Healthcare Reform Since 2003

Mass course #C22758, 39 credits

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Table of Contents

From Moliere, The Imaginary Invalid

On patients

What is vexatious is that, when they are ill, they positively expect their doctor to cure them.

How impertinent!
You are not placed near them for that, but only to receive your fees and to prescribe remedies.

Chapter 1
Healthcare System Evolution

Part 1: Employer Based Health Insurance

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 they ban it from competing with the national system (Canada). Over time our employer based health coverage has slipped from a peak of 168 million people in 2000 [1] to about 140 million in 2010 [2] with a confluence of factors affecting the decline. The US Census Bureau estimates that the percentage of *employed* people receiving employer sponsored health insurance slipped from 76% in 1997 to 70% in 2010 to about 49% in 2020. [3] These coverage rates generate a different focus of healthcare system concerns here and abroad: We worry about *coverage* and costs; They worry about *outcomes* and costs

Our employer based system finances all medical care with **insurance** rather than **payment plans** probably for historical reasons that we'll discuss shortly. This confuses *insurance* (protection against financial harm caused by random events) with financing normal, routine and expected medical events like flu shots and knee replacements. Compare health insurance to auto insurance. Auto insurance pays for *un*expected events, like crashes; it doesn't pay for expected events like oil changes, tire rotations or transmission rebuilds. Yet we expect health insurance to cover all medical events, from the most routine and predictable to the most random and unpredictable. This leads to enormous inefficiencies because, many argue, insurance is the wrong financing mechanism for routine medical events.

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

We can imagine lots of medical payment programs, underwritten and priced for individuals or banded for groups. Middle aged men might buy 5 or 10 year orthopedic and urologic plans but not birthing; younger women the opposite. This kind of program pools need more efficiently than blanket insurance plans that cover every possible medical situation, for all people, that might occur this year.

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[1] EBRI Issue Brief # 321, September 2008, The 2020 data from Kaiser Family Foundation https://www.ehealthinsurance.com/resources/small-business/how-many-americans-get-health-insurance-from-their-employer

[2] Employment based health insurance 2010, Janicki, US Census Dept, February 2013

[3] Ibid.

'Insurance' then provides a safety net for the unexpected or random events not covered by specific payment plans.[4]

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.

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: 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

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

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 $800+ billion annually or $3000+ 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' [5] 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.

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, fruits 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.

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

[5] 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

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. 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.

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* would 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.

Among developed countries, the US has the highest rates of diabetes, sexually transmitted diseases, and teen pregnancy. 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. [6] Are sexually transmitted disease and alcohol abuse 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

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

- 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. The employer-based model rests on businesses, organizations well able to invest and lobby to protect their interests. Those interests include keeping health insurance premiums – and taxes - low to maintain higher profits. Perhaps as a result, we spend far less as a percentage of our economy 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) than do most other developed countries. Spending more on these factors would either require businesses to fund them through premiums – anathema to business – or through higher taxes. The tragedy here is that, though we're highest internationally in medical spending, we're only #13 in 'medical and social spending' combined. We have the ratios reversed from most other countries including the ones whose populations live longer than ours. 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. [7]

By our relentless focus on keeping premiums low and affordable in the employer based model, we consistently underfund the social programs that determine so much of our medical cost structure. This self-defeating approach to medical cost control has a long history…keep reading! As just one example of how our social-spending failures have harmed our healthcare system, consider this observation from Professor Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy about Covid costs and outcomes: 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.[8] This counter-intuitive and counter-productive 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.)

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

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

Uwe Reinhardt, professor of healthcare economics at Princeton, suggests 3 consequences of placing employer based health insurance at the center of healthcare financing. [9] First, it is tremendously expensive. In 2021, for example. a typical family health insurance plan cost about $22,000, up about $7,000 from 2011. That's about triple. This compares to an average 2021 family income of around $90,000 [10] up less than double from 2011.

