

# **Health Ins Risks and Reforms Connecticut**

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## Table of Contents

Preface .....	Page 3
Introduction.....	Page 4
Part 1: Health Insurance Risks	
Risks, costs and causes.....	Page 13
Part 2: The Health Insurance System	
Employer Based Health Insurance.....	Page 59
Components of a Health Insurance Premium.....	Page 94
Deductibles and Plan Management.....	Page 141
Part 3: Healthcare Reforms	
The Medicare Modernization Act of 2003.....	Page 187
Extending the Med Modernization Act with HRAs and ICHRAs.....	Page 233
Extending the Med Modernization Act with Association Health Plans.....	Page 240
The Affordable Care Act.....	Page 255
Extending the ACA, Biden’s Inflation Reduction Act.....	Page 311
Overview of Health Insurance Reforms Since 2000.....	Page 340

## 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 leper 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](mailto: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’<sup>1</sup> and ‘insane’<sup>2</sup> 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.<sup>3</sup>

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

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<sup>1</sup> See Richmond and Fein, *The Healthcare Mess*, 2005. Both gentlemen were Harvard Medical School professors, with Richmond the US Surgeon General under President Carter.

<sup>2</sup> 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.

<sup>3</sup> 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 1<sup>st</sup> 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**.<sup>4</sup>

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.

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<sup>4</sup> 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.<sup>5</sup>

'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:<sup>6</sup>

- 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'

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<sup>5</sup> See Vinay Prasad's insightful study A Decade of Reversal, Mayo Clinic Proceedings, 2013

<sup>6</sup> 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.<sup>i</sup>

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,<sup>ii</sup> things like

Imaging for eye disease, overused according to one large study about 74% of the time,<sup>iii</sup>

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.<sup>iv</sup> 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. <sup>v</sup>

- How to identify, explore and compare treatment options, available to patients about 85% of the time. <sup>vi</sup> 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. <sup>vii</sup>

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: <sup>viii</sup>

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.<sup>7</sup>

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 7<sup>th</sup> 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.

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<sup>7</sup> 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.<sup>8</sup>

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.<sup>9</sup> 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.<sup>10</sup>

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

<sup>8</sup> CDC Diabetes Basics <https://www.cdc.gov/diabetes/basics/getting-tested.html>

<sup>9</sup> Boston Globe, Nov 22, 2021 'The Obesity Pandemic Has Made Covid Much More Deadly'

<sup>10</sup> 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 as 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. <sup>11</sup>

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<sup>12</sup>, the syndrome increases your risk of developing

- Coronary heart disease
- Erectile dysfunction
- 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 preeclampsia, 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.<sup>13</sup>

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<sup>11</sup> AARP, Metabolic Syndrome, Levine

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

<sup>13</sup> 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: diabetes.<sup>14</sup> 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 diabetes, 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.<sup>15</sup> 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.

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<sup>14</sup> Cleveland Clinic, November 2021 'Diabetes: How Obesity is Related to Diabetes', slightly edited in the following quote.

<sup>15</sup> 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.<sup>16</sup> He had a BMI of 29.2, almost obese. He gained about 1.5 pounds per year. According to online calorie consumption estimates<sup>17</sup>, 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 /

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<sup>16</sup> 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](http://www.Calculator.net)

Daily calories to gain 1.5 lbs / year from [www.Calculators.net](http://www.Calculators.net)

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

<sup>17</sup> In this case I used [www.calculator.net](http://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.<sup>18</sup>

We know that Joe earns \$1,144 / week – that's \$59,488 per year - thanks to various Bureau of Labor Statistics studies.<sup>19</sup> 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)<sup>20</sup> 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.<sup>21</sup>

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

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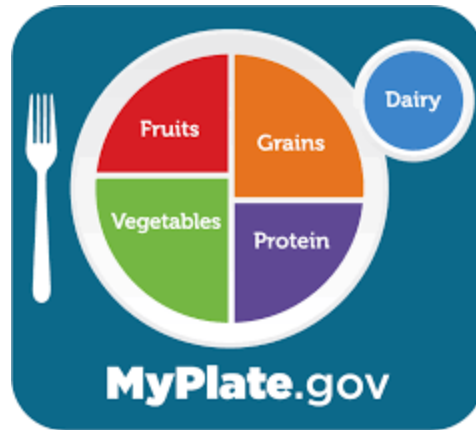
<sup>18</sup> US Dept of Agriculture estimate 2021, [https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=76967#:~:text=In%202021%2C%20U.S.%20consumers%20spent,from%20home%20\(5.1%20percent\)](https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=76967#:~:text=In%202021%2C%20U.S.%20consumers%20spent,from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

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

<sup>20</sup> 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,th e%20median%20for%20White%20men.>

<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup>

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:<sup>24</sup>

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

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<sup>22</sup> 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>

<sup>23</sup> 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>

<sup>24</sup> What's On Your Table: How America's Diet Has Changed Over the Decades, Drew Desilver, Dec 13, 2016

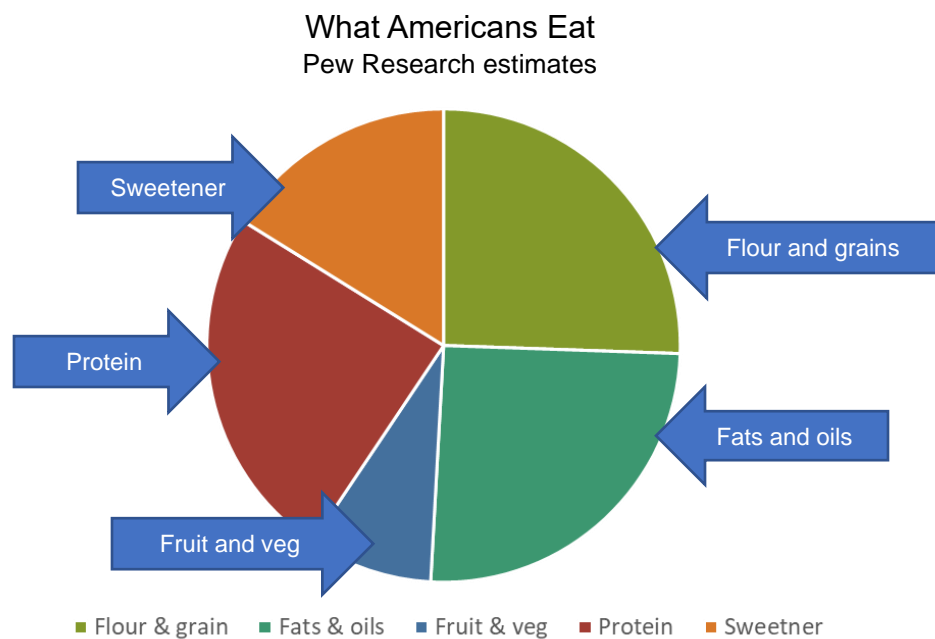
about 40 gallons of soft drinks per person annually, 72% non-diet.<sup>25</sup> Soft drink sales run about \$318 billion per year. Not on the Food Plate.

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.<sup>26</sup>

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.

<sup>25</sup> Diet vs regular soda percent estimates from statistica.com

<https://www.statista.com/statistics/1133019/carbonated-soft-drinks-regular-vs-diet-volume-us/>

<sup>26</sup> 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 diet below comes to 2239 calories for a day (very close to our theoretical goal of 2237); the typical diet comes to 2648 calories (very close to our daily estimate of 2650). Some minor rounding issues, a calorie or penny here or there. But 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
- .3 lb chicken breast @ 748 calories per pound = 224 calories, \$1.20
- 1 pita = 90 calories, \$.37
- Apple = 95 calories, \$.66
- 623 calories
- \$7.47 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 (872 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 (.5 pint) = 115 calories, \$1.00
- Strawberries (.5 lb.) = 74 calories, \$2.50
- 1061 calories
- \$11.97 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 decisions. 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. 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.<sup>27</sup> 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.

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.

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<sup>27</sup> This analysis comes from Barth, Congress Finally Passed a New Farm Bill, January 7, 2019, Modern Farmer

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.<sup>28</sup> 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 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

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<sup>28</sup> 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>

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<sup>29</sup> and a Nestle Crunch Bar 66 milligrams<sup>30</sup> and why Jif peanut butter contains 2 grams of sugar per serving<sup>31</sup> and Barilla pasta 7 grams<sup>32</sup>.

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.

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

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<sup>29</sup> <https://www.hersheyland.com/products/hersheys-milk-chocolate-candy-bar-1-55-oz.html>

<sup>30</sup> <https://www.heb.com/product-detail/nestle-crunch-candy-bar/98268>

<sup>31</sup> <https://www.jif.com/peanut-butter/creamy/simply-jif>

<sup>32</sup> <https://www.heb.com/product-detail/barilla-traditional-sauce/1637428>

in 2012 but 78,092 in 2020.<sup>33</sup> 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.

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,

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

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.<sup>34</sup>

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.<sup>35</sup> "The study shows that shows that exercise in general, but especially interval training, is able to partially or completely reverse metabolic syndrome," according to lead author Arnt Erik Tjønnå.

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".<sup>36</sup>

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.

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<sup>34</sup> The Deadliest Sin, Harvard Magazine, April – May 2004

<sup>35</sup> <https://norwegianscitechnews.com/2016/08/exercise-to-combat-metabolic-syndrome/>

<sup>36</sup> 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

- 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.”<sup>37</sup> 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.”

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.<sup>38</sup> 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

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<sup>37</sup> Myers et al, Physical Activity, Cardiorespiratory Fitness, and the Metabolic Syndrome, *Nutrients*, July 19, 2019

<sup>38</sup> Only 23% of adults meet guidelines, *Time Magazine*, Ducharme, June 28, 2018.

would therefore value 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.<sup>39</sup> 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.<sup>40</sup> “The relationship is nearly as strong as what you see between smoking and lung cancer.” Wow.

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.

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<sup>39</sup> Hubbard, Outside of Sleeping, Americans Spend Most of Their Time Watching TV, US News, July 22, 2021. Also Statista, 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>

<sup>40</sup> The Way We Eat Now, Craig Lambert, Harvard Magazine, May-June 2004



The average American child sees over 40,000 TV commercials per year according to estimates by the American Psychological Association.<sup>41</sup> 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.<sup>42</sup>

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:<sup>43</sup>

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

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<sup>41</sup> 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.>

<sup>42</sup> 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-statin-keeps-rising-cdc-694895.html> or <https://www.ahrq.gov/data/infographics/statin-use.html>

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

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

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.<sup>46</sup>

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.<sup>47</sup>

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.

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

<sup>45</sup> Madhursodanan, op cit

<sup>46</sup> Ibid.

<sup>47</sup> Weghuber et al, One-Weekly Semaglutide in Adolescents with Obesity, NEJM, Nov 2, 2022

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.<sup>48</sup>

- 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.<sup>49</sup>
- 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 qualify 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'<sup>50</sup>, i.e., becomes diabetic and therefore eligible for treatment.

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

- 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?

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<sup>48</sup> 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/>

<sup>49</sup> 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.

<sup>50</sup> Ibid.

- 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 8<sup>th</sup> grade, an A- average in 9<sup>th</sup> grade, a B average in 10<sup>th</sup> grade and a C- average on the first half semester report card in 11<sup>th</sup> 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 it 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:

<p><b>Before (Physical 8/2020)</b>  <b>Weight 225</b></p> <ul style="list-style-type: none"> <li>• BMI 30.5</li> <li>• BP 168/104</li> <li>• Total Cholesterol 203</li> <li>• Triglycerides 269</li> <li>• HDL 29</li> <li>• LDL 120</li> <li>• TC – HDL ratio 6.9</li> <li>• A1C 5.3</li> <li>• Heart Rate 91</li> </ul>	<p><b>Guidelines</b></p> <ul style="list-style-type: none"> <li>• Should be &lt; 25; obesity = 30+</li> <li>• Should be &lt; 150/90 (over 60 yrs old, AHA)</li> <li>• Should be &lt; 200</li> <li>• Should be &lt; 200</li> <li>• Should be &gt; 45</li> <li>• Should be &lt; 130</li> <li>• Should be &lt; 4.9</li> <li>• Should be &lt; 5.7</li> <li>• Should be 60 - 100</li> </ul>
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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:

<p><b>After (Physical 8/2022)</b>  <b>Weight 189</b></p> <ul style="list-style-type: none"> <li>• BMI 24.9</li> <li>• BP 142/80</li> <li>• Total Cholesterol 172</li> <li>• Triglycerides 83</li> <li>• HDL 44</li> <li>• LDL 112</li> <li>• TC – HDL ratio 3.9</li> <li>• A1C 5.3</li> <li>• Heart rate 61</li> </ul>	<p><b>Guidelines</b></p> <ul style="list-style-type: none"> <li>• Should be &lt; 25; obesity = 30+</li> <li>• Should be &lt; 150/90 (over 60 yrs old)</li> <li>• Should be &lt; 200</li> <li>• Should be &lt; 200</li> <li>• Should be &gt; 45</li> <li>• Should be &lt; 130</li> <li>• Should be &lt; 4.9</li> <li>• Should be &lt; 5.7</li> <li>• Should be 60 - 100</li> </ul>
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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.

Before (8/2020)	After (8/2022)
Weight 225	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

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.<sup>51</sup> 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.

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<sup>51</sup> 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 1/2 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 (\$)
<b>Healthy breakfast</b>							
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
<b>Total</b>						<b>552</b>	<b>\$ 2.58</b>
<b>Healthy lunch</b>							
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
<b>Total</b>						<b>623.43</b>	<b>\$ 7.47</b>
<b>Healthy dinner (Rice Bowl)</b>							
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
<b>Total</b>						<b>1061.84</b>	<b>\$ 11.97</b>
<b>Total Daily Calories &amp; Cost</b>						<b>2237.27</b>	<b>\$ 22.02</b>

Item	Cost / package (\$)	Servings / package	Calories / serving	Cost / calorie	# servings	Total # calories	Total cost (\$)
<b>Typical breakfast</b>							
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
<b>Total</b>						<b>487</b>	<b>\$ 1.56</b>
<b>Typical lunch</b>							
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
<b>Total</b>						<b>1083</b>	<b>\$ 4.88</b>
<b>Typical dinner</b>							
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
<b>Total</b>						<b>1078</b>	<b>\$ 6.46</b>
<b>Total Daily Calories &amp; Cost</b>						<b>2648</b>	<b>\$ 12.90</b>

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### Addendum: My battle with metabolic syndrome

A version of this is available from [www.lulu.com](http://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 as 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.<sup>52</sup> 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.”<sup>53</sup>

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

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<sup>52</sup> 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>.

<sup>53</sup> 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.<sup>54</sup> 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.

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<sup>54</sup> 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 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.

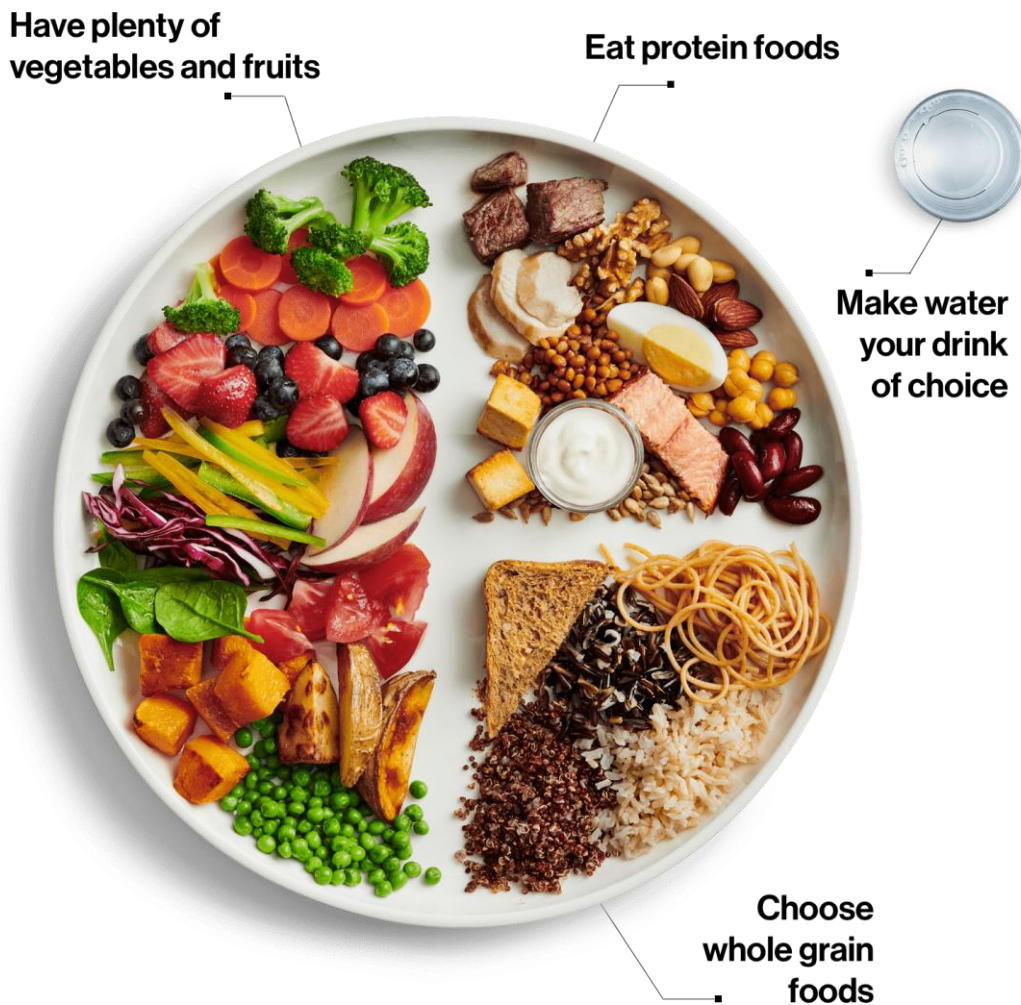
Plus I don't have that sugary thirst like I used to after eating cookies or cake.

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.<sup>55</sup> 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.

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<sup>55</sup> 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?



Causes head hunger



Removes head hunger

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.<sup>56</sup> 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.

\*\*\*\*\*

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**

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

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 bolognese 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), 1/2 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

<b>Tues</b>	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
<b>Wed</b>	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)  Total 600	Oatmeal (170) Cashews (320) 2 cups frozen fruit (140) Honey (70)  Total 700	Baked apple & cinn (200) Yogurt & Ovaltine (200)  Total 400	2100
<b>Thurs</b>	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
<b>Fri</b>	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
<b>Sat</b>	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)	Beans (200) Rice (200) 1/3 cup cashews (250) Salad and dressing (150) Blueberries (100)	Baked apple & cinn (200) Yogurt & Oval (100) Orange (100)  Total 400	2260



		Total 580	Total 900		
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**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 4<sup>th</sup> 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		<b>-.9 lb. per week</b>

## Part 2: The Health Insurance System

### Employer Based Health Insurance 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 unexpected 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.<sup>57</sup>

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.

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<sup>57</sup> 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' <sup>58</sup> 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.

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<sup>58</sup> 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.<sup>59</sup>

**First**, it is tremendously expensive. In 2021, for example, the average family health insurance annual premium was \$22,221<sup>60</sup> up about \$17,000 from \$4,969 in 2011.<sup>61</sup> 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.<sup>62</sup> This system, as the two previously mentioned, also has its own access rules, reporting rules, prices and payment rules

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<sup>59</sup> 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.

<sup>60</sup> KFF.org 2021 Employer Health Benefits Survey

<sup>61</sup> How much does health insurance cost, Nov 2, 2011, eHealth news release

<sup>62</sup> 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.<sup>63</sup>

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.<sup>64</sup>

- 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.

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<sup>63</sup> 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.

<sup>64</sup> 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'.<sup>65</sup>

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.

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<sup>65</sup> 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.<sup>66</sup>

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<sup>66</sup> 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.<sup>67</sup>

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.<sup>68</sup> Divide \$197 by \$2.53 to see this.

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<sup>67</sup> See The American Healthcare Paradox by Bradley and Taylor for more on this. I only summarized their research here.

<sup>68</sup> 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.<sup>69</sup>

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.<sup>70</sup>

### **'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.<sup>71</sup>

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**.

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<sup>69</sup> Wage estimates from the Bureau of Labor Statistics 'Usual Weekly Earnings of Wage and Salary Workers, Third Quarter 2019'

<sup>70</sup> 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.

<sup>71</sup> 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'.<sup>72</sup>

Consider this story from Bradley and Taylor's book *The American Healthcare Paradox* about Joe, a 28 year old, very low income diabetic:<sup>73</sup>

- 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

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<sup>72</sup> See Bradley and Taylor, *The American Healthcare Paradox* for a longer explanation of this point.

<sup>73</sup> 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.<sup>74</sup>

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'.<sup>75</sup>

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.<sup>76</sup> The business problem for Baylor University Hospital in Dallas was that it didn't have enough money to pay its bills.

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<sup>74</sup> 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](http://elsa.berkeley.edu/pub/users/webfac/held/157_VC2.pdf)

<sup>75</sup> See Gawande's second book 'Better', chapter entitled Piecework

<sup>76</sup> This suggestion comes from Richmond and Fein, The Healthcare Mess, page 30.

Prior to the stock market crash, 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 choose 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 <sup>77</sup>

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

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<sup>77</sup> 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.<sup>78</sup>

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.<sup>79</sup>

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);

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<sup>78</sup> Enthoven and Fuchs, 'Employment Based Health Insurance: Past, Present and Future' Health Affairs, Nov/Dec 2006

<sup>79</sup> 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.<sup>80</sup> 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?**

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<sup>80</sup> 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:

#### World Economy, 1945 – 2000 +/-

Little foreign competition for American manufacturers;

Japan and Western Europe needed time to rebuild;

US manufacturers could keep prices high and afford health benefits

#### Importance of Large Firms, Regulated Industries and Unions

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

<u>Year</u>	<u>Number Medicare Enrollees</u>	<u>% of US population</u>
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 <sup>81</sup>) 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.

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<sup>81</sup> 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 <sup>82</sup>

- 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

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<sup>82</sup> 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.)<sup>83</sup> I could have included more countries but you get the idea from this limited comparison.

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<sup>83</sup> 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% <sup>84</sup> 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. <sup>85</sup> This is roughly 3x the mortgage interest tax deduction.

<sup>84</sup> Gruber & Madrian, 'Health Insurance, Labor Supply and Job Mobility' Working Paper 8817, NBER, March 2002

<sup>85</sup> Health Affairs *Health Policy Brief*, August 1, 2013 'Premium Tax Credits', [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=97](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.<sup>86</sup>

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.<sup>87</sup>

### **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

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<sup>86</sup> Turner, Capretta, Miller and Moffit, Why ObamaCare is Wrong for America, Forward

<sup>87</sup> 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.' <sup>88</sup>

Or, as Lady Macbeth might put it,

*The employer based healthcare financing system simply doesn't work. Band-aids 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!)

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<sup>88</sup> 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

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Correct answers in bold

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## 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. <sup>89</sup>

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. <sup>90</sup>

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<sup>89</sup> CNBC Meeting of the Minds: The Future of Healthcare, broadcast July, 2009

<sup>90</sup> 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. <sup>91</sup>

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. <sup>92</sup> 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.

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<sup>91</sup> Richmond and Fein, *The Healthcare Mess*, pages 94 and 92

<sup>92</sup> "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<sup>93</sup> - and to 3600 in 2017.<sup>94</sup>

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<sup>93</sup> 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

<sup>94</sup> Several articles refer to a Business Insider study that suggested 3600 calories per day. I've seen 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.<sup>95</sup>
- 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.<sup>96</sup>
- Adults with more education are more likely to meet the 2008 Physical Activity Guideline for aerobic activity than adults with less education.<sup>97</sup>
- 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.<sup>98</sup>

Obesity, caused largely by dietary and exercise behaviors, increases healthcare costs. Here are some examples courtesy of US government researchers:<sup>99</sup>

- 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.<sup>100</sup> Hypertension is a major risk factor for heart disease, stroke, congestive heart failure, and kidney disease. Dietary factors that increase

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<sup>95</sup> 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>

<sup>96</sup> 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>

<sup>97</sup> <http://www.cdc.gov/physicalactivity/data/facts.html>

<sup>98</sup> <http://www.cdc.gov/physicalactivity/data/facts.html>

<sup>99</sup> Dietary Guidelines for Americans, op cit. page 3

<sup>100</sup> Estimated Hypertension Prevalence, Treatment and Control Among US Adults,

[https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html#:~:text=Nearly%20%20out%20of%202,modifications%20only%20\(24.3%20million\).](https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html#:~:text=Nearly%20%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.<sup>101</sup>

Let's state this differently: obesity raises healthcare costs about as much as does 20 years of aging, according to one estimate.<sup>102</sup> 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.<sup>103</sup>

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.<sup>104</sup>

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.**<sup>105</sup>

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<sup>101</sup> American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018;41:917–928.)

<sup>102</sup> Strum 'The Effects of Obesity, Smoking and Drinking' Health Affairs, March 2002

<sup>103</sup>

<sup>104</sup> Obesity and the Economics of Prevention, Fit not Fat, © OECD 2010  
From Executive Summary

<sup>105</sup> 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.<sup>106</sup>

### **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.<sup>107</sup> 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.<sup>108</sup> 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.<sup>109</sup>

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 \*<sup>110</sup>
- Total Cholesterol < 200
- Triglycerides < 200
- HDL (good cholesterol) > 45
- LDL (bad cholesterol) < 130
- Total Cholesterol / HDL should be < 4.9

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<sup>106</sup> Quoted in Boston Globe, November 8, 2010, page G6

<sup>107</sup> WebMD, good summary article <https://www.webmd.com/heart/metabolic-syndrome/metabolic-syndrome-what-is-it>

<sup>108</sup> Ibid.

<sup>109</sup> National Heart, Lung and Blood Institute <https://www.nhlbi.nih.gov/health/metabolic-syndrome/living-with>

<sup>110</sup> 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 disproportionately? 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.<sup>111</sup> This expansion is stimulated, many suggest, by our federal food production subsidies that averaged \$30 billion annually from 2018 – 2020.<sup>112</sup> By some estimates, corn subsidies totaled more than \$116 billion from 1995 – 2020.

Our total corn production generated 15 billion bushels in 2020.<sup>113</sup>

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

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<sup>111</sup> 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>

<sup>112</sup> EWG Analysis <https://www.ewg.org/news-insights/news-release/2022/06/ewg-analysis-2018-2020-farmers-reaped-916b-taxpayer-funded-usda>

<sup>113</sup> 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. <sup>114</sup>

Each American, on average, consumes over **half a ton** of food that uses corn as an ingredient. Here's the breakdown: <sup>115</sup>

- 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 <sup>116</sup> (**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.” <sup>117</sup>

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

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<sup>114</sup> Michael Pollan, The Omnivores Dilemma, page 18

<sup>115</sup> From National Public Radio’s report on food consumption by correspondent Allison Aubrey, December 31, 2011

<sup>116</sup> Estimate from Chartbins.com

<sup>117</sup> Paraphrased from Pollan, Omnivores Dilemma, page 18

Europeans <sup>118</sup> - 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*. <sup>119</sup>

The US government actually recommends against eating that much meat. Here are recommendations from the US Department of Agriculture's Dietary Guidelines for Americans: <sup>120</sup>

#### 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.

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<sup>118</sup> 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.

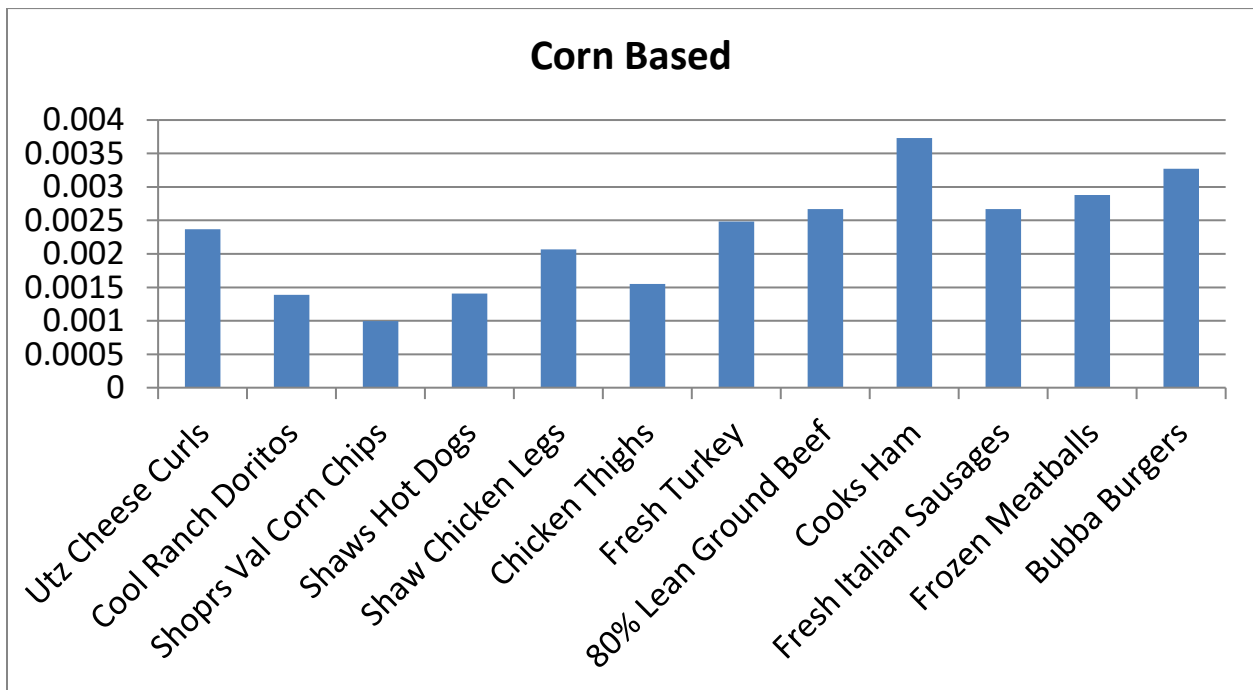
<sup>119</sup> See the USDA Dietary Guidelines for Americans, 2005 edition. They Guidelines are basically the same every iteration, and are the same as other country's guidelines.

<sup>120</sup> 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.

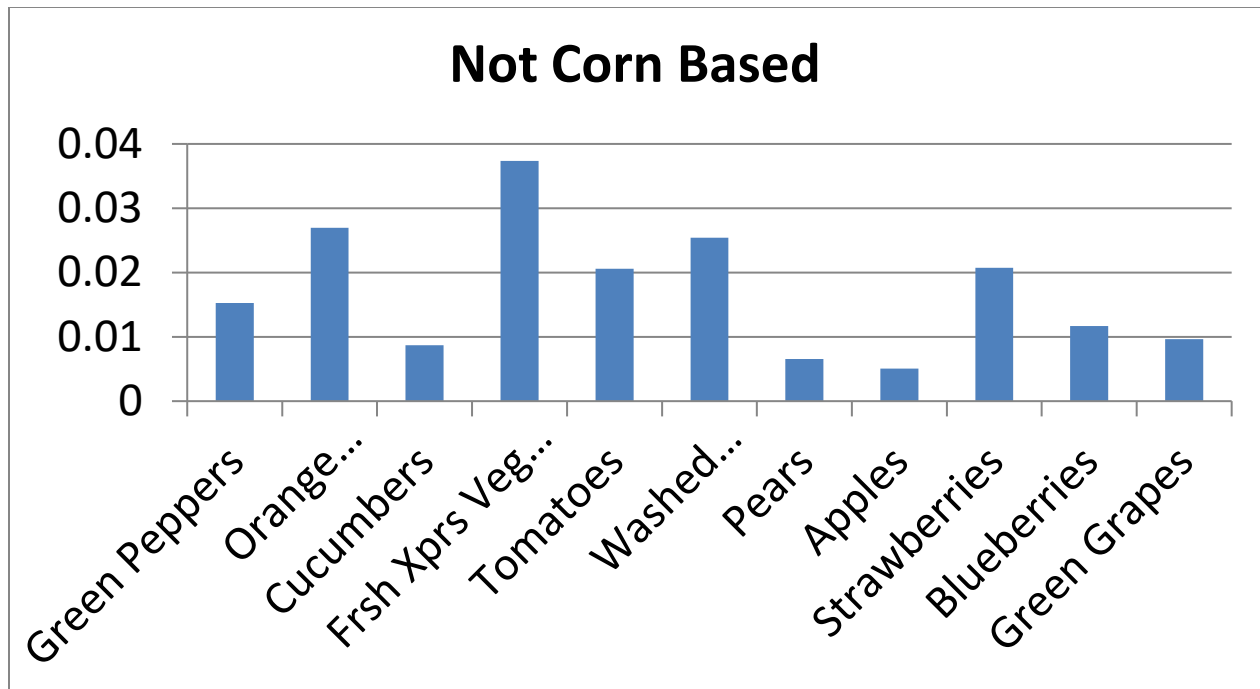
I used the relatively conservative 2700 calories / person / day, not the higher 3600 calorie estimate. My calculations below would be 33% higher using the 3600 calorie / day figure.

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.

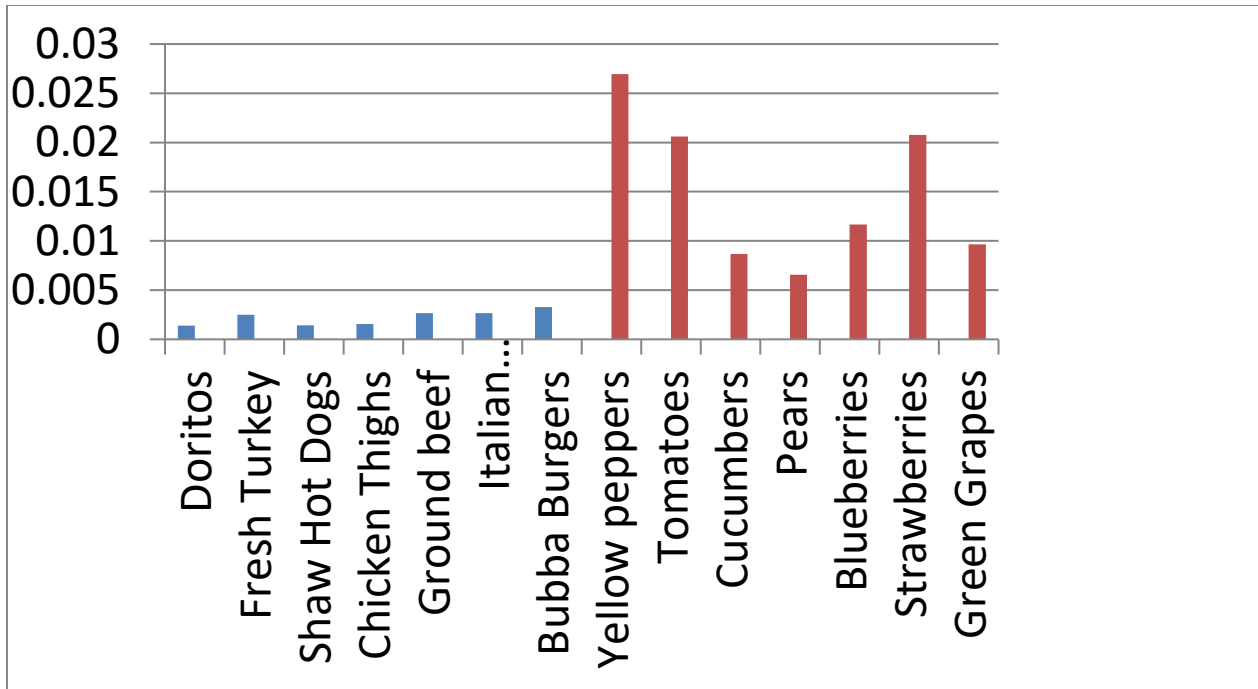
Let's assume you're a cash-strapped, low income person, trying to feed your family. You need to purchase 2700 calories of food per day to satisfy them, so when you buy the non-corn based 'healthier' foods, you choose the cheapest like apples and pears, costing about half a cent per calorie. Orange peppers, 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 Deepak Chopra and 3 other academic physicians to write in the Wall Street Journal <sup>121</sup>

*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. <sup>122</sup>

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 <sup>123</sup>

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. <sup>124</sup> Soda consumption has doubled since the 1970s to about 50 gallons per person per year. <sup>125</sup>

Michael Pollan summarized this nicely in the New York Times: <sup>126</sup>

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<sup>121</sup> Chopra et al, Alternative Medicine is Mainstream, Wall Street Journal, January 9, 2009

<sup>122</sup> *Economist* 7/9/11, If you build it, they may not come

<sup>123</sup> USDA agricultural fact book

<sup>124</sup> 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>

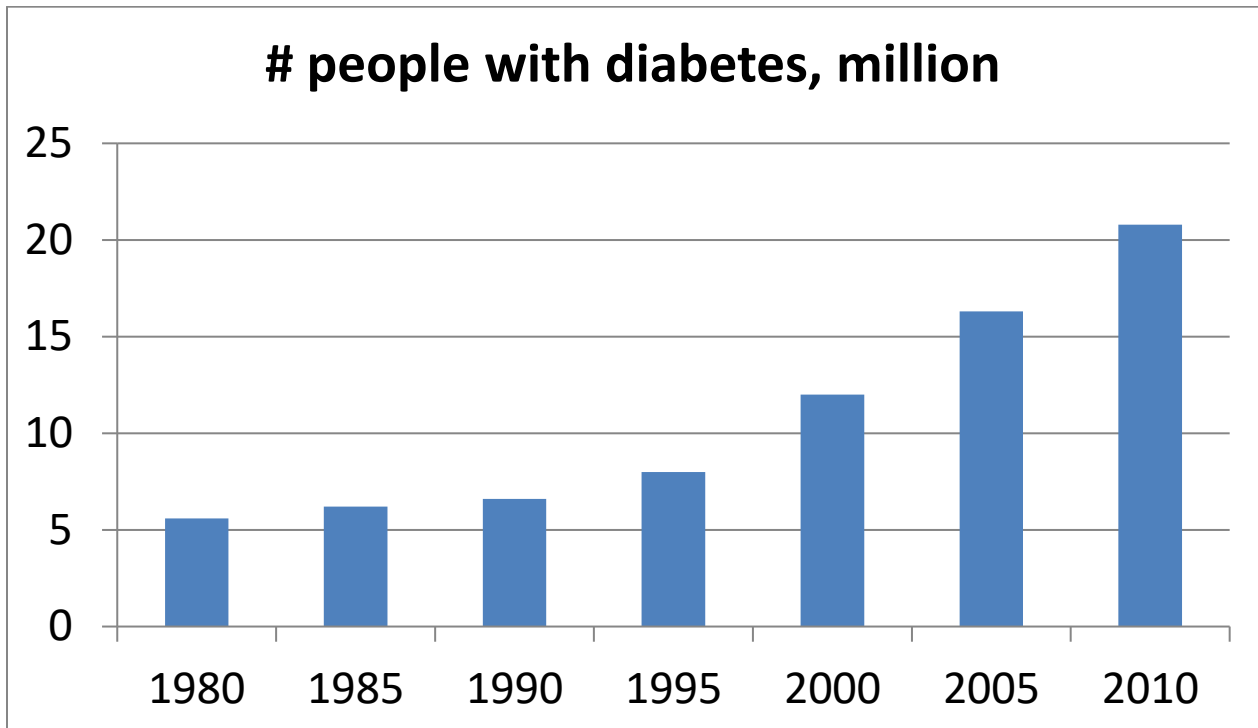
<sup>125</sup> Duffrey, Food Price and Diet, Archives of Internal Medicine, March 2010

<sup>126</sup> 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. <sup>127</sup>

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

<sup>127</sup> 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:

	<b>Sugars (grams)</b>	<b>Calories</b>	<b>Saturated Fat (grams)</b>	<b>Sodium (mg)</b>
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
<b>Totals:</b>	<b>95</b>	<b>1120</b>	<b>18</b>	<b>2220</b>
<b>US Daily Recommendation</b>	<b>25</b>	<b>2000</b>	<b>11 – 13</b>	<b>2300</b>

Or perhaps you prefer Taco Bell. Their \$2 Beefy 5-Layer Burrito Value Meal with Mountain Dew and Nacho Cheese Doritos consists of

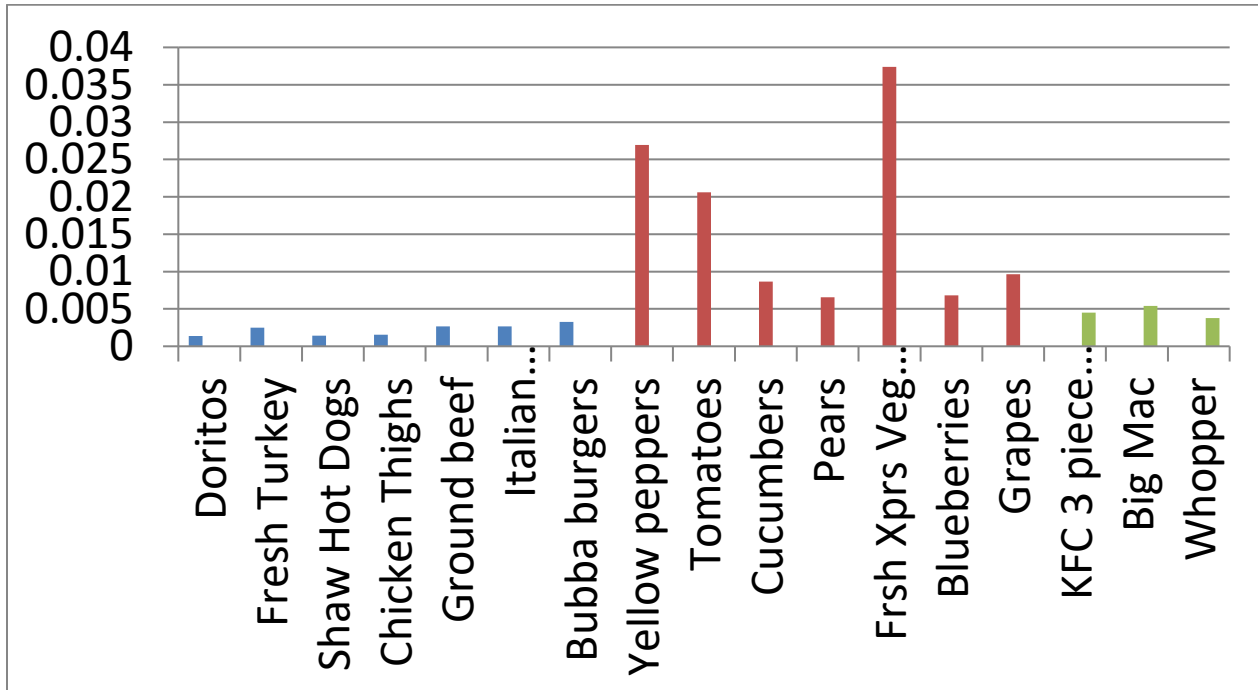
- chips (corn, subsidized)
- beef (corn based, subsidized)
- cheese (corn based, subsidized)
- tortilla (corn, subsidized)
- soda (HFCS, subsidized)

For \$2, you get 1020 calories, 35 grams of fat, 66 grams of sugar and 2000 grams of sodium.<sup>128</sup>

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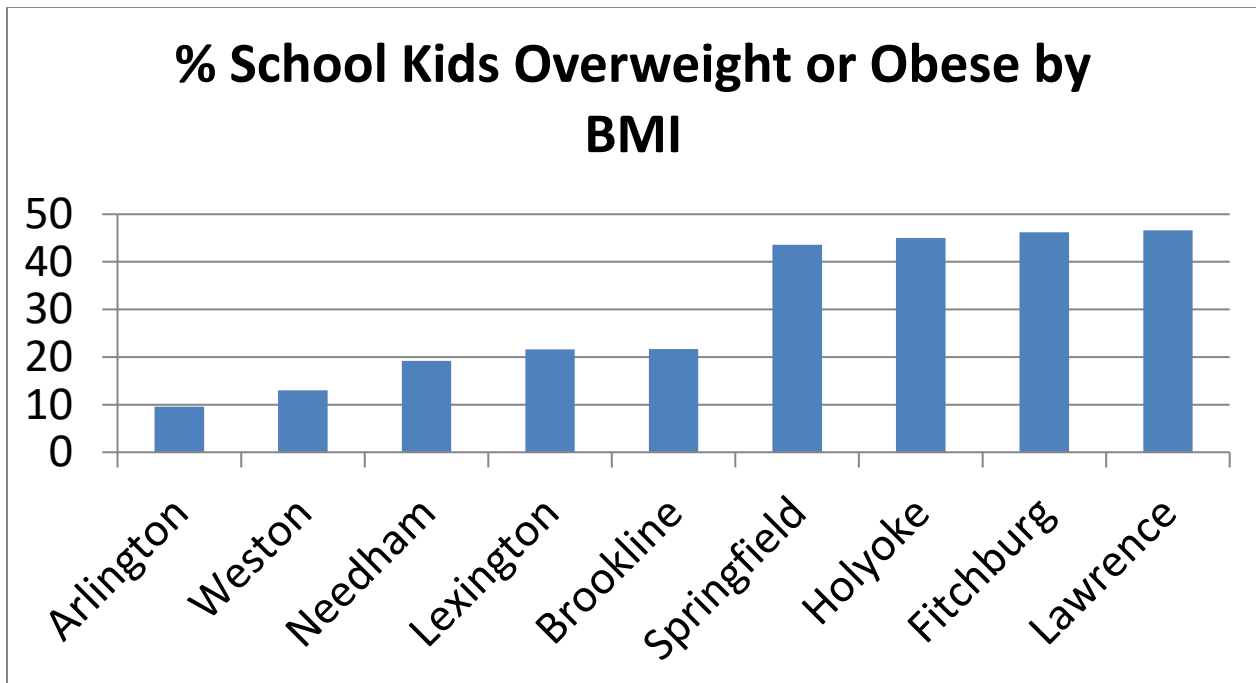
<sup>128</sup> Information downloaded from Taco Bell's website in 2010 or 2011 according to my notes. It was apparently not offered in 2015 when I wrote this chapter.

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: <sup>129</sup>

- 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

<sup>129</sup> 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 guideline 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.<sup>130</sup> 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 7<sup>th</sup> 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

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<sup>130</sup> 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.<sup>131</sup> 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.<sup>132</sup> 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.<sup>133</sup> 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).

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<sup>131</sup> Cost Effectiveness of Diabetes Interventions, National Center for Chronic Disease Prevention and Health Promotion, undated web page

<sup>132</sup> American Diabetes Association. Economic costs of diabetes in the US in 2017. *Diabetes Care*. 2018;41:917–928.)

<sup>133</sup> <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.<sup>134</sup>

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

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<sup>134</sup> <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:

Weight 225	Guidelines
• BMI 30.5	• Should be < 25; obesity = 30+
• BP 168/104	• Should be ≤50/90 (over 60 yrs old, AHA)
• Total Cholesterol 203	• Should be < 200
• Triglycerides 269	• Should be < 200
• HDL 29	• Should be > 45
• LDL 120	• Should be < 130
• TC–HDL ratio 6.9	• Should be < 4.9
• A1C 5.3	• Should be < 5.7
• Heart Rate 91	• Should be 60-100

My numbers in red, for Body Mass Index, Blood Pressure, Total Cholesterol, Triglycerides, 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<sup>135</sup> 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

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<sup>135</sup> 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.

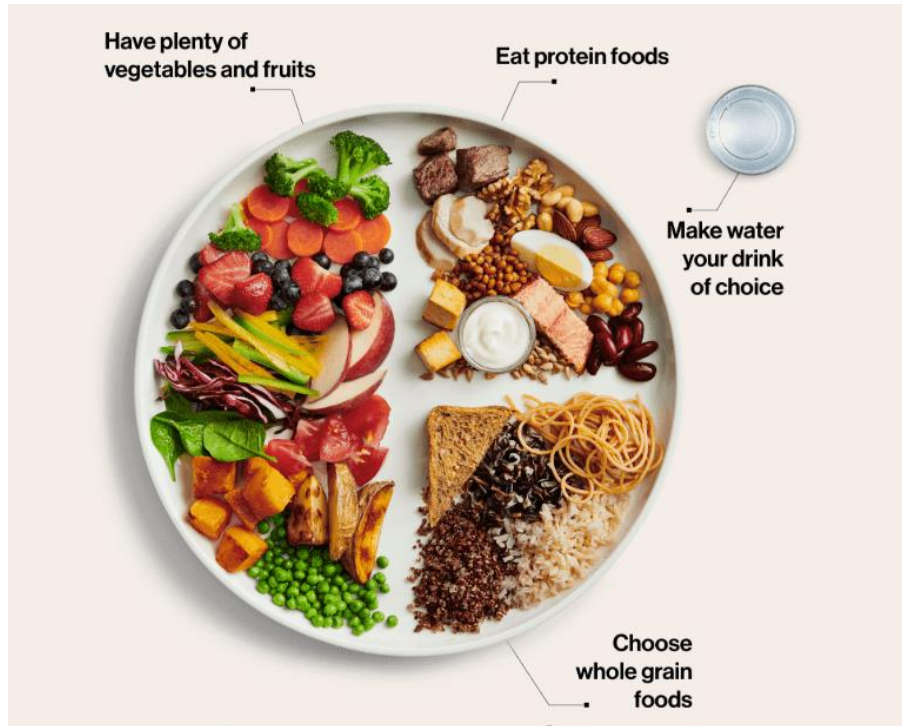
That said, my physical results / numbers acted as a wake up call to me. I was clearly in the medical syndrome arena and was unhappy about it, more-or-less the same feeling I remember from high school when I got a B on a paper that I thought was worth an A. 'I could do better.'

I considered my options and opted against nutritional consultants – too much medical care – or commercial diets, too expensive. 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.

Here, for comparison, is the US government's presentation of food consumption recommendations.<sup>136</sup> Similar message to the Canadian food plate but I find the Canadian graphic easier to grasp.

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<sup>136</sup> Dietary Guidelines for Americans 2020 – 2025, graph #4.1, page 109

## Healthy U.S.-Style Dietary Pattern for Adults Ages 19 Through 59, With Daily or Weekly Amounts From Food Groups, Subgroups, and Components

CALORIE LEVEL OF PATTERN <sup>a</sup>	1,600	1,800	2,000	2,200	2,400	2,600	2,800	3,000
FOOD GROUP OR SUBGROUP <sup>b</sup>	Daily Amount of Food From Each Group (Vegetable and protein foods subgroup amounts are per week.)							
Vegetables (cup eq/day)	2	2 ½	2 ½	3	3	3 ½	3 ½	4
	Vegetable Subgroups in Weekly Amounts							
Dark-Green Vegetables (cup eq/wk)	1 ½	1 ½	1 ½	2	2	2 ½	2 ½	2 ½
Red & Orange Vegetables (cup eq/wk)	4	5 ½	5 ½	6	6	7	7	7 ½
Bears, Peas, Lentils (cup eq/wk)	1	1 ½	1 ½	2	2	2 ½	2 ½	3
Starchy Vegetables (cup eq/wk)	4	5	5	6	6	7	7	8
Other Vegetables (cup eq/wk)	3 ½	4	4	5	5	5 ½	5 ½	7
Fruits (cup eq/day)	1 ½	1 ½	2	2	2	2	2 ½	2 ½
Grains (ounce eq/day)	5	6	6	7	8	9	10	10
Whole Grains (ounce eq/day)	3	3	3	3 ½	4	4 ½	5	5
Refined Grains (ounce eq/day)	2	3	3	3 ½	4	4 ½	5	5
Dairy (cup eq/day)	3	3	3	3	3	3	3	3
Protein Foods (ounce eq/day)	5	5	5 ½	6	6 ½	6 ½	7	7
	Protein Foods Subgroups in Weekly Amounts							
Meats, Poultry, Eggs (ounce eq/wk)	23	23	26	28	31	31	33	33
Seafood (ounce eq/wk)	8	8	8	9	10	10	10	10
Nuts, Seeds, Soy Products (ounce eq/wk)	4	4	5	5	5	5	6	6
Oils (grams/day)	22	24	27	29	31	34	36	44
Limit on Calories for Other Uses (kcal/day) <sup>c</sup>	100	140	240	250	320	350	370	440
Limit on Calories for Other Uses (%/day)	6%	8%	12%	11%	13%	13%	13%	15%

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

- BMI 24.9
- BP 142/80
- Total Cholesterol 172
- Triglycerides 83
- **HDL 44**
- LDL 112
- TC– HDL ratio 3.9
- A1C 5.3
- Heart rate 61

### Guidelines

- Should be < 25; obesity = 30+
- Should be < 150/90
- Should be < 200
- Should be < 200
- Should be > 45
- Should be < 130
- Should be < 4.9
- Should be < 5.7
- Should be 60-100

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

- BMI 30.5
- BP 168/104
- Total Cholesterol 203
- Triglycerides 269
- HDL 29
- LDL 120
- TC– HDL ratio 6.9
- A1C 5.3
- Heart rate 91

### After (8/2022)

#### Weight 189

- BMI 24.9
- BP 142/80
- Total Cholesterol 172
- Triglycerides 83
- HDL 44
- LDL 112
- TC– HDL ratio 3.9
- A1C 5.3
- 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.<sup>137</sup>

### 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.

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<sup>137</sup> 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.<sup>138</sup> 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

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<sup>138</sup> 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.<sup>139</sup> 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.<sup>140</sup> 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:

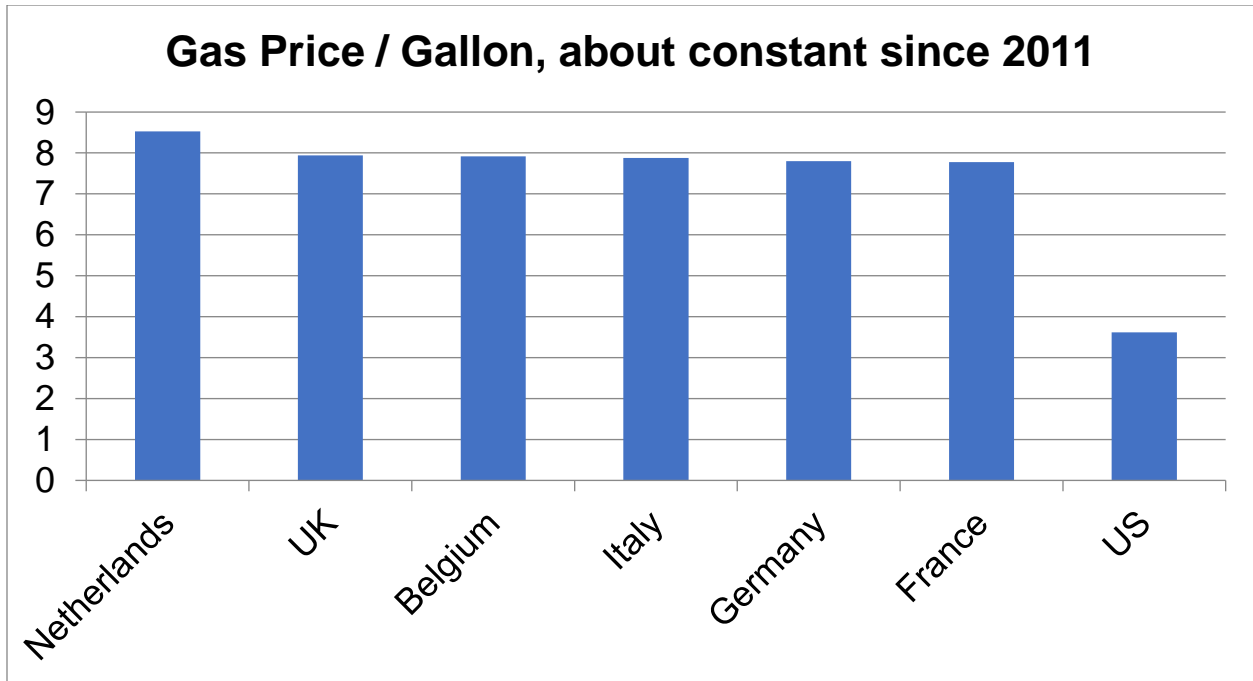
- Pass 100 homes on single acre lots = go 100 linear acres (about **4 miles** if square acres). Too far to walk. And too difficult to locate a public transportation hub nearby.
- Pass 100 homes in cluster = perhaps 5 linear acres (about **1/5 of a mile**). Easily walkable and, with high population density, 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:

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<sup>139</sup> Pucher, Why Canadians cycle more than Americans, Transportation Policy, 2006  
[http://vtpi.org/pucher\\_canbike.pdf](http://vtpi.org/pucher_canbike.pdf)

<sup>140</sup> 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:<sup>141</sup>

- *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*

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<sup>141</sup> 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 <sup>142</sup>

- 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 <sup>143</sup>

- 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 ...' <sup>144</sup>

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<sup>142</sup> September 9, 2004

<sup>143</sup> 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

<sup>144</sup> Drexler, The People's Epidemiologists, Harvard Magazine, March 2006



The 2015 Dietary Guidelines Advisory Committee report echoes this, saying (in typical governmental bureaucratese)

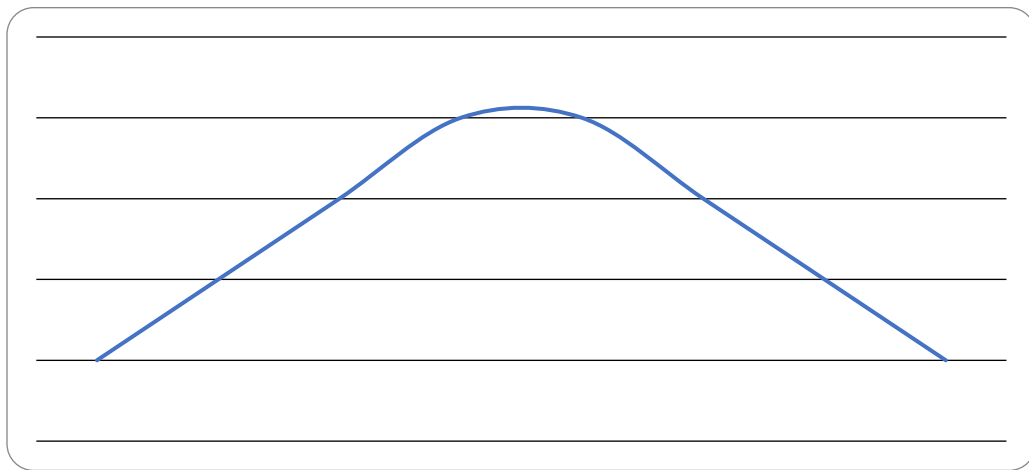
- Health and optimal nutrition and weight management cannot be achieved without a focus on the synergistic linkages and interactions between individuals and their environments <sup>145</sup>

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 <sup>146</sup>

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.



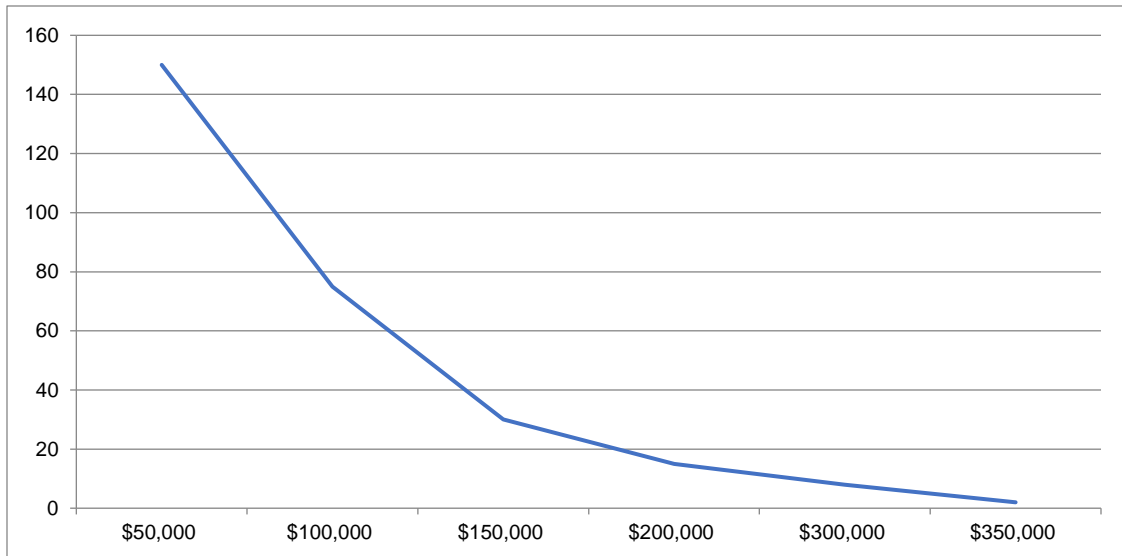
A few people at the far left have low cholesterol, blood pressure or blood sugar and are unlikely to get sick, while people at the far right have high levels and are therefore at risk. Most people fall in the middle. The appropriate wellness program focus using this model is the group at the far right.

But Whitehall, the New England Journal of Medicine, Madeline Drexler and Stuart Wolf suggest a different disease risk model:

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<sup>145</sup> 2015 Dietary Guidelines Advisory Committee report issued February 19, 2015, Part D, Chapter 4

<sup>146</sup> 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'.<sup>147</sup> More than 49 million people in the United States, including nearly 9 million children, live in food insecure households.<sup>148</sup> For these people, the issue is not

<sup>147</sup> From the Executive Summary of <http://www.health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf>

<sup>148</sup> 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.<sup>149</sup> 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.<sup>150</sup>

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

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<sup>149</sup> DGAC report, Part D, Chapter 4, Question 2

<sup>150</sup> 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

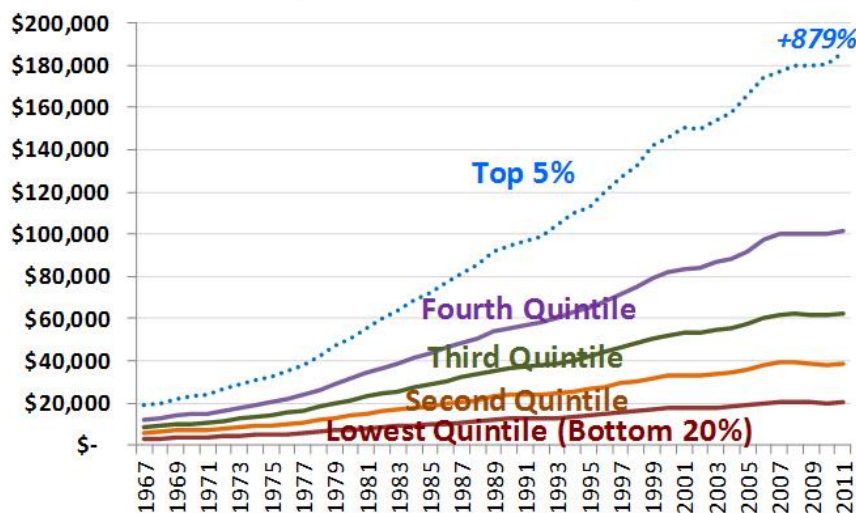
Whitehall and related studies indicate that lower socio-economic groups have higher disease rate than higher socio-economic groups. Whitehall and the others also found a gradient: the greater the socio-economic and status differences, the greater the disease rate differences too, even after controlling 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.

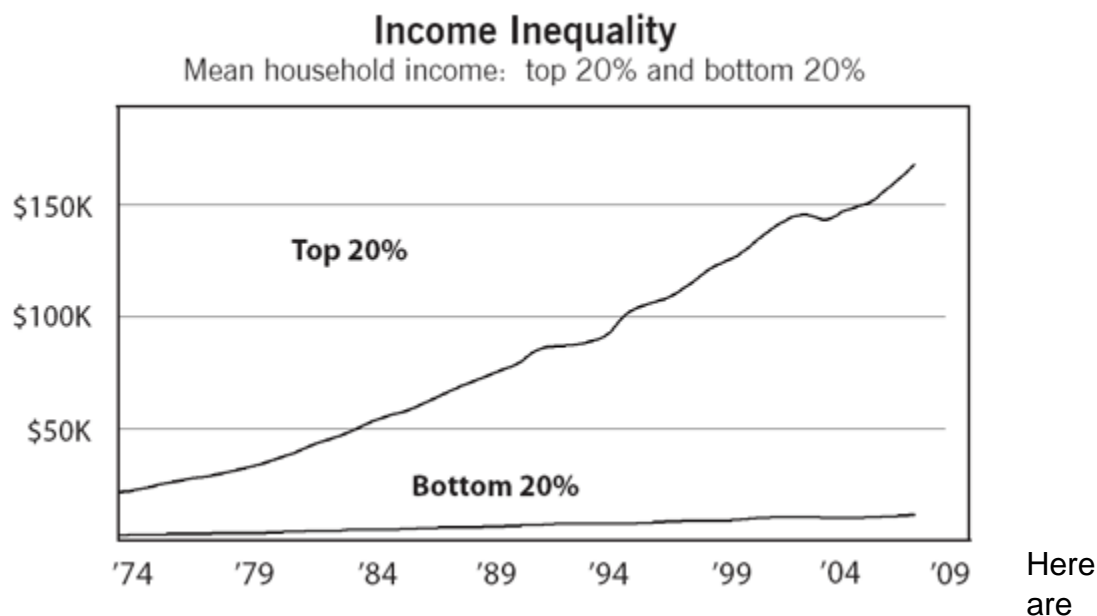
## Historical US Income Inequality

Source: US Census Bureau, Income Limits for Each Fifth and Top 5 Percent of Households

(Current Dollars)



Or this one, more starkly showing income differences between the top and bottom 20% of households. <sup>151</sup>



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

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<sup>151</sup> This comes from [theeconomiccollapseblog.com](http://theeconomiccollapseblog.com), apparently a doomsday commentary that I don't necessarily endorse. I use their graph here only because it is so cleanly presented

- 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 <sup>152</sup>
- 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 Pediatrics <sup>153</sup>
- Probably won't reduce the number of pediatric antibiotic prescriptions for ear aches, unnecessary 95% of the time and harmful about 15% <sup>154</sup>
- 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 <sup>155</sup>
- 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 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.

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<sup>152</sup> 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.

<sup>153</sup> See ChoosingWisely, <http://www.choosingwisely.org/?s=ct+scans+sinusitis&submit=>

<sup>154</sup> See Antibiotics for Otitis Media on the NNT website, <http://www.thennt.com/nnt/antibiotics-for-otitis-media/>

<sup>155</sup> See Prasad et al, A Decade of Reversal, Mayo Clinic Proceedings, August, 2013 <http://www.mayoclinicproceedings.org/cms/attachment/2007391767/2029532464/mmc2.pdf>



## 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 ballpark 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

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## 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**

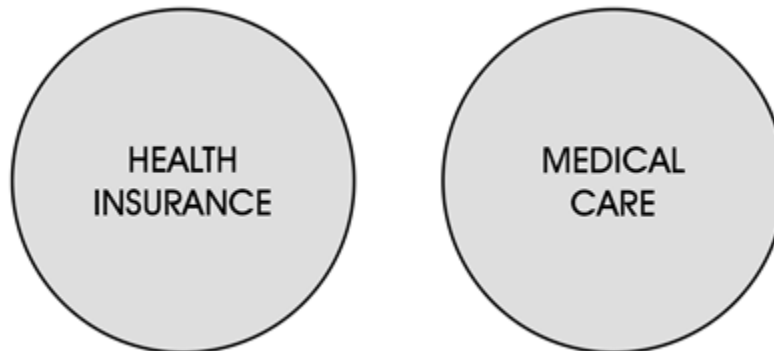
I suggest that corporate healthcare programs have as their #1 priority teaching employees how to choose care based on the outcomes they're likely to enjoy.

Design and develop that program first. This book can help. So can my online education program [www.TheMedicalGuide.net](http://www.TheMedicalGuide.net).

Then design a financing system to enhance and support your educational effort.

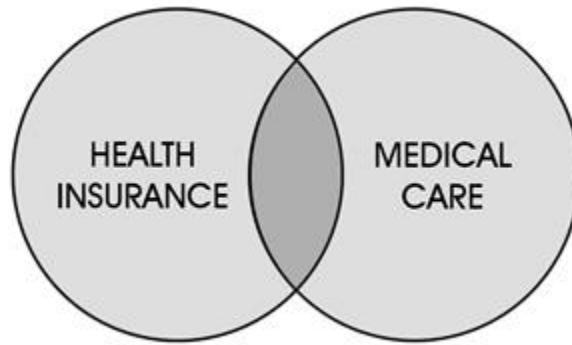
Don't do it the other way around.

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 your 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](http://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.

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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.

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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.

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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.

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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](http://www.TheNNT.com) lists about a hundred. ChoosingWisely [www.ChoosingWisely.org](http://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.

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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 accidentally-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.

<b>Some physician issues and concerns</b>	<b>Some patient issues and concerns</b>
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.

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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 suggest 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 is 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 is 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

### **Part 3: Healthcare Reforms**

#### **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 sponsors 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 thereof), 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 enrollees 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 Health 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) pneumococcal 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 recouping 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 occurring 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 mileage 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 scarcity 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 originating 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 be 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 statute 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 legitimate 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 quality 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 available 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 establish 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 localities 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 renal 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 rehabilitation 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 accommodate 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 achieved 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 pharmacoeconomics 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 suppliers, to maintain an Internet website which provides answers in an easily accessible format to frequently asked questions, and includes other published materials of the contractor, that relate to providers of services and suppliers under Medicare.

Prohibits a Medicare contractor from using a record of attendance at (or failure 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 Comptroller 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 responsible 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 (QIC) 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 intent 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 controversy 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 paroled 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 Assistant 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.



## **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.<sup>304</sup> 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.<sup>305</sup>

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.<sup>306</sup> 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 (ICHRA)**

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](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, limited duration 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/employers-shared-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.

## **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.<sup>1</sup>

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.)<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup> 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.<sup>5</sup>

This paper considers how the introduction of AHPs and HealthMarts would affect premiums and coverage in the small-group health insurance market.<sup>6</sup> (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.<sup>7</sup> 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.)<sup>8</sup>

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.<sup>9</sup> 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).<sup>10</sup> Such significant rate variation, and even cancellation of policies, characterized the small-group market during the late 1980s.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup>

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.<sup>14</sup>

## 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.<sup>15</sup>

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.<sup>16</sup> 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.)<sup>17</sup>

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.<sup>1</sup> 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.<sup>2</sup> (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.<sup>3</sup> 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.<sup>18</sup> 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.<sup>19</sup> 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 favorable selection 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."<sup>20</sup> 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.<sup>21</sup>

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.<sup>22</sup>

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 favorable-selection 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.<sup>23</sup>

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.<sup>24</sup> 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 low-cost 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.<sup>25</sup> 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

## **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 Medicare Advantage (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 health 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 conducted 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 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 identify 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 Medicare Advantage 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.

## Biden's Inflation Reduction Act

The Biden administration managed to pass part of its healthcare reform vision in the 2022 Inflation Reduction Act, the key component of which address prescription drug prices. We include that section here to show how healthcare reforms evolve and build on each other.

### 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.

## 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 summaries 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 Herzlinger, 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 Health 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.

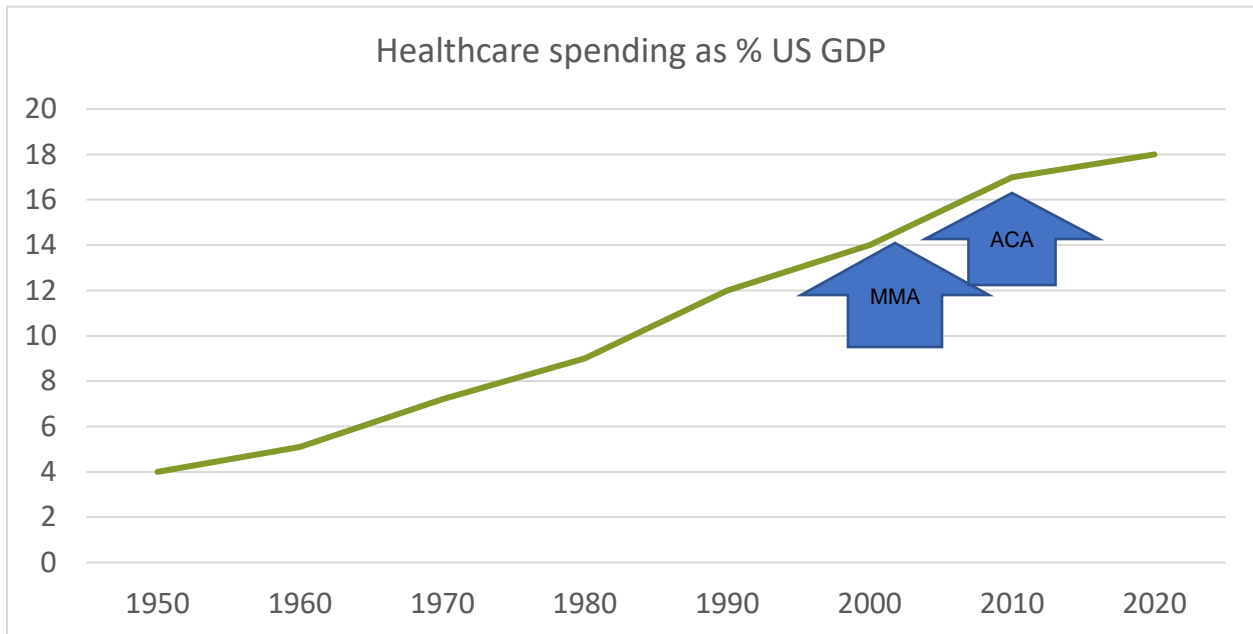
Thus, despite the higher 2022 sticker price, the average 2022 new car, with all those additional safety and other features, cost less economically than the 2003 ones.

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.

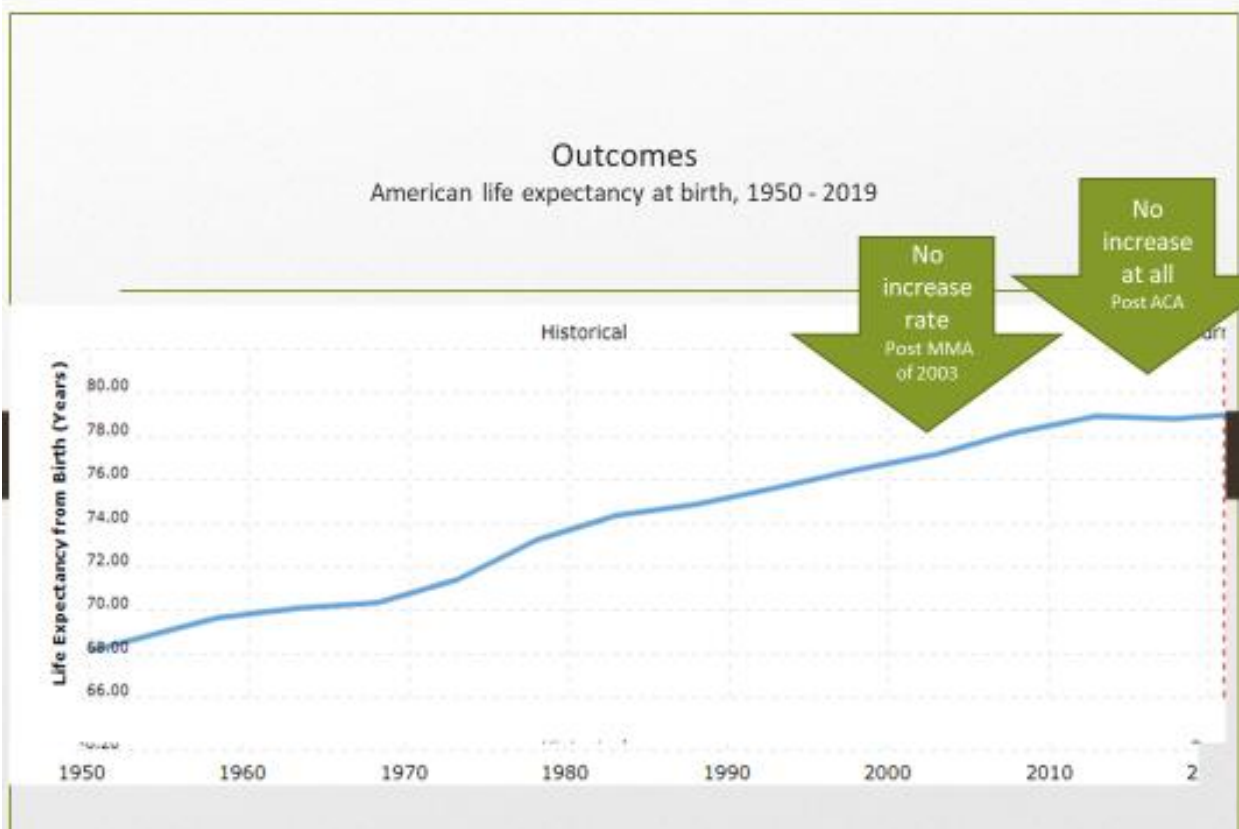
In economic / public policy terms, if our healthcare system keeps people alive longer, then it is arguably worth more funding; but if it does not, then I question whether the additional costs provide any value.

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.

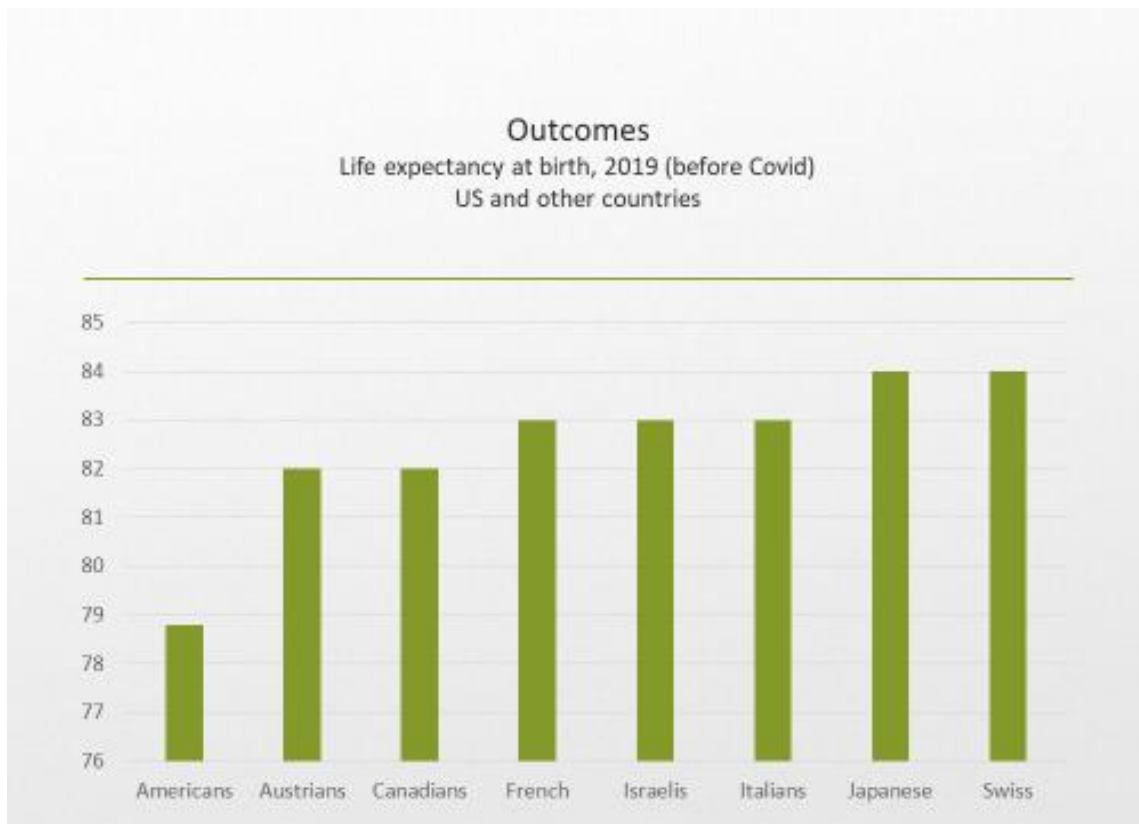
The chart below showing American average longevity at birth ends in 2019 on purpose: I did not want any Covid issues to interfere.



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 trends 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.<sup>156</sup> 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.

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<sup>156</sup> 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.”<sup>157</sup> 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.

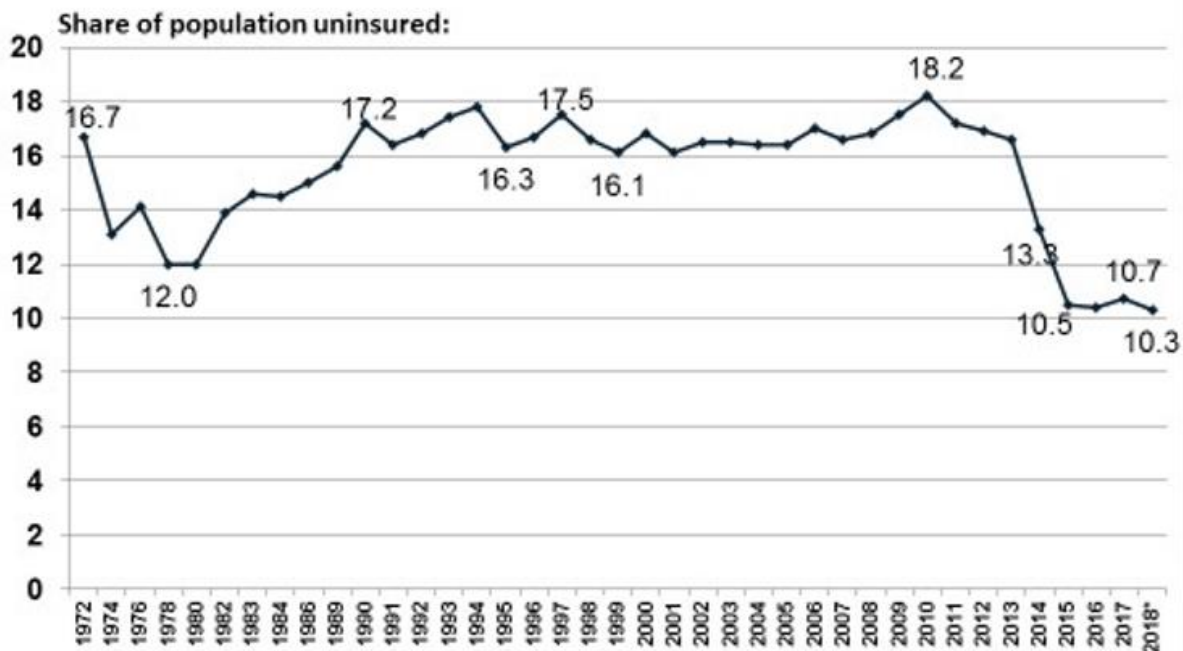
There is good evidence that all 4 factors combined in 2019 to describe that increase in our healthcare efficiency metric. We’ll discuss some of this below. Regardless, though, of the exact cause, my underlying point here is that neither healthcare reform package – the 2003 Medicare Modernization Act 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. See the chart below.

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<sup>157</sup> HHS Inspector General Data Brief, **February 2021** OEI-01-18-00380

## Uninsured Rate Among the Nonelderly Population, 1972-2018\*



Source: CDC/NCHS, National Health Interview Survey, reported in [http://www.cdc.gov/nchs/health\\_policy/trends\\_hc\\_1968\\_2011.htm#table01](http://www.cdc.gov/nchs/health_policy/trends_hc_1968_2011.htm#table01) and <https://www.cdc.gov/nchs/data/nhis/earlyrelease/insur201808.pdf>.  
 \*Note 2018 data is for Q1 only.



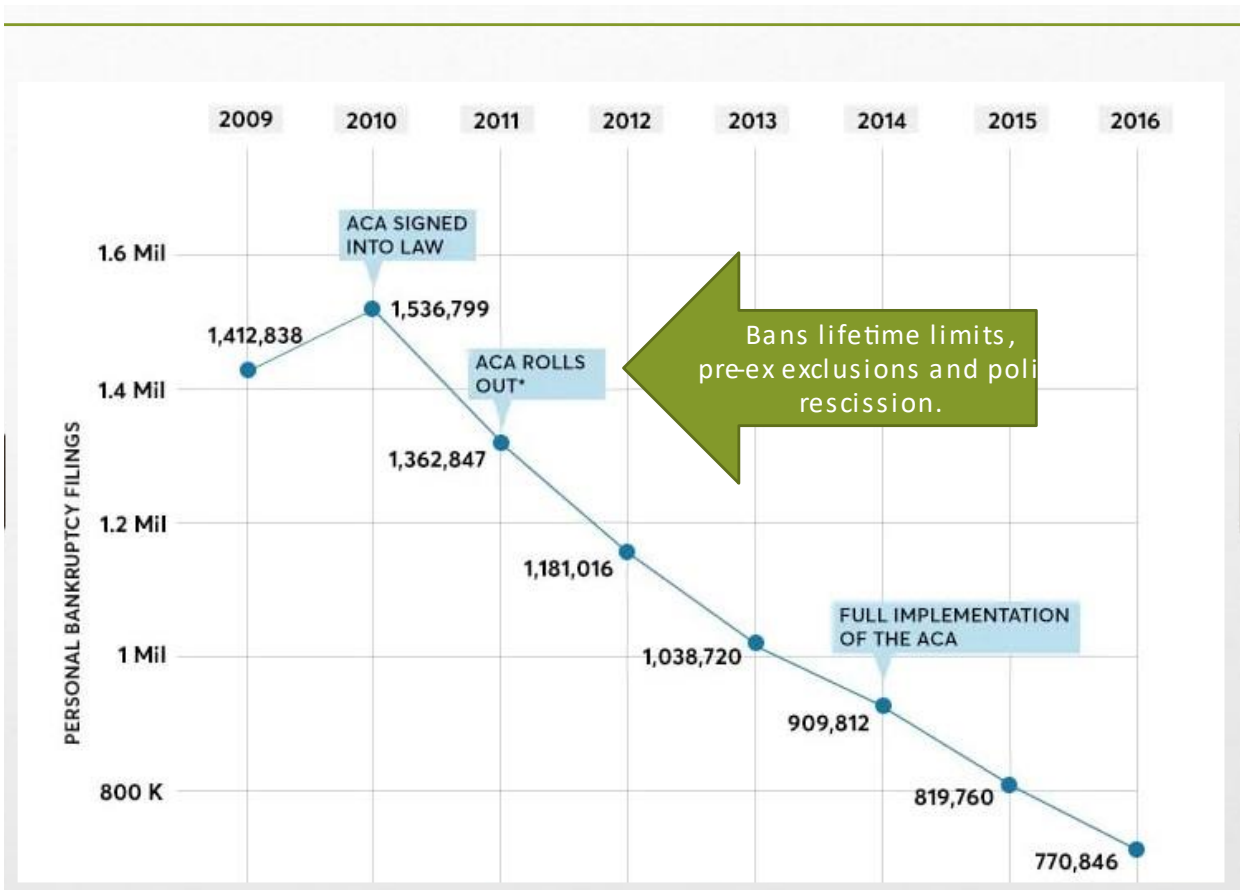
Wider health insurance coverage post-Affordable Care Act but no life expectancy gain. We'll discuss why below, but this initial analysis raises an interesting question: should we grade healthcare reforms *only* on coverage rates? After all, coverage rates are something we can control fairly easily (nothing 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.

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 manage 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.



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.<sup>158</sup> 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.<sup>159</sup> 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

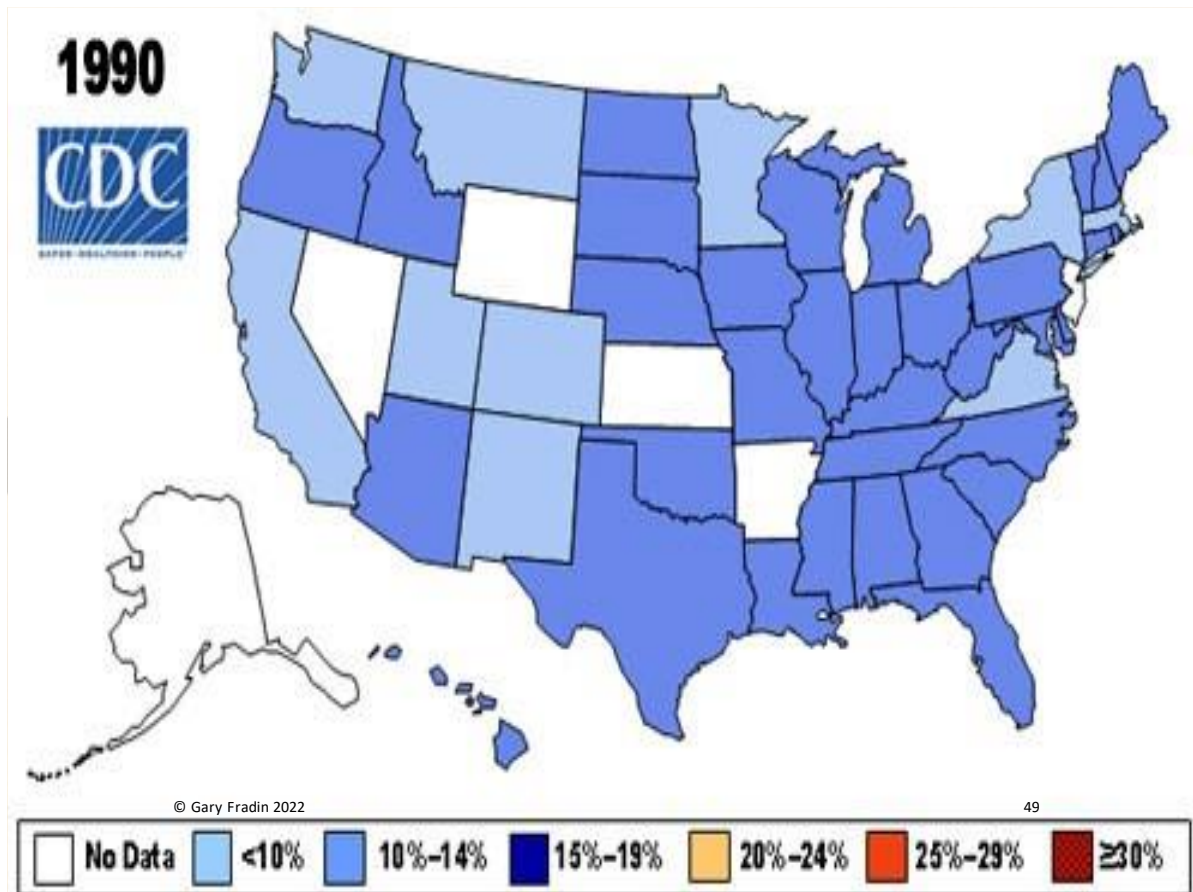
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<sup>158</sup> Average charge for Covid 19 hospitalization by state, Alia Paavola, Becker's Hospital Review, October 20, 2021

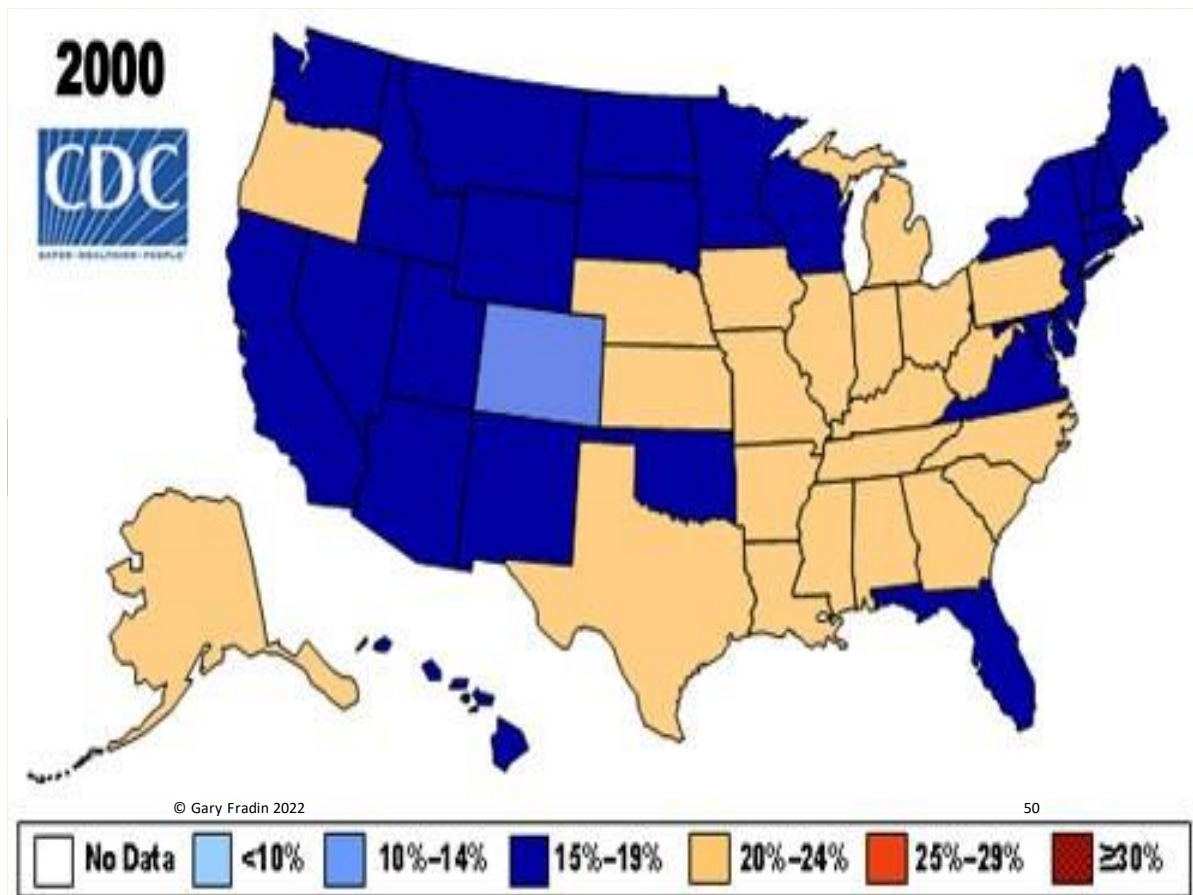
<sup>159</sup> Rising growth in expenses and rising inflation fuel financial challenges for America's hospitals and hospital systems, <https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial#:~:text=Medical%20supply%20expenses%20grew%2020.6,%2C%20from%20pre%2Dpandemic%20levels.>

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.

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.

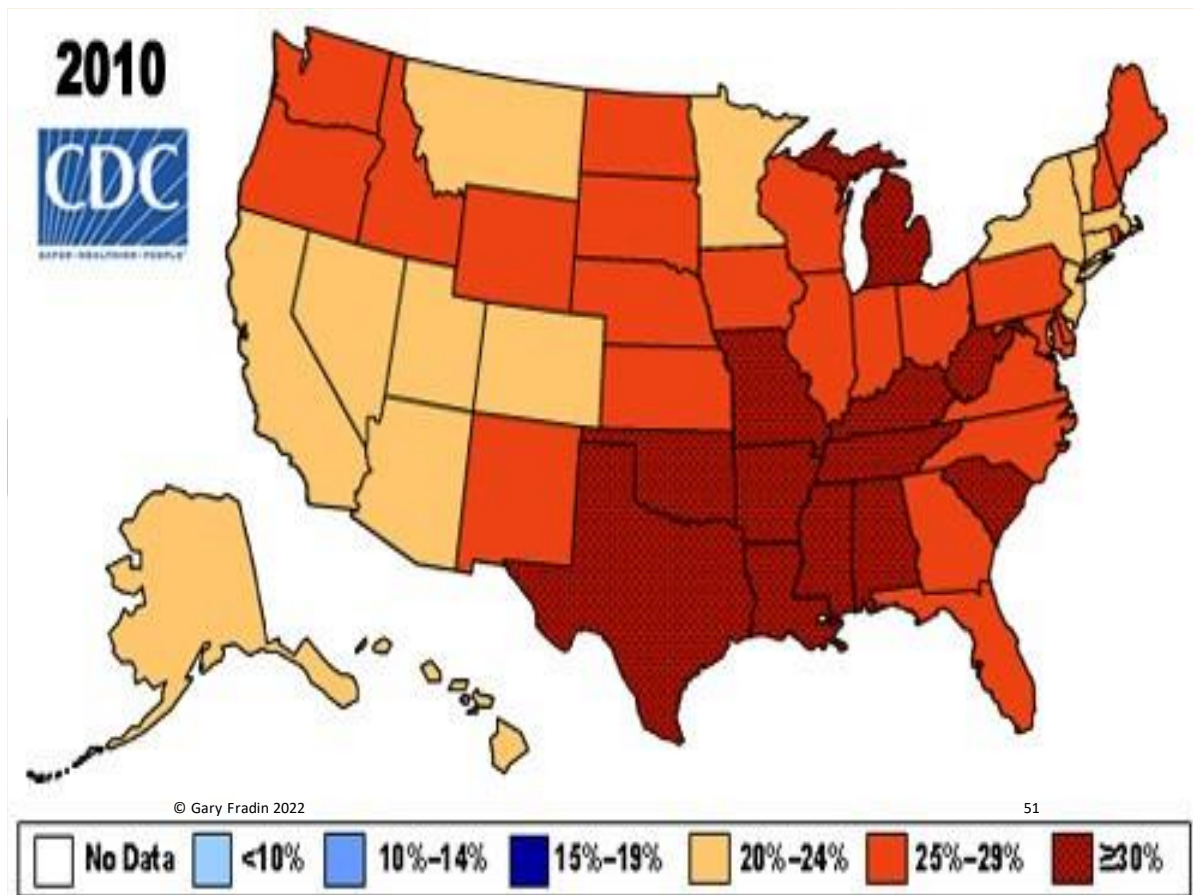


Then, 10 years later, our map changed. Same CDC methodology, same metrics, same format but a vastly different obesity map in only 10 years.



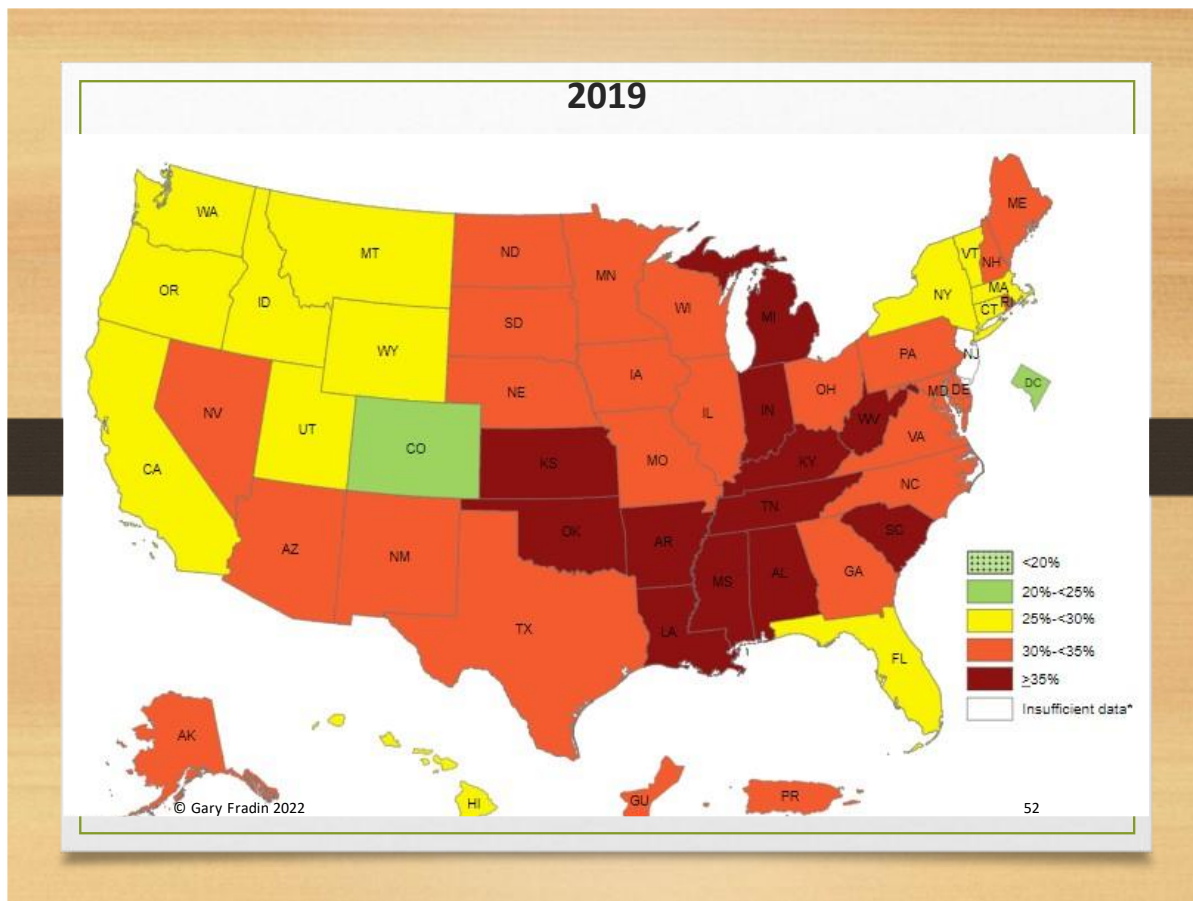
No state is less than 10% obese and only Colorado is less than 14% - the highest level of any state just 10 years before. Now, in 2000, over half the states are 20 – 24% obese, a level no one had reached in 1990.

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 2<sup>nd</sup> 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.<sup>160</sup> 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".<sup>161</sup> (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%'.<sup>162</sup>

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<sup>160</sup> Beaulieu et al, Changes in Quality of Care After Hospital Mergers and Acquisitions, New England Journal of Medicine, 2020

<sup>161</sup> HHS Inspector General Data Brief, February 2021 OEI-01-18-00380

<sup>162</sup> 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.<sup>163</sup>
- 500,000 Americans have died from drug abuse since 1999 including 107,000 in 2021.<sup>164</sup>
- 48,000 annual suicides.<sup>165</sup>

Note that neither the Medicare Modernization Act of 2003 nor the Affordable Care Act of 2010 ameliorated this mortality trend.

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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>

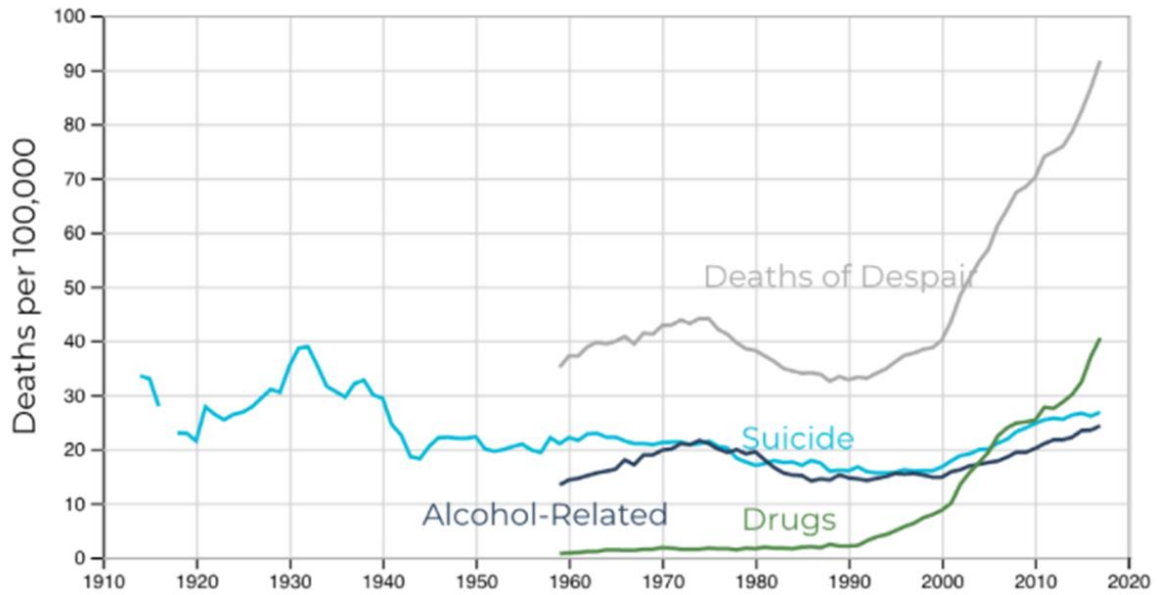
<sup>163</sup> Forbes <https://www.forbes.com/sites/joshuacohen/2018/07/19/diseases-of-despair-contribute-to-declining-u-s-life-expectancy/#277e57f0656b>, Gunshot deaths <https://www.cdc.gov/nchs/fastats/injury.htm>

<sup>164</sup> CDC estimate <https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html>

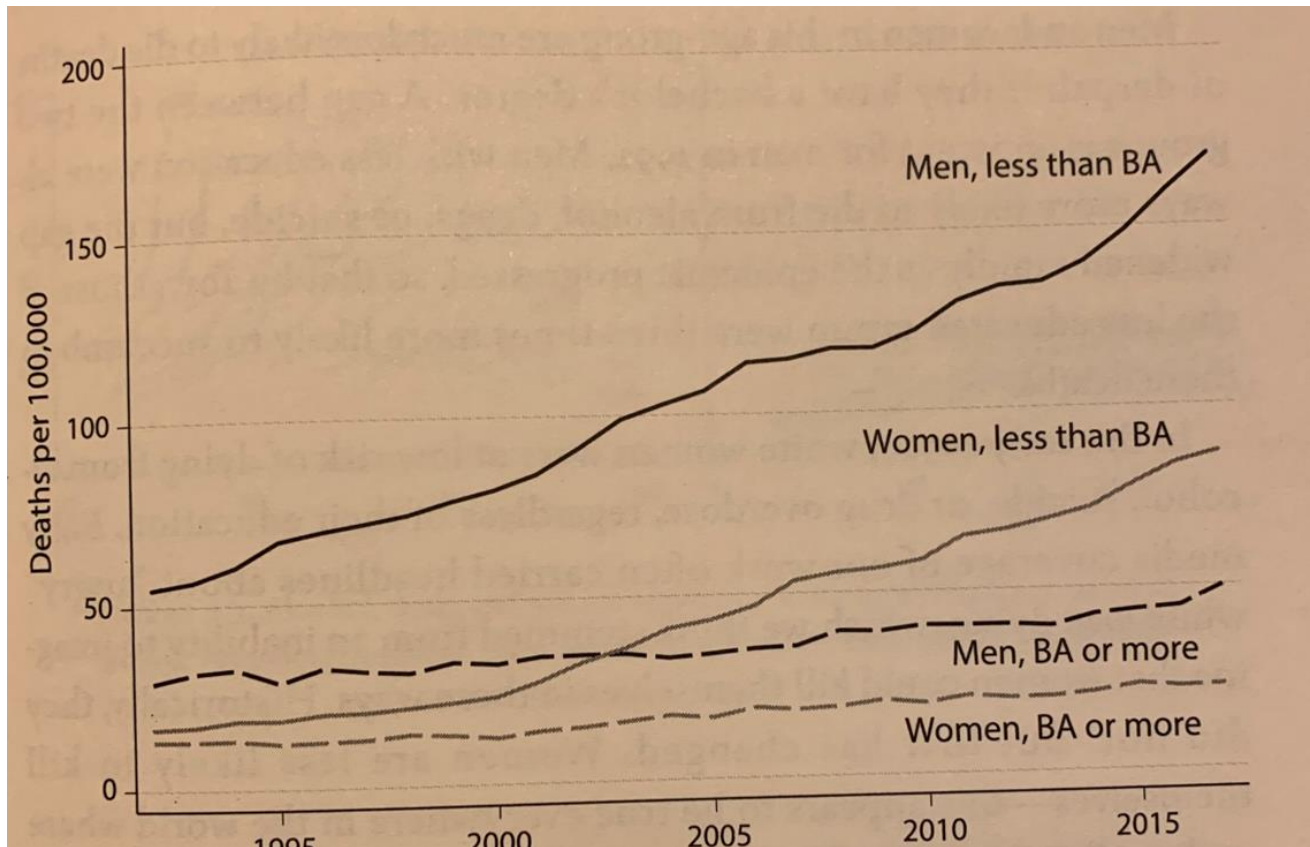
<sup>165</sup> Reference for Figure 3 chart **SEP 05** 2019 United States Congress Joint Economic Committee "Long term trends in deaths of despair"

<https://www.jec.senate.gov/public/index.cfm/republicans/2019/9/long-term-trends-in-deaths-of-despair>

**Figure 3. Deaths of Despair and Its Components, 1914-2017, Crude Rates, Non-Hispanic Whites Ages 45-54**



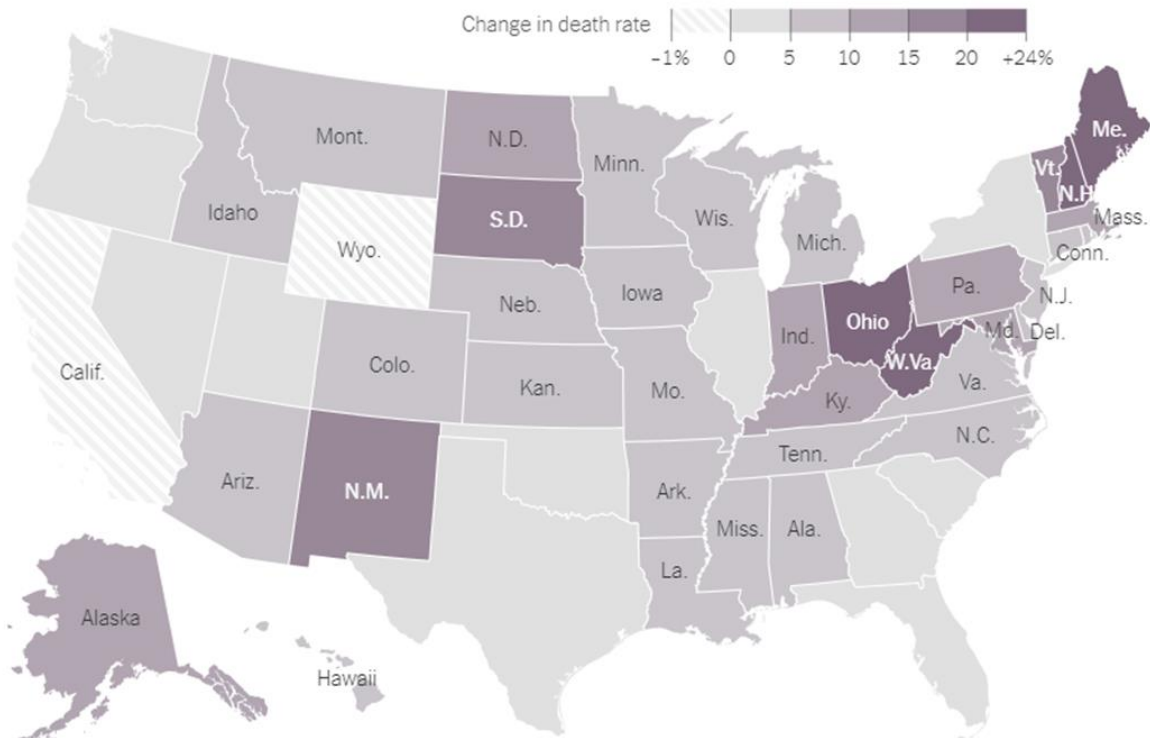
Deaths of despair fall disproportionately on middle aged, white, non-college educated men. The following chart, 'drug, alcohol and suicide mortality among white, non-Hispanics aged 45 – 54' shows this. It's from the 2020 book Deaths of Despair by Angus Deaton and Anne Case.



The next chart shows the net impacts of both healthcare reforms, the Medicare Modernization Act and Affordable Care Act. It shows the increase in mortality 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, 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.<sup>166</sup>

Death rate **increases** per state 2010 - 2017, people aged 25 – 64

<sup>166</sup> 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>



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.

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.<sup>167</sup>

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 of 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.

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

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<sup>167</sup> Lee, When Horses Posed a Public Health Hazard, NY Times, June 9, 2008

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.<sup>168</sup> '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 succeed. 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.

Which, if any, of these potential healthcare equivalent of cars will succeed? I don't know. Maybe all, maybe none.

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<sup>168</sup> 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

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<sup>i</sup> Richard Harris, Rigo Mortis and John Wennberg, Tracking Medicine for example.

<sup>ii</sup> See the Dartmouth Atlas of Healthcare for example on this.

<sup>iii</sup> State of Washington 2018 report First Do No Harm. I used this source for the other examples in this section also.

<sup>iv</sup> Wennberg, Tracking Medicine. He estimates that patients have options about 85% of the time.

<sup>v</sup> 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.

<sup>vi</sup> See Wennberg, Tracking Medicine, Chapter 1

<sup>vii</sup> HHS, Quick Guide to Health Literacy,  
<https://health.gov/communication/literacy/quickguide/factsbasic.htm>

<sup>viii</sup> Mulley, et al, Patient Preferences Matter, Kings Fund and the Dartmouth Center for Health Care Delivery Science, 2012, page 9



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