price generates benefits for us both individually and collectively.

Why prices don't matter (much)

Prices do not tell us

- If we will benefit from the medical care
- If we will be harmed by the medical care
- If we use excellent, average or mediocre providers and treatments.

In short, shopping for medical care primarily based on price can lead patients to cheaper unnecessary or poor quality medical care. And, since it's cheaper, perhaps to *more* unnecessary or poor quality care.

How much unnecessary and poor quality care exists in the US?

The standard estimate of unnecessary care quantity in our healthcare system today is about 1/3. That comes from the Dartmouth Atlas of Healthcare and is based on the amount of geographic treatment variation identified by studying Medicare intensity levels by geographic region. Some regions routinely provide more care to residents while others routinely provide less. The Dartmouth researchers added up all the differences and concluded that the variation equaled about 1/3 of all medical spending.

With our total healthcare expenditures approaching $3 trillion annually, this '1/3' estimate accounts for about $700 billion annually and perhaps as much as $900 billion. Aetna claims the actual amount is at least $765 billion.

But I think this a low estimate, and perhaps a very low one based on two analyses that we'll discuss in some detail later in this chapter.

- First, Dr. Vinay Prasad and his team from the National Cancer Institute and National Institutes of Health, in a very rigorous, detailed study, estimated that about half of all established treatments are ineffective or harmful.[209]

  If we cut geographic 'low intensity' utilization rates by about half to account for Prasad's findings, **we might double the Dartmouth waste estimate to $1.5 trillion *or more***…potentially well over half of all medical spending.

- Second, Dr. Al Mulley and his team from Dartmouth Medical School estimated the potential systemic savings from incorporating patient preferences into treatment designs at about 20%.[210] Mulley's insight, along with others who have studied the same phenomenon, was that patients who understood their options tended to choose less medical care – both a lower number of procedures and less intense / aggressive / expensive ones.

  If we cut geographic 'low intensity' utilization rates by 20% to account for Mulley's findings, **we increase the Dartmouth waste estimate to about 40% of all medical spending.**

Add the Prasad and Mulley numbers to Dartmouth's original waste estimate and you get a very large number. I think a perfectly reasonable, even conservative estimate is 40% of all medical spending.

But I won't argue with higher estimates.

Overestimating treatment benefits

[209] Prasad, A decade of reversal, Mayo Clinic Proceedings, August 2013

[210] Mulley, Patient Preferences Matter, The King's Fund, 2012 http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/patients-preferences-matter-may-2012.pdf

Patients typically overestimate the benefits of medical care and underestimate the risks. Sometimes they think all the tests, drugs and treatments are crucial to maintaining their health. Other times they discount the risk and side effect warnings. Still other times they think the care quality is all equally good from all providers.

In general, patients seem to think that medical care is always – or, at least *almost* always - beneficial and necessary.

But patients often miss on their benefit estimates and overstate them by quite a bit. One study, for example, found that women without the BRCA genetic mutation overestimated their cancer risk reduction benefit from prophylactic bilateral (double) mastectomy 4 fold or more. [211]

- The average estimated risk reduction was 65%. Most women in the study group estimated their chance of developing breast cancer *without* surgery at 76%, and their chance of still developing breast cancer *with* the double mastectomy at 11%.
- Meanwhile, the real risk of developing breast cancer without surgery was 17%. Whatever the prophylactic mastectomy benefits, they were no greater than 17%, far less than the estimated 65% risk reduction anticipated by most patients.

Another study found that 80% of patients overestimated the benefit of hip fracture prevention medications, 90% overestimated the benefits of breast cancer screening and 94% the benefits of bowel cancer screening.

Clifton Leaf, assistant managing editor of Fortune magazine, makes pretty much the same point in his upsettingly insightful analysis of the war on cancer, The Truth in Small Doses. Most patients seem to believe that 'the newest cancer fighting drug, or at least the next one after this one, will certainly provide terrific treatment benefits, so I have to have it.'

Unfortunately, as Leaf shows in almost excruciating detail, those apparent benefits are often illusory or statistical manipulations. Take our war on breast cancer, for example, and consider all the 'newest and greatest' drugs developed since 1970, then see the impact on both our ***actual*** number of female breast cancer deaths and our national breast cancer death rate per 100,000 women: [212]

---

[211] These examples come from If Patients Only Knew How Often Treatments Could Harm Them, Austin Frakt, New York Times, March 2, 2015. Frakt summarizes 30+ studies of patient expectations of medical care benefits, based largely on Patient's Expectations of the Benefits and Harms of Treatments, Screening and Tests by Hoffman and Del Mar, JAMA Internal Medicine, Feb 2015

[212] Leaf, The Truth in Small Doses, page 127. Data from the National Center for Health Statistics (CDC) and National Vital Statistics System

Year	Actual Number of Breast Cancer Deaths	Crude Breast Cancer Death Rate (deaths per 100,000 women)
1970	29,652	28.4
1975	32,158	29.4
1980	35,641	30.6
1985	40,093	32.8
1990	43,391	34.0
1995	43,844	32.2
2000	41,872	29.2
2005	41,116	27.3
2010	40,996	26.1

I did my own 'back of the envelope' analysis of breast cancer mortality gains over the past 20 or so years and found equally unimpressive improvements. I learned that from the mid-1990s to 2006 our national age of breast cancer death remained the same: 68, despite improved technologies, treatments, access and more widespread screening.

	Mid-1990s	2010 [213]
Average age of breast cancer diagnosis	62 [214]	61
Average age of breast cancer death	68 [215]	68
Number of survival years post-diagnosis	6	7

[213] 2006 data from National Cancer Inst, SEER Stat Fact Sheet: Breast downloaded Oct 2012

[214] Glockler, Cancer survival and incidence, The Oncologist, Dec 2003

[215] Saenz, Trends in Breast Cancer Mortality, Population Reference Bureau, Dec 2009

My concern: frightened patients may, under the influence of myth, ads, hope or hype, make unwise medical care choices, 'unwise' in the sense that the care probably won't benefit them much and may harm them some. But they may justify their choices based on relative prices: 'it cost $5,000 from Supplier A and only $1,000 from Supplier B. I'll give it a try. Saves me / my employer / my HSA $4,000!'

Would they have 'given it a try' for $5000?

We often think, as behavioral economists like to point out, in relative, not absolute terms. That $4,000 savings seems pretty good, a motivation to buy. That's why so many consumer products advertise '$500 off this weekend only' without telling the actual price. It's a good deal *relatively*, perhaps especially appealing to scared patient consumers.

That's why I find studies that indicate patients would opt for less, or at least very different care if they had better information about the likely benefits and harms, critically important. [216]

With these types of benefit overestimates and harm underestimates in mind, I'd like to propose a 4-Step Decision Making paradigm.[217] I suggest that patients who follow this process will make better medical decisions, end up more satisfied with their outcomes and save some money along the way.

Perhaps quite a bit of money.

How to make a wise medical decision

I suggest that wise patients use the following decision criteria when considering and accessing medical care. Price considerations are 4th on this list of 4, meaning they're relevant but that other factors are far more important.

First decide if medical care will help you**.** You can learn this from comparative studies of patient outcomes.

Care may not benefit you for a two main reasons.

- You may not be 'sick' even though some indicator or other shows you to be 'at risk'. Our sickness indicators change overtime, with some becoming more expansive and others more restrictive. Someone, for example, with blood sugar of 130 mg/dl was 'not sick' prior to 1997 but 'was sick' after, when a new threshold definition was adopted.

[216] Frakt, op cit

[217] This is the 2nd or 3rd time I discuss this in this book. My excuse: seems like a pretty worthwhile approach to medical decision making. Hope repetition serves to reinforce the message rather than bore readers.

Similarly, a 65 year old with blood pressure of 145/90 'was sick' prior to new definitions adopted in 2013, but was 'not sick' after. [218]

As a general rule, medical care cannot improve your health if you're not sick.

- You may be sick but treatments may not work. We learn from comparative studies which treatments work most of the time, which some of the time and which infrequently.

  Sometimes simply waiting for the 'sickness' to heal itself is the best strategy. This seems the case for pediatric ear aches - the NNT of antibiotics to reduce pain caused by Otitis Media in the first 7 days is 20, for example [219] - and most back pain. ChoosingWisely states that 'back-pain sufferers who had an MRI in the first month were eight times more likely to have surgery, and had a five-fold increase in medical expenses—but didn't recover faster.' [220]

  In your own case, unfortunately even if you're sick, medical care may not be able to help you.

Once you determine that medical care can help you - *if* that's what you determine and *if* you determine that it can help you *enough* - then **second**, decide which care *process* you prefer. You almost always have options: mastectomy or lumpectomy for early stage breast cancer, spinal fusion surgery or physical therapy for back pain, acupuncture or injections for a sore shoulder and many others.

- The various options sometimes (often?) generate similar outcomes though the treatment, risk and recovery processes may differ significantly.
- There's often no one 'right' answer for everyone, only 'right' answers for each individual

Once you decide which process you prefer, then, **third**, determine which medical provider gets the best outcomes.

- One spinal surgeon, for example, may generate far better patient outcomes than another so, if you've already decided you prefer spinal fusion surgery to physical therapy, choose the better surgeon. Ditto for hospitals.
- A good indicator of likely outcomes is the annual volume of patients like you that each physician and hospital treats. Though this is not foolproof – far from it, in

[218] http://www.webmd.com/hypertension-high-blood-pressure/news/20131218/new-blood-pressure-guidelines-raise-the-bar-for-taking-medications

[219] See Otitis Media evaluation on www.TheNNT.com

[220] Imaging tests for low back pain on www.ChoosingWisely.org

fact – it's about the best indicator we currently have to predict likely patient outcomes.

Finally, **fourth,** *after* you determine that medical care can benefit you, and *after* you decide which treatment process you prefer, and *after* you decide which provider gets the best results for patients like you, consider prices.

- You may find that two equally good providers charge different prices for your preferred treatment process. In that case and ***only in that case***, the wise patient chooses the low cost provider.

Be sure to follow these steps in order and rigorously. That will ensure you get the best outcomes, from the process you prefer, at the lowest cost. Don't short circuit this decision tree or you risk getting sub-optimal outcomes, from a process you really don't like, from a provider who's not very good and perhaps overpaying along the way.

Why this decision making process is so important Part 1
The story and legacy of J. Alison Glover: physicians rely on hunches too much

Dr. Glover was a British physician and researcher, perhaps the first to identify the role that physician 'hunches' had in medical care. Glover studied tonsillectomy procedure rates and impacts in the 1920s – 30s. [221] He learned that in Scotland between 1931 and 1935, 60 people died from enlarged tonsils and 513 from tonsil removal including 369 children under 15 years old.

- In this case, even though people were sick, the available medical care couldn't help them much.
- Had they applied Step 1 above, many would have opted against having tonsillectomies and, perhaps, lived as a result.
- Had they applied Step 4 only, the dismal results would have been the same, but some people would have saved money in the process, a Pyrrhic victory if ever there was one.

The US healthcare system, during the same years, was expanding its rate of tonsillectomies in children. Knowing the Scottish experience, however, the Americans tried a different approach, radiation to treat tonsillitis between the 1930s and 50s. This was both unnecessary and ubiquitous, according to the Chicago Tribune's 2004 analysis. [222] The treatments led to increases in thyroid, salivary gland and jaw cancer.

---

[221] See In pursuit of the Glover phenomenon http://the-141.blogspot.com/2012/05/in-pursuit-of-glover-phenomenon-what.html and John Wennberg A debt of gratitude to J. Alison Glover http://ije.oxfordjournals.org/content/37/1/26.long

[222] Goldman, Radiation Babies, Chicago Tribune, Nov 14, 2004

- Patients rigorously using our 4-step process above would, again, have learned in Step 1 that medical care would possibly generate more harm than good.
- They may also have determined in Step 1 that they really were not sick. As such, medical treatments could not make them ‘better’. See below.
- They might also have determined, in Step 2, that tonsillectomies were less risky than radiation.

Glover hypothesized that physician preferences, rather than patient need, drove tonsillectomy rates. He tested this hypothesis by reviewing tonsillectomy rates at the Hornsey Borough School in north London, in the late 1920s.

British children in those days got their medical care through the local school with the school physician acting, more or less, like a Primary Care Physician does today in the US, while sometimes even performing surgeries like an American specialist would. As such it was the school’s responsibility to diagnose and treat tonsillitis, along with lots of other illnesses.

Glover found that in 1928, an unnamed Hornsey school physician performed 186 tonsillectomies. A new doctor named Garrow arrived in 1929 and the number of tonsillectomies fell to 12.

- The average number of tonsillectomies per year from the previous physician, 1921 – 1928: 169
- The average number of tonsillectomies per year after Garrow took over, 1929 – 1933: 13
- The percent of apparently unnecessary tonsillectomies between 1921 and 1928: about 92%.

Glover identified no outcome differences or population changes during this time. It appeared, though, that some 156 children received unnecessary tonsillectomies annually from the previous doctor. They were not, in our terms, ‘sick’.

- Again, to tie this back to our price transparency discussion, wise Hornsey parents would have determined whether or not tonsillectomies provided benefit first and then considered price (if that was a factor in 1929 Britain. I’m not sure it was.)
- Unwise parents would have assumed something about the procedure benefits then jumped to our Step 4 and compared prices from available providers.

OK, one might say. The Hornsey situation happened a long time ago, in a country far away. It doesn’t apply to American medicine today.

John Wennberg follows in Glover’s footsteps

Wennberg, then a young researcher at Dartmouth Medical School, built on Glover's ideas and tracked tonsillectomy rates in Vermont in the 1970s. He found exactly the same thing as Glover did in Hornsey:

- 7% of children under age 16 had tonsillectomies in Middlebury Vermont, while
- 70% did in Morrisville, despite these two communities being demographically similar.

Wennberg identified a similar treatment variation rate when comparing Waterbury Vermont to next door Stowe, again two socio-economically and demographically similar towns (among the full time residents though not necessarily the ski vacationers who didn't generally have tonsillectomies there anyhow).

Parents choosing the cheapest tonsillectomy provider in Morrisville or Stowe would have received less expensive though still unnecessary care about 80% of the time. Not a vast improvement over the 92% unnecessary rate discovered by Glover in Hornsey, years before.

'Too long ago' you still might say. 'My doctor uses the most up-to-date technology, so this wouldn't happen to me. Those Vermont studies are 50 years old.'

In 2013, Wennberg, now an elderly senior researcher and his colleagues at Dartmouth published a tonsillectomy rate analysis among kids in Northern New England during the period 2007 – 2010. They found that the average rate in Burlington Vermont and Bangor Maine was about 3 tonsillectomies per 1000 children while the average rate throughout New Hampshire was about 9, a 3-fold rate difference. The unnecessary tonsillectomy rate in New Hampshire between 2007 and 2010: about 68%, better than Glover's Hornsey example 80 years before but still awfully high.

The Dartmouth researchers could not identify population health differences that explained this treatment rate difference, just as Glover had been unable to in Hornsey. Nor could they identify population health gains from the excessive tonsillectomies.

Throughout this story, the treatment rate differences appear due to physician preferences, not patient need.

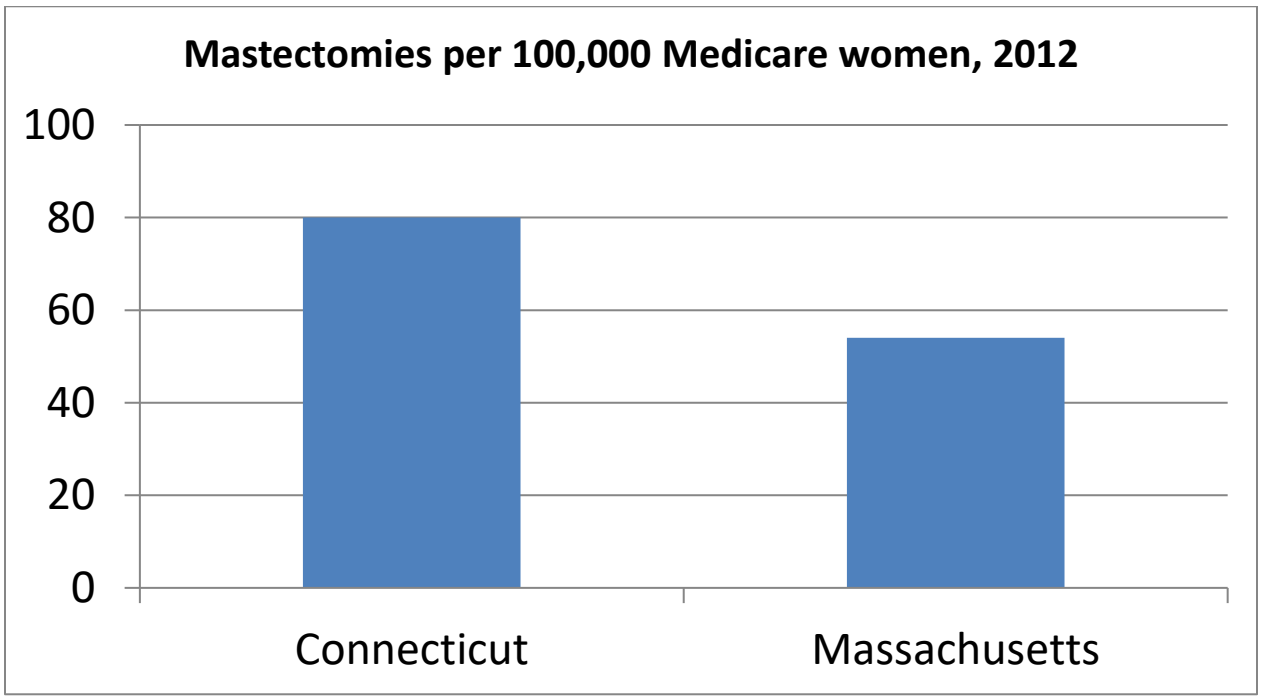
- The appropriate mechanism to avoid unnecessary care remains consumer education and use of our 4-Step Program, not price lists and not google searches.
- Parents choosing the cheapest tonsillectomy providers in New Hampshire would have received less expensive unnecessary care for their children 2/3 of the time…just like the parents in Stowe or Morrisville 50 years earlier or Hornsey 80 years before. Not much systemic evolution over the years.

Physicians appear, according to Wennberg, to rely on ‘hunches’ too often, rather than data and scientific outcome evidence from comparative studies when making treatment recommendations to patients, just as they did in Hornsey and Morrisville many years before.

But perhaps the most shocking treatment variation example comes in the mastectomy rate differences among Massachusetts and Connecticut Medicare beneficiaries. Note that both Massachusetts and Connecticut patients have access to outstanding medical care in facilities affiliated with Harvard and Yale medical schools respectively. It just doesn’t get any better than that!

I say ‘most shocking’ because in this breast cancer treatment case we have disease incidence rates, disease treatment rates and patient outcome rates. This puts to bed the ‘population difference’ justification for treatment variation rates.

Here’s a chart showing mastectomy rates in both Massachusetts and Connecticut, per 100,000 Medicare beneficiaries, from the Dartmouth Atlas of Healthcare, 2012.



Connecticut women are about 50% more likely to have mastectomies than Massachusetts women.

This raises the ‘sickness’ question: are Connecticut women sicker than Massachusetts women? Do they get breast cancer 50% more frequently?

The answer is no, according to breast cancer incidence rate data from the American Cancer Society. [223] The breast cancer rates are virtually identical.

Breast cancer incidence rates per 100,000 women

	Non Hispanic White	African American	Hispanic
Connecticut	139	113	127
Massachusetts	137	109	104

Now, if women in both states were equally sick but received different treatments, did Connecticut women benefit from the additional mastectomies?

Again the answer is no. Breast cancer mortality rates are almost identical in both states. [224]

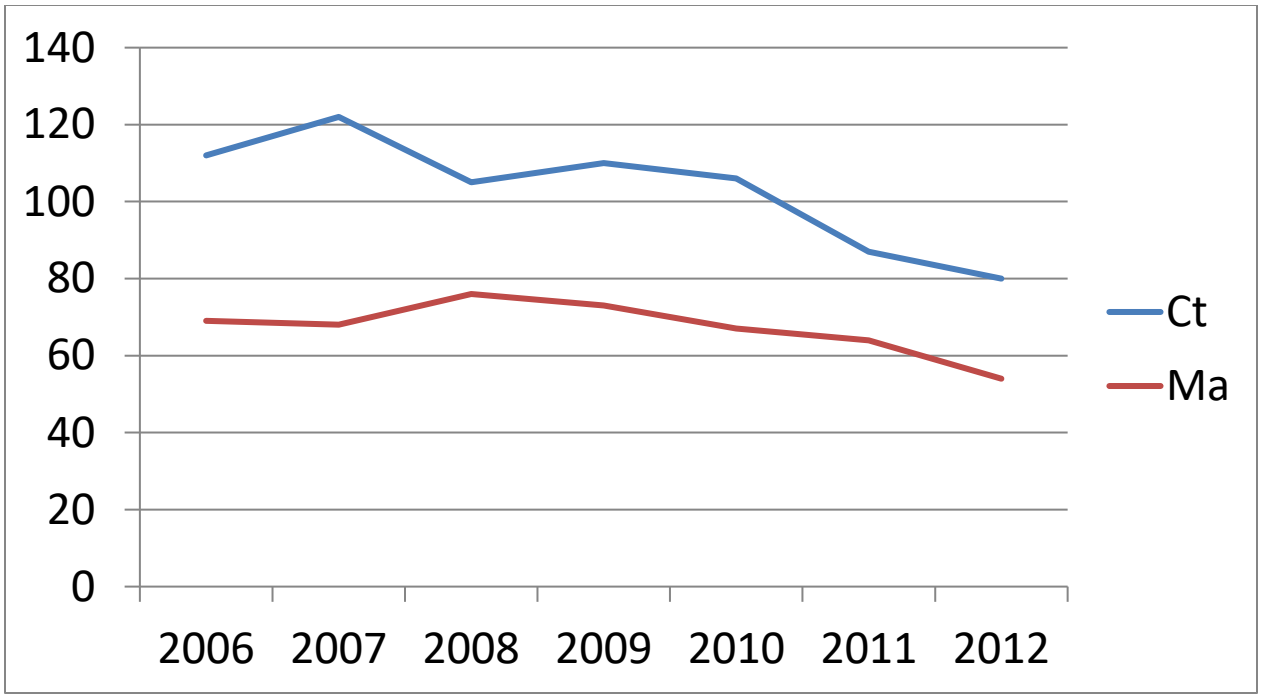
Breast cancer mortality rates per 100,000 women

	Non-Hispanic White	African American	Hispanic
Connecticut	24.0	27.4	12.1
Massachusetts	23.5	27.3	12.1

This treatment variation situation has existed for years. Connecticut always has more, per thousand women. Here are the rates from 2005 – 2012, again using data from the Dartmouth Atlas:

[223] American Cancer Society, Cancer Facts and Figures, 2011-2012

[224] http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-030975.pdf



That 50% more in Connecticut rate has existed for many years.

If the additional mastectomies Connecticut women received over time had any benefit, then we would see breast cancer mortality rate differences that approximate the treatment differences. That is not the case.

Rate discrepancies like these exist for dozens of medical tests and treatments.

These situations – tonsillectomy rates in Vermont in the 1970s and northern New England from 2007 – 2010, and mastectomy rates in Massachusetts and Connecticut in the 2000s – are exactly the same as Glover identified in Hornsey in the late 1920s.

- Knowing treatment prices would no more help a Connecticut women in 2010 avoid an unnecessary mastectomy – or a Scot in the 1920s avoid dying from a botched procedure or an American in the 1940s avoid radiation-induced thyroid cancer - than a Hornsey child in 1928 avoid an unnecessary tonsillectomy.
- Most likely, price transparency would only have helped that Hornsey child or Connecticut women get cheaper unnecessary care.

An underlying cause of this problem, according to many who have studied it: physicians like to use the newest available technology [225] and patients generally believe that more medical care is better medical care. Wennberg put it this way: [226]

[225] See Dr. Lazris's comment at the beginning of this chapter.

[226] http://ije.oxfordjournals.org/content/37/1/26.long

- Few surgeons are hesitant believers in the efficacy of the operations they perform, nor do they doubt their clinical necessity.
- Most patients are convinced that the benefits of surgery exceed the risks by a wide margin.

Yet, as we have just seen, these two certainties do not add up to patient benefit as often as either doctors or patients would like. Knowing prices adds nothing to the patient's chance of benefit.

Why this decision making process is so important Part 2
The impact of Vinay Prasad's research: half of established medical interventions are found to be useless or harmful when subjected to comparative studies

Dr. Prasad, Senior Fellow at the National Cancer Institute and National Institutes of Health, was lead author in an extraordinary, though little discussed, study published in the Mayo Clinic Proceedings in 2013, *A Decade of Reversal*. [227] Prasad and his team reviewed every article published in the New England Journal of Medicine between 2001 and 2010 and found that 363 studied an 'established' medical practice, meaning a commonly used medical protocol.

Of those, 146 studies or 40% reversed the practice.

In other words, 40% of comparative studies on existing, established, routine medical practices showed those practices were ineffective or harmful. The actual percentage is probably closer to 50% being ineffective or harmful when Prasad's 'inconclusive' group, 139 practices or 22% is included.

Stated differently, about half of what doctors do doesn't work. As Prasad told the New York Times

> They all sound good if you talk about the mechanisms… the nuts and bolts, what does it do, how does it work….but the real question is: Does it work? [228]

Or, as he said in his fascinating You Tube summary: [229]

> Of all those things we're doing currently that lack good evidence, probably about half of them are incorrect.
>
> Patients who are embarking on procedures, screening tests, diagnostic tests should really try to ascertain whether or not those are based on good evidence.

---

[227] http://www.mayoclinicproceedings.org/article/S0025-6196%2813%2900405-9/abstract

[228] http://well.blogs.nytimes.com/2013/07/26/medical-procedures-may-be-useless-or-worse/

[229] https://www.youtube.com/watch?v=fB1qEoDO2nE

> By good evidence, I mean randomized controlled trials powered for hard endpoints such as mortality or morbidity and not surrogate endpoints.
>
> Consequences of medical reversal are quite dire. All the people who were subject to the intervention during the years it fell in favor… in retrospect, we realize, received no benefits
>
> These are practices that should never have been instituted, that were instituted in error…even for things that make perfect sense.
>
> The take away message from our paper is that a large proportion of medical practices which are based on little to no evidence are probably incorrect. Their continued use jeopardizes patient health and wastes limited healthcare resources.

Remember Prasad's definition of *evidence*: randomized controlled studies powered for hard endpoints, not biological, anatomical or physiological explanations of why some intervention makes sense. Wise patients discuss outcome evidence with their doctors; unwise discuss anatomy and physiology. Prasad clearly explains why the latter approach doesn't work.

Here are some of Prasad's examples of medical reversals. You can find the entire list on the Mayo Clinic Proceeding website. As you review this list, ask yourself if you would like to have the *cheapest* of the reversed procedure or test. My guess: you don't want it at all, regardless the price.

I tried to choose relatively non-technical discussions. Many of Prasad's 146 reversals are very technical, specialized interventions and his discussions are often aimed at a medically trained audience.

Intensive Blood Glucose Control and Vascular Outcomes in Patient with Type 2 Diabetes	A target A1C of 7.0% or less was the guideline for most patients with diabetes. However data were inconsistent how glucose control played a role in vascular disease. In the Action in Diabetes and Vascular Disease (ADVANCE) trial, the effects of glucose control on major vascular outcomes were evaluated. There was no evidence of reduction in macrovascular events and intensive glucose control was associated with increased risk of severe hypoglycemia and increased rate of hospitalization.

A Randomized Trial of Arthroscopic Surgery for Osteoarthritis of the Knee	Arthroscopic surgery is widely used for osteoarthritis of the knee even in the face of scant evidence of its efficacy. This failed to show a benefit of arthroscopic surgery for treatment of osteoarthritis of the knee as assessed by WOMAC scores
Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus	Fibrate therapy has long been used in the treatment of dyslipidemia in type II diabetes. Though statins are considered primary therapy to reduce the risk of cardiovascular events, rates remain elevated despite use. Two large previous studies of fibrate therapy in type II diabetics conflicted with regard to their effect on cardiovascular events. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Lipid study demonstrated here that statin and fibrate combination therapy did not differ in outcomes compared with statin therapy alone at similar levels of serum lipids.
Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease	Many patients with persistent symptoms of Lyme disease receive prolonged courses of antibiotics, although the effectiveness of this practice remains unknown. This randomized, placebo-controlled, double-blinded trial failed to show any significant improvement in symptoms after a prolonged 90- day course of antibiotics in patients with persistent symptoms.
Calcium plus Vitamin D Supplementation and the Risk of Fractures	Observational evidence and data from randomized clinical trials suggested that calcium or vitamin D supplements or both may slow bone loss and reduce the risk of falls. However, in this randomized clinical trial involving 36,000 postmenopausal women, calcium with vitamin D supplementation did not

	significantly reduce hip fracture, and increased the risk of kidney stones

Consider our mastectomy data from Connecticut and Massachusetts above. Rates are down in both states, more dramatically in Connecticut, even though Medicare enrollment is up. Does this mean 20 or 30% of the Connecticut mastectomies performed in 2006 – 2010 (and earlier – I didn't include those data to keep the above chart easy-to-read) were performed in error (Prasad's term)?

That's in addition to the rate discrepancy between Connecticut and Massachusetts.

Why this decision making process is so important Part 3
Al Mulley and the problem of patient preference misdiagnosis: well informed patients often prefer treatments that differ from what their doctor thought they would want

Dr. Albert Mulley and his team from Dartmouth's Geisel School of Medicine evaluated the phenomenon and impact of physician attempts to diagnoses patient treatment preferences. [230] Patients who learn of all their treatment options, it turns out, often choose very differently from their physicians, or indeed, from what their physicians would expect them to choose.

Mulley summarizes his conclusion this way:

> Well-informed patients consume less medicine – and not just a little bit less, but much less. When doctors accurately diagnose patient preferences, an enormous source of waste – the delivery of unwanted services – is eliminated. It is particularly notable that when doctors accurately diagnose the preferences of patients struggling with long-term conditions, those patients are far more likely to keep their conditions under control, leading to fewer hospitalizations and emergency department visits.

But rushed doctors treat as *they think* the patient wants. This 'silent misdiagnosis' harms both patients and the system:

- It harms patients by providing care to them that they would not have chosen had they been better informed. Patients, according to Mulley, can suffer just as much from a missed *preference* diagnosis as from a missed *medical* one.
- It harms the entire system when doctors select more aggressive, invasive and expensive treatments than the patients themselves would, thus increasing overall

[230] http://www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/patients-preferences-matter-may-2012.pdf . See especially page 9, source of quote in the next paragraph

costs. ‘Patients choose fewer treatments when fully informed’ according to Mulley, a conclusion reached in other studies. [231]

This echoes Wennberg’s suggestion above about specialist enthusiasm for surgery and Lazris’s about the system promoting the more aggressive care far too often.

Mulley estimated the overall system savings from better patient preference diagnoses at 15 – 20%, but this comes with a huge caveat. He and his team evaluated the impact of improved patient preference diagnosis in the Britain’s National Health Service. The UK averages spending less than half per capita on healthcare as we do, about $3,400 per person compared to over $9,000 per American. The potential savings for our healthcare system is enormous, possibly well over that 20% estimate.

Dr. Sandeep Jauhar, cardiologist and author of ‘Doctored’ agrees with Mulley’s thesis, suggesting that healthcare reforms

> will have to focus less on payment models and more on education…better-informed patients might be the most potent restraint on overutilization …Shared decision making would be more likely to get patients the treatments they want [while helping them avoid unnecessary or inappropriate care]

Adding to this whole line of thinking, Atul Gawande, one of the key thought-leaders in this field, suggests a new role for doctors that builds on Glover, Wennberg, Prasad, Mulley and Jauhar’s thinking:

> **the ideal modern doctor should be neither paternalistic nor informative but rather interpretive, helping patients determine their priorities and achieve them** [232]

I think this is a brilliant summary of the doctor’s role. But it takes time to ‘help patients determine their priorities and achieve them’; it’s not a role one can play in a time compressed environment.

What this means for price transparency

Step 1 of our 4 step ‘how to make a wise medical care decision’ really matters. This step, in case you forgot, is ‘determine that medical care can benefit you’.

That, I think, is where our medical care system should point patients first. Prices are where our medical care system should point patients last.

Dr. Andy Lazris summarizes the problem nicely:

---

[231] See the Dartmouth Atlas of Healthcare, sections on Preference-Sensitive Care and Reflections on Variation

[232] Sheri Fink, New York Times Book Review of Gawande’s Being Mortal, November 6, 2014

an idea has blossomed within our medical thinking that equates aggressive, specialized care with good care … with enough perseverance, our healthcare delivery system is capable of virtually anything…the perception that science and technology can cure everything …[but] as little as 15% of what doctors do is backed up by valid evidence … [instead] technology is king

the public – from patients and their families to doctors and experts and politicians and journalists – perceive that more is better [233]

Knowing prices does nothing to fix this problem.

When I think of the various healthcare problems we face, and of price transparency as the solution, I am reminded of a quote I heard at a convention some years ago – sorry, can't remember exactly where or when – about healthcare: Never have so many bright and talented people worked so incredibly hard to achieve so little.

That quote and the energetic price transparency movement also remind me of Ronald Reagan's famous campaign response to a tried-and-failed political initiative of an opponent: *There you go again*.

In healthcare *'there you go again'* means yet another attempt to solve clinical problems with financial tools. It never works. Dr. Meador told us that in the beginning of this chapter.

The problems raised by attempting to solve clinical problems with financial tools

Our healthcare financing tools, commonly called 'health insurance', focus almost exclusively on 'financing' and almost totally disregard 'health'. David Dranove of Northwestern University summarized the impact of this fallacy in his book The Economic Evolution of Managed Care on cost control reforms in the 1980s and 90s: they 'utterly failed, on all accounts'.

Though there are many reasons for this, I think the two fundamental are:

- A primary financial focus almost inevitably reduces the ***amount of time*** each physician has for each patient. Time is the physician's primary inventory, one which he or she must use wisely to maximize his or her income. As the payment for each inventory unit – i.e. each minute – decreases, physicians need to maximize their income per unit. Hence, they see more patients per hour or day.

  Michael Porter, Harvard Business School's great business strategy professor, put this succinctly in his 2006 book Redefining Healthcare: Without the discipline of

[233] Lazris, Curing Medicare, page xviii

value-based competition on results, carriers have incentive to reduce the time physicians spend with patients. [234]

Price lists and price transparency programs take us exactly where Porter warned we don't want to go. We need to focus on outcomes, not prices, to improve outcomes. We cannot improve value (outcomes per dollar spent) otherwise and we'll probably end up decreasing it.

- Financial / price based solutions lead to 'simplistic actions such as across-the-board cuts in expensive services, staff compensation, and head count' according to Porter. [235] More succinctly, he says,

  'It is a well-known management axiom that what is not measured cannot be managed or improved' [236] meaning financial solutions to clinical problems may lead to cuts that negatively impact care quality. Rather than *managing* some critical but unquantifiable care components, market pressures may lead to across the board *cuts*.

  That was, more or less, our experience with HMOs in the late 1990s and early 2000s: fairly brutal cuts and cost controls that led, among other things, to the Patient's Bill of Rights. Might we simply re-create the same experience, only this time motivated by price lists?

I'll let some physicians express all this in their own words.

Dr. Vikas Siani, President of the Lown Institute, suggests that publishing prices lists will put more pressure on clinicians to improve their efficiency. This will limit the amount of time for each patient's care and serve to erode, not enhance, the doctor-patient relationship.[237]

Dr. Joshua Fenton of UC Davis Medical School, lead author of a study that concluded ''Patient satisfaction is linked to higher healthcare expenses and mortality, study of 50,000 people over 7 years' claims [238]

Doctors may order requested tests or treatments to satisfy patients rather than out of medical necessity, which may expose patients to risks without benefits. A

---

[234] I wrote this quote in my notes while reading Porter and Teisberg's Redefining Healthcare, but can't find the exact reference. This article in the Harvard Business Review says pretty much the same thing. https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care

[235] Ibid

[236] https://hbr.org/2011/09/how-to-solve-the-cost-crisis-in-health-care

[237] http://www.doconomics.com/blog/?p=4647

[238] http://www.ucdmc.ucdavis.edu/publish/news/newsroom/6223

> better approach is to explain carefully why a test or treatment isn't needed, but that takes time, which is in short supply…

…and which may decrease in supply under the increased billing pressures that result from excessive price considerations.

Publishing prices absent the critical and, as yet poorly developed quality metrics may make this situation worse, not better. The net result may be *more* unnecessary tests and treatments, not fewer according to Dr. Jauhar who says

> There is no more wasteful entity in medicine than a rushed doctor.[239]

To save time, he says, doctors order more tests or refer to more specialists. This adds costs and risks; it doesn't decrease them.

Time compressed physicians have less time to develop personal relationships with each patient. This leads, according to a study of 20,000 diabetics and their care givers, to less empathy for patients and poorer outcomes. [240]

- Patients of high empathy doctors had about 35% fewer metabolic complications like hyperglycemia or diabetic comas.
- Empathy means sharing feelings with other people, not belittling, undermining or judging, according to Dr. Rana Awdish, a critical care physician at Henry Ford Hospital who's involved in hospital's empathy program. These skills can be taught and practiced, she says, but this requires emotional availability on part of physician, something he or she needs time with patients to develop.
- Dr. Jauhar addresses the empathy issue from a typical physician's point of view: 'Among my colleagues I see an emotional emptiness created by the relentless consideration of money.' [241]

Kaplan and Haas, in their 2014 Harvard Business Review article 'How Not to Cut Health Costs' give an example:

- Starting kidney dialysis with a fistula (a surgical procedure to connect to an artery or vein) rather than catheter generates better outcomes, meaning longer lives with fewer complications.
- Patients starting at optimal times in their disease progression cost tens of thousands of dollars less per year than otherwise.

[239] Jauhar, New York Times, 7/20/14

[240] Bakalar, NY Times, Doctor Empathy a Factor in Diabetes Care

[241] Jauhar, Doctored, page 170

- One nephrologist said that spending 30 minutes more per patient with advanced kidney disease could dramatically improve rate of fistula or graft starts, *but there was no time or compensation for the discussion*.
- Publishing nephrology office price lists will, suggest these authors, take us in the wrong direction, generate more patient harm and ultimately cost our system more.

Actions like helping patients choose doctors based on price destroys healthcare system value.

But actions that (1) increase the amount of time physicians have with patients and that (2) enhance the doctor-patient relationship, that (3) help doctors diagnose preferences better and that (4) help patients choose effective care based on their preference and high quality outcome studies, add value.

How to turn price transparency from value-destroying to value-creating

Our definition of value includes two components: costs and outcomes, value being measured as outcomes per dollar spent. Focusing only on spending will probably decrease systemic value by reducing outcomes, for all the reasons above.

Including critical outcome factors along with prices can turn this positive, into a value creating exercise. I'll list some components below as examples. The chapter on Decision Aids goes into this in much more detail.

Consider first **birthing**, about 10% of non-Medicare hospital income. Along with price lists by hospital, an informed patient would need to know

- Infant mortality rates by hospital
- Infant and maternal readmission rates
- C-section rates
- Plus have some indication of whether or not each hospital's catchment area population was abnormal in some critical respect.

For **preventive care**, a wise patient would need to know

- Mortality and morbidity rates both with and without the preventive care
- Harm rates from the preventive care such as false positives and test and treatment harms
- Plus have an ability to understand what all these numbers and statistics really mean.

For **hospital choice**, patients need to know

- Infection rates
- 30 and 60 day readmission rates
- Tendency / process information by hospital per 1000 people in each hospital's catchment area, similar to Dartmouth Atlas information
- Volume of similar patients treated annually. Though an imprecise metric, care quality correlates relatively well with care quantity, and the hospitals performing the highest number of similar surgeries annually tend to generate the best patient outcomes.

For **surgeon choice**, patients need to understand

- Infection rates, complication rates, mortality rates, return-to-operating room rates and hospital readmission rates by surgeon / by procedure
- It does not seem fair that hospitals should be privy to this important information while prospective patients, whose health could be influenced by it are not, says Dr. Paul Ruggieri, general surgeon and former clinical instructor at Harvard Medical School. [242]
- Absent that information, patients need volume rates by surgeon. 'Patients can improve their chances of survival substantially – even at hospitals with high volumes of a procedure - by selecting surgeons who perform the operations frequently,' according to Dr. John Birkmeyer, former Chief of General Surgery at Dartmouth – Hitchcock Medical Center in New Hampshire.

For **pharmaceuticals**, note that the Americans average about 13 prescriptions / capita / year, double other OECD countries that generate similar or better population statistics.

- Several new Decision Aid reference sources provide useful drug information though in different forms. I particularly like Number Needed to Treat and Harm analyses. I'll discuss much more of this in the chapter on Decision Aids

Patients who know this quality information can use their doctors as 'interpreters' (Gawande's term) to help them determine which care they really want and which process they prefer. Prices can have a role in those discussions but, I suggest, probably a relatively limited one.

Conclusion

Good health is cheaper than poor health. That's both axiomatic and true.

[242] Ruggieri, The Cost of Cutting, page 127

Activities that get patients healthier are almost always less expensive than activities that either keep people unhealthier or do not positively impact health.

Well informed patients who understand their options tend to cost less than poorly informed patients. Well informed patients who use our 4-Step Decision Process will chose care wisely by balancing the likely benefits against the likely harms. They will use outcome data from comparative studies to help them make their decisions, consult with their physicians about options and alternatives and ultimately end up healthier.

Poorly informed patients assume that more medical care is better medical care, tend to assume higher likelihoods of benefit and lower of risk than are true, and are ultimately somewhat less likely to end up in good health.

Turning patients from poorly informed to well informed saves money. Shopping by price, especially for medical interventions that do not benefit patients, does not.

I conclude that Price Transparency is value-creation neutral:

- Listing prices alone, absent the critical quality indicators discussed above and in detail elsewhere in this book, probably destroys value.
- But listing prices *along with* those critical quality metrics, and using prices to engage patients in a discussion of care quality can increase system value.

It's too early in this process to know where this is headed and to issue a definitive conclusion.

[1] Richard Harris, Rigo Mortis and John Wennberg, Tracking Medicine for example.

[1] See the Dartmouth Atlas of Healthcare for example on this.

[1] State of Washington 2018 report First Do No Harm. I used this source for the other examples in this section also.

[1] Wennberg, Tracking Medicine. He estimates that patients have options about 85% of the time.

[1] See the Dartmouth Atlas of Healthcare and various research papers from the Dartmouth Institute for Health Policy and Clinical Practice, for example. Also David Cutler's estimate in The Quality Cure, page 20.

[1] See Wennberg, Tracking Medicine, Chapter 1

[1] HHS, Quick Guide to Health Literacy, https://health.gov/communication/literacy/quickguide/factsbasic.htm

[1] Mulley, et al, Patient Preferences Matter, Kings Fund and the Dartmouth Center for Health Care Delivery Science, 2012, page 9

Review Questions

Answers on next page

1. Do prices among vendors vary much for the same medical service?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

2. Can you determine which vendor provides the highest quality medical services from price lists?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

3. Can a patient determine if he or she will benefit from a specific medical service by learning its price?

    a. Yes
    b. No
    c. Only in New Hampshire
    d. Rarely in New Hampshire

4. About how much ineffective or harmful medical care exists in this country?

    a. About 2% of medical care is ineffective or wasteful
    b. About 40 – 50% of medical care is ineffective or wasteful
    c. About 97.8% of medical care is ineffective or wasteful
    d. Well over 100% of medical care is ineffective or wasteful

5. This text suggested 3 reasons that explain why medical care is sometimes ineffective or wasteful. Which below is NOT one of those reasons?

    a. Physicians rely on hunches, not science, too often
    b. Medical care that has not been subjected to comparative studies is proven ineffective or harmful about half the time when subjected to those studies
    c. Physicians too frequently treat patients according to physician preference, not patient preferences
    d. Doctors are poorly trained in this country

6. This text suggested a Four Step Process for making wise medical care decisions. Which below is Step 1 of that process?

    a. Determine if medical care provides more benefits than harms or than doing nothing

b. Pray
c. Ask a trusted friend or relative what to do
d. Learn as much as you possibly can about the anatomical and physiological causes of your medical problem

7. Which below is NOT an element of the Four Step Process?

a. Determine which treatment process you prefer
b. Determine which doctor and hospital generates the best outcomes for your preferred process
c. If two providers generate the same outcomes from your preferred process, consider prices
d. Pray

8. Which, below, is *most likely* to happen if medical prices become widely known to patients?

a. Doctors will spend less time with each patient
b. Our national 30 day hospital readmission rate will drop
c. Our infant mortality rate will drop
d. Americans will live longer

9. Which, below, is *least likely* to happen if medical prices become widely known to patients?

a. Care quality will improve
b. Prices for many ineffective treatments will fall
c. Doctors will advertise the prices of their (often ineffective or harmful) services
d. Hospitals will advertise the prices of their (often ineffective or harmful) services

10. Americans seem to perceive that more medical care is better and that higher technology care is better than lower. How will posting prices affect these perceptions?

a. It won't
b. It may reduce moral hazard when people understand what care costs
c. It may induce more moral hazard when people learn true care costs
d. It may incent people to drop insurance coverage

Review Questions

Correct answers in bold

1. Do prices among vendors vary much for the same medical service?

a. Yes
b. No
c. Only in New Hampshire
d. Rarely in New Hampshire

2. Can you determine which vendor provides the highest quality medical services from price lists?

a. Yes
b. No
c. Only in New Hampshire
d. Rarely in New Hampshire

3. Can a patient determine if he or she will benefit from a specific medical service by learning its price?

a. Yes
b. No
c. Only in New Hampshire
d. Rarely in New Hampshire

4. About how much ineffective or harmful medical care exists in this country?

a. About 2% of medical care is ineffective or wasteful
b. About 40 – 50% of medical care is ineffective or wasteful
c. About 97.8% of medical care is ineffective or wasteful
d. Well over 100% of medical care is ineffective or wasteful

5. This text suggested 3 reasons that explain why medical care is sometimes ineffective or wasteful. Which below is NOT one of those reasons?

a. Physicians rely on hunches, not science, too often
b. Medical care that has not been subjected to comparative studies is proven ineffective or harmful about half the time when subjected to those studies
c. Physicians too frequently treat patients according to physician preference, not patient preferences
d. Doctors are poorly trained in this country

6. This text suggested a Four Step Process for making wise medical care decisions. Which below is Step 1 of that process?

a. Determine if medical care provides more benefits than harms or than doing nothing
b. Pray
c. Ask a trusted friend or relative what to do
d. Learn as much as you possibly can about the anatomical and physiological causes of your medical problem

7. Which below is NOT an element of the Four Step Process?

a. Determine which treatment process you prefer
b. Determine which doctor and hospital generates the best outcomes for your preferred process

c. If two providers generate the same outcomes from your preferred process, consider prices
d. Pray

8. Which, below, is *most likely* to happen if medical prices become widely known to patients?

a. Doctors will spend less time with each patient
b. Our national 30 day hospital readmission rate will drop
c. Our infant mortality rate will drop
d. Americans will live longer

9. Which, below, is *least likely* to happen if medical prices become widely known to patients?

a. Care quality will improve
b. Prices for many ineffective treatments will fall
c. Doctors will advertise the prices of their (often ineffective or harmful) services
d. Hospitals will advertise the prices of their (often ineffective or harmful) services

10. Americans seem to perceive that more medical care is better and that higher technology care is better than lower. How will posting prices affect these perceptions?

a. It won't
b. It may reduce moral hazard when people understand what care costs
c. It may induce more moral hazard when people learn true care costs
d. It may incent people to drop insurance coverage

---

[i] Richard Harris, Rigo Mortis and John Wennberg, Tracking Medicine for example.

[ii] See the Dartmouth Atlas of Healthcare for example on this.

[iii] State of Washington 2018 report First Do No Harm. I used this source for the other examples in this section also.

[iv] Wennberg, Tracking Medicine. He estimates that patients have options about 85% of the time.

[v] See the Dartmouth Atlas of Healthcare and various research papers from the Dartmouth Institute for Health Policy and Clinical Practice, for example. Also David Cutler's estimate in The Quality Cure, page 20.

[vi] See Wennberg, Tracking Medicine, Chapter 1

[vii] HHS, Quick Guide to Health Literacy, https://health.gov/communication/literacy/quickguide/factsbasic.htm

[viii] Mulley, et al, Patient Preferences Matter, Kings Fund and the Dartmouth Center for Health Care Delivery Science, 2012, page 9