Under what definition is this 'affordable'? 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 over the past decade. Good question.

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. [11] This system, as the two previously mentioned, also has its own access rules, reporting rules, prices and payment rules
- 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

[9] This section based on Reinhardt's lecture at the Pioneer Institute in Boston, 2014

[10] Family premium estimate from CNN. Average family income for 3 person family from US Census Department https://www.justice.gov/ust/eo/bapcpa/20201101/bci_data/median_income_table.htm

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

- A seventh system, actually a subset of #2 above, for people with kidney disease, provided it's end-stage.[12]

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. 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 the third of Reinhardt's consequences of employer based health insurance are the different prices from all these categories for the same service. [13]

- 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.

- 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.

[12] 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.

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

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

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 $800 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 of Athenahealth, 'unnecessary care is part of the hospital business model'. [14] This raises the interesting question: 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. 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 or servicing widgets, and generate profit on those.

CFOs lack 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, 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.

[14] Jonathan Bush, Where Does It Hurt?

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. If premiums rise quickly, wages rise more slowly. The employer corporation doesn't care – economically – if it pays employees wages or premiums. It only concern itself with the total employee costs.

Consider this economic impact: 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. [15] Divide $197 by $2.53 to see this. In 2020, the average wage had risen to $30/hour, healthcare cost to about $12,500 per person, requiring the average person to work 416 hours (10.4 weeks) to pay for healthcare.[16] This strikes many as a pretty poor track record.

Most employees labor under an economic misperception about health insurance funding, that the employer pays insurance premiums out of overhead or profit. This is incorrect according to most economists. The employee pays for coverage either by payroll deductions or foregone wages. Consider Mary, a single woman who earns $35,000 a year. [17] 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. 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.

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

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

[16] Wage estimates from the US Bureau of Labor Statistics

[17] 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.

Part 2: How the US healthcare system developed

The generally accepted history is that employer based model started in Dallas in 1929 as a reaction to the stock market crash and financial meltdown, originally instigated by Baylor University Hospital. [18] The business problem for Baylor University Hospital was that it didn't have enough money to pay its bills.

Prior to the 1929 stock market cash, hospitals raised funds in two ways. First they had paying customers who were billed for services rendered - a fairly modest percentage of the population because most people didn't have a lot of money. Second, they received money from the community chest, i.e. 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. Baylor said, "School system, you raise money from taxes. You always have money. Pay us $.25 every other week, $6 a year, for each of your employees and when they get sick we'll take care of them." Employer based health insurance arrived.

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), $.25 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 $.25 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.

In business terms, Baylor was a vertically integrated system. Vertical integration means medical care provision and medical care financings are housed in the same company. In theory at least, this eliminates conflict between providers and finance. In a truly vertically integrated healthcare system, physicians are paid on salary, not fee-for-service based on the number of treatments they provide. The great advantage of vertical integration is that it eliminates many kinds of waste from the healthcare system by eliminating conflict between the payers (today we call them insurance carriers) and providers (hospitals and physicians). The conflict between finance and service provision results in higher prices. The conflict arises when finance and service provision are separate, independent

[18] This section is an edited and updated transcript of my lecture on Employer Based Health Insurance given at Health Services Administrators in Braintree Massachusetts on September 29, 2009.

companies. Providers always try to bill more to make more money, plus they have an incentive to provide more services and to bill more.

On the other hand, the finance people always try to pay less, and you always have a fight when finance and service provision are separate entities. The fight is over distribution of dollars, not over patient outcomes, because it's extremely hard to quantify outcomes as a basis for physician payment – we haven't yet even begun to address this issue, 80 years after the Baylor experiment. Physicians get paid to perform treatments, so the more treatments they provide the more they get paid. Physician economic incentives collide with carrier economic incentives. But in a vertically integrated healthcare system where finance and service provision are in the same company, you eliminate these incentive conflicts and focus more on patient needs. At least, that's the theory. One big problem with the vertical integration model: limited hospital or provider 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, etc, etc. And what problem began to arise?

Shortly after Baylor and the Dallas Schools began their collaboration, patients wanted more care options, a choice of hospital for example. 'What do I know about Baylor University Hospital?' they wondered. '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 someone else who had a negative experience at any hospital. So employees, concerned patients in this case, wanted hospital options.

Once you introduce hospital choice, you create a split between medical service provision and medical care financing and end vertical integration. Baylor Hospital only managed financing for itself, not for any other hospitals in Dallas. It couldn't handle premium collection from school system employees and then payment to, for example, Dallas General Hospital for employees who preferred it to Baylor, let alone Dallas Methodist Hospital or any others; it wasn't in that business. A new entity needed to be created to handle financing only. And, to foreshadow what's coming up soon, once you have a split between service provision and financing, you have a conflict between the two with hospitals wanting to get paid more and the financing entity wanting to pay less. But that's coming.

Back to Dallas. The hospitals are cranking along with the employer based financing model, each treating their captive clients within their vertically integrated model. The hospitals are happy. They're making money. But then Blue Shield came along to offer hospital choices to employees. 'Dallas teachers' Blue Shield 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 Blue Shield so doctors could get paid because the same depression that was affecting all medical providers, both hospitals and physicians. Blue Cross for your hospital bills and Blue Shield for your doctor bills. Both organized to protect provider incomes, both established in the early 1930s. Interestingly, the National Association of Health Underwriters, the national professional organization representing health insurance broker interests, was founded at about the same time, in 1930.

The Blues developed a couple of very clever ideas. First, from a marketing point of view, they offered this attractive provider choice option. Americans, it turns out, really like choices in the medical care arena. Second, they began searching for the healthiest subscribers. Consider their interesting business idea: if they could find the healthiest people, they could offer lower priced policies and gain a competitive edge over other insurance carriers and their vertically integrated competitors. Enter underwriting.

Underwriting vs. Community Rating

The Blues figured that they would underwrite better – meaning identify healthier customers better than their competition, and price unhealthier customers more exactly than the competition - 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. Community rating means offer the same price to all customers. Underwriting allows carriers to charge healthier people less than sicker people. Underwriting serves the economic interests of the carriers. It doesn't improve healthcare outcomes. It doesn't improve the healthcare system overall. It doesn't improve medical care quality. It doesn't create patient value. It only makes one carrier lower cost than another by having it attract more healthy people. The healthy pay less, the sick pay more. Carriers gamble in their underwriting that their competition does a poorer job of running their business and monitoring their numbers, so they'll get stuck with all the sick people and go out of business.

This financing system has nothing to do with getting people healthy. 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.

Once you split finance from service provision, you have wider consumer choice and it leads to conflict. But not necessarily healthier patients. If you're the finance person, you're paying fee for service to me, the physician. I want to do as many treatments as I possibly can because the more treatments I do, the more you pay me. As soon as you split finance and service provision there's an incentive on me, as a medical care provider, to do more treatments. You're paying me by treatments, so I will do more treatments. You, the finance company, on the other hand, want to limit the number of treatments. You want to look over my shoulder all the time and say, "No, you don't have to do that." I say, "Yes, I do have to do that." We fight all the time. That's the conflict between healthcare payers and medical service providers. Not to mention that I, the service provider, want to get paid more for each service and you, the financier, want to pay me less. 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 I, the service provider says, "Yes I do. Yes I do."

Developing and Determining Prices

How much does the financier pay the service provider? Hospital A has usually and customarily been charging $10. Hospital B says 'We do this procedure better, so pay us $11' and provides lots of reasons to justify the higher payment. Then Hospital C says 'Last year you paid us $10, but this year we bought this expensive new equipment for the procedure, so now pay us $11.50.' There's a built-in provider economic incentive -- once you get the split -- under usual and customary to charge more and more. The incentive is even bigger when you're in a system of ***cost plus***. Cost plus reimbursement rewards the least efficient providers the most. The hospital with the most overhead, that buys the most expensive technologies (whether or not they're necessary), has the highest staffing ratios and the least efficient managerial operation gets paid the most. The 'plus' is a fixed percentage of cost. 'Cost plus' is an incentive to become inefficient! Once you get the split, you have all these incentives that are inflationary, few of which are related to quality. To reiterate the same point, all we've been discussing in this entire history of insurance -- and we haven't even gotten to World War II yet -- is protecting providers' incomes – the doctors and hospitals. That's why health insurance originated.

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 <u>inappropriate</u> or <u>unflattering</u> 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. Not only could they make more money based on quantity rather than quality --- we've already discussed that. 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. The Split between finance and service provision led us down this road.

Early Development of Employer Based Coverage

Let's continue with our historical / conceptual history of employer based health insurance. During World War II, and largely as a function of it, more and more people got insured, most notably people in the military then wanted to continue with insurance coverage after the war. In a relatively short period over 130 million more Americans got covered for hospitalization insurance.

1942: 10 million hospital insurance / health insurance subscribers

1946: 32 million

1951: 77 million

1963: 142 million

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. Among the most significant were the introduction of sulfa drugs and antibiotics to combat infections, development of ultrasound (originally to check tank structural integrity after battles, later used for prenatal care) and skin grafting. These advanced medical technologies, especially in the case of antibiotics, helped turn hospitals from infection breeding institutions into patient treatment and improvement centers. The net effect of these technology developments 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 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 industrial, trade and professional groups.

Tax Subsidies for Employer Based Health Insurance

One successful lobbying effort resulted in passage, in 1953, of IRS regulations that exempted fringe benefits from income tax. These benefits became tax deductible to the employer but not income

taxable to the employee and were 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. To understand how this is a subsidy, let's look at both the employer and employee tax situations briefly. Let's say 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.

Here's a quick economic axiom: whenever you subsidize anything, people buy more of it. If you subsidize milk, that reduces the price and people buy more. If you subsidize mortgages, people buy more expensive houses. And if you subsidize health insurance in an employer based model, employers provide more coverage and employees use hospitals more. This subsidy 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.[19] 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.

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. 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

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

costs and made insurance even more valuable. [20] 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). Brokers liked the system because they could sell policies and make money doing so. 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. Two byproducts: First, we used hospitals for almost all medical care, even if less expensive settings existed; Second, we developed fewer outpatient, home based, preventive or non-hospital types of medical care. These two factors would become hugely important a few years later as our healthcare became increasingly expensive.

There's an interesting underlying question here: how were employers able to make increasingly large health insurance premium payments for their employees post WWII while expanding their businesses? 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 difficulty and even decline? It turns out that for a number of years, from 1950 to 2000 more or less, many countries in the world 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 even 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 you see from World War II to about the 1980s. Big firms could set the standard and then small businesses filled in the holes. They had to compete for labor based on offering health insurance, and they 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 – 1990 +/-

Little foreign competition for American manufacturers, Japan and Western Europe needed time to rebuild, US manufacturers could keep prices high and afford health benefits

All these conditions changed in the 1990s and beyond. So you have this nice system supporting the employer based health insurance idea during this 40 or so year period, all of which changed post 1980 or 1990. After that the trends changed and employers began to have problems maintaining the

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

same benefit levels due to foreign competition and healthcare costs. Our ability to generate excess profits, if you will, to afford for the employers to pay for healthcare started to disintegrate as foreign competition got going. From World War II until about 1990 we could afford employer based health insurance and there was no significant political group that was lobbying or arguing against it.

The Impact of Medicare and Medicaid on Commercial Health 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 was potentially a very potent political force that could have lobbied in favor of single payer healthcare, universal coverage or something like that, just like in other countries. By introducing Medicare and Medicaid in the 1960s, this potential political force went away. Elderly and unemployed people were happy. They got access to medical care. They stopped demanding universal coverage because they got coverage. Where were politicians going to find a block of supporters who lobby for single payer systems, universal healthcare? They didn't exist for years, and maybe still don't (I'm writing this in late 2019) because Medicare and Medicaid took these potentially uninsured populations 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 – 2018

Year	Number Medicare Enrollees	% of US population
1970	20 million	10%
1980	28 million	12%
1990	34 million	13.5%
2000	39 million	13.8%
2010	47 million	15.2%
2020	63 million	19%

Medicaid covers about the same population size.

The argument here is that Medicare and Medicaid were 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 reached its peak of 165 million people in 2000 and then it started to decline. Why did it decline? Because the international economic conditions changed. American firms faced increasing difficulties passing 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. Lower cost alternatives to large general hospitals – freestanding outpatient clinics, for example – never took hold in the 1900s, 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. By the end of the 1990s, 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.

Since 2000 or so, we have attempted to reform the employer based healthcare financing system. One attempt was the Medicare Modernization Act of 2003 that introduced Health Savings Accounts and Health Reimbursement Accounts. Another was the Affordable Care Act of 2010 which provided subsidies to lower income commercial market subscribers.

The 5 Key Components of Today's Employer Based Health Insurance

Different components of the employer based system operate under different goals and incentives. Unfortunately 'promoting good health' or 'returning sick people to good health as quickly and efficiently as possible' and 'saving the system money' are not goals shared by many. As we'll see, this has some strong negative effects on our healthcare system.

The key components here are:

1. Employers
2. Employees
3. Providers
4. Carriers, and
5. Government regulators

Let's look at the goals, incentives and operations of each.

Employers

Employers supply health insurance benefits for one primary reason: to attract and retain good employees. That's the reason employers started offering benefits during World War II and is still the primary reason for offering them today. Employers do not, as an economic function of their business, aim to get people as healthy as they possibly can. They're interested in selling widgets and a mechanism to do that is to get good employees. If they didn't have to provide healthcare, they wouldn't. They want to make widgets. They make money selling widgets. That's why they're in business. They have to trade off the quality of the health insurance they provide with investments in their firm's growth. If they invest too much in employee health they may harm the firm's financial health. For an employer, 'good enough' healthcare is good enough because they want to make widgets. By contrast, a sick employee does not want 'good enough' healthcare. He / she wants 'excellent' healthcare. (More on this soon.)

'Good enough' healthcare in the 1980s, 1990s and early 2000s included some or all of the following:

- Provider network restrictions;

- Annual / lifetime benefit caps;
- Pre-existing or other medical condition exclusions;
- Strict specialist referral restrictions;
- Waiting periods;
- Other obstacles to medical treatment

These were designed to keep insurance premiums low so the firm's financial health remained strong; they were acceptable to employers.

One Year Plans

Employers were also interested in short term healthcare commitments – generally 1 year, not multi-year renewable insurance policies. The employer could not predict the firm's financial health far into the future so wanted to avoid committing to long term liabilities. The employee census could change, business conditions could change, etc. Remember that employers are the health insurance purchasing agents. If they are comfortable only with 1 year policy commitments, then that's what the carriers will sell. But note the effect of 1 year policies: they focus carriers on short term cost control, not total disease cost control. Carriers compete for employer business by showing the lowest year-to-year premium increases. Here's another economic axiom: in healthcare, short term cost control always leads to higher long term costs. Remember that 70% of our healthcare spending goes to people with chronic diseases. Short term cost control often means skimping on this year's preventive or maintenance treatments – resulting in higher costs in the future. Short term cost control is bad medicine. Our business schools sometimes discuss business strategies for healthcare. There seems a general agreement that the way to generate the lowest healthcare costs is to focus on total disease costs, from diagnosis to treatment to rehabilitation. This is efficient ---- generating the best outcomes per dollar invested.[21] But calculating lowest total disease treatment costs include savings generated in the future – years 2+. This does not fit the employer's purchase criteria; they only care about costs in year 1. This leads to three unfortunate effects:

1. Higher total disease treatment costs;
2. Relatively mediocre outcomes, as evidenced by poor hospital safety records and high readmission rates;
3. A mind-numbingly confusing set of irrational cost control programs that neither control costs nor improve patient outcomes.

Employers choose plans with the lowest year-to-year premium increases. This leads carriers to focus on short term cost controls that do not necessarily improve healthcare. Here are some inappropriate forms of short term cost controls that we accept:

[21] For more on this, see Porter and Teisberg, 'Redefining Health Care: Creating Value-Based Competition on Results' or Regina Herzlinger 'Who Killed Healthcare: America's $2 Trillion Medical Problem', both Harvard Business School professors, among many other books.

- Failure to develop world class IT networks within and among providers;
- 'In network' hospital choice based on price, not quality;
- Over reliance on pharmaceutical companies for product testing;
- Underinvestment in infection control and patient safety;
- Rx formularies based on cost rather than long term results;
- Underinvestment in disease prevention;
- Restrictions on number of maintenance physician visits per day;
- Restrictions on number of specialist consultations per day

Fee for Service Cost Controls via Codes

The mechanism adopted by most carriers in the 1970s and beyond was fee-for-service cost control via billing codes. We'll discuss some fee-for-service issues shortly. But I'd like to make a couple points about billing codes now. New Jersey originally introduced codes called Diagnostic Related Groups to help control Medicaid costs in the 1970s. New Jersey hired Yale Medical School to develop the program, and the Yalies introduced 470 categories of medical DRGs. 470 seems like a lot but may be a reasonable number of categories to control. But by about 2005, this had grown to perhaps 20,000 + categories. This seems an unreasonable number of categories to control.

Let's also remember a key economic axiom: if you pay by categories, you get more categories. But you don't control spending. That's exactly what has happened to fee-for-service payments by billing code. Today we have both more billing codes and more spending. Remember how we got here. Employers want to purchase 'good enough' healthcare for their employees, and are keenly interested in short term costs. This forces carriers to develop short term cost control mechanisms that simultaneously fail to control short term costs and lead to higher long term costs. The 3 central employer goals are cost control, cost control, and cost control, not efficient healthcare distribution nor having employees treated as efficiently (best outcomes at the lowest cost) as possible. This excessive focus on cost control is problematic, at best.

Employees want excellent healthcare. When diagnosed with cancer, for example, they do not want to hear about cost control issues, or 1 year policy issues, or comparative health insurance premium increases. They want to get cured. Employee goals do not coincide with employer's goals. Employees want the ideal healthcare system described above. Employers are satisfied with 'good enough' healthcare. Employees want access to the 'best' hospitals, not just the 'in network'. They want access to the Cleveland Clinic for coronary problems, or Duke University Hospital for brain cancer, like Ted Kennedy – not just the local 'in-network' hospital. They also want true prevention. Why is Weight Watchers an outside fee? Why must they pay for a personal trainer or nutritionist? Both lead to good health and lower employer premiums. Why must employees pay out-of-pocket to save employers money? In effect, the employees ask 'Why must I wait until prevention fails before receiving medical care?'

In economic terms this is inefficient: it adds cost without adding value. It does not keep them healthy --- which is the cheapest way to go. It does not get them healthy most quickly –-- which is the most

efficient way to go. Instead, it puts off expenses until next year, which serves the employers' short term interest. Under our system, the employee is unable to exercise consumer sovereignty. They are unable to shop wisely because the employer has shopped for them. They are restricted. They can't go to the Cleveland Clinic easily because it's out-of-network. By eliminating hospital competition and consumer sovereignty, you eliminate the trend of Massachusetts' employees going to the Cleveland Clinic for care. (Or Nebraska employees, or Oklahoma employees.)

In short, the employer based system creates barriers to employee good health.

What might happen if employees went from state-to-state (i.e. out of network) to receive the best healthcare? First, they might get healthier less expensively and more quickly, which is economically efficient. Second, local hospitals might improve in the face of competition. But employees – healthcare consumers – are not able to register their votes for excellent healthcare. They're restricted because the employer has restricted choice. Employees want the ideal healthcare system described above. But employer based health insurance stands in their way.

Carrier Goals

Carriers respond to employers because employers buy policies. Carriers compete on short term cost control, not on long term cost control, not on total disease cost controls, not on quality. Carriers do not reward excellence. They only reward short term cost control because they respond to employer purchasing criteria. The carrier says to the employer "You want one year policies? We'll give one year policies. You don't mind out-of-network restrictions? We'll give you out-of-network restrictions." Carriers, at core, take instructions from employers about the types of policies employers want, then price the associated medical risks. What else does the carrier try to do? Enroll healthy people to make more money. Put off expenses because maybe the diabetic subscriber will switch to another carrier next year before needing an amputation. Then the government steps in to correct all this abusive short term cost control. When carriers try to enroll only healthy people, the government passes regulations and coverage mandates to stop this private sector systemic abuse. The government puts a band-aid over the problems that shouldn't have existed in the first place, but they do exist because we have a fundamentally screwed up system.[22] We'll talk about the government's role in a few minutes. But for now, let's use this equation:

Tension between employer and carrier economic interests and healthcare system quality = Government regulations to reduce short term cost control abuse.

Providers compete for carrier funding. Thus the carrier, not the patient, is the hospital's ultimate client. Let's look at how hospitals act. They get involved in the Medical Arms Race. What's the Medical Arms Race? "Our competitor hospital just bought a brand new million dollar machine and they're getting more patients. So we need to buy the same brand new million dollar machine and then publicize it. We're not sure that it provides better patient value – better outcomes per dollar invested. But we compete for patients based on medical inputs not value for outcomes." The Medical Arms Race describes competition among hospitals for physician referrals and patients; hospitals compete with each other by offering the latest in medical technologies and most modern

[22] I got the verbiage 'fundamentally screwed up' from a lecture by Harvard Business School's Michael Porter. See http://www.hcp.med.harvard.edu/node/1975

facilities. This adds cost but doesn't always relate to better outcomes. In fact some studies indicated that hospitals with *more* competitors had *higher* costs than hospitals without competitors. [23] This is exactly the opposite of most other businesses that compete on outcomes, and results from our convoluted employer based payment system. When your competitor buys new equipment, then you must buy it also – but if you have no competitor, then you don't need to buy it. That's convoluted. But this gets worse. Studies again suggest that these higher priced, competitive hospitals sometimes had higher mortality rates (i.e. poorer outcomes) than non-competitive hospitals because of the 'volume-outcome relationship' in medicine. [24]

The 'volume outcome relationship' simply means that practice makes perfect. The more of a particular procedure a surgical team or hospital performs, the better the outcomes. But when hospitals compete for patients by offering the same services and the same technologies, each surgeon, surgical team and hospital may have less practice. There may, in other words, be too few patients for each hospital to generate outstanding outcomes but enough patients for hospitals to generate satisfactory profits.

Thus, by spreading the same number of procedures over more hospitals and surgical teams, the medical arms race may reduce the amount of experience of each team – leading potentially to higher mortality rates.

Government Actions

The government enacts mandates to protect patients from abusive short term cost controls. The government says to the carriers 'You have to cover these services.' The carriers respond 'We don't want to cover those services. It's going to raise premium prices.' The government then passes regulations and imposes mandates – in effect saying to the carriers 'Now you have to cover these services.'

Or the government says to providers 'We want you to act in this way' like having minimum nurse to patient ratios. The providers respond 'We don't want to act that way because it will drive up costs.' So the government passes regulations and mandates that force providers to act in certain ways.

Rather than affecting outcomes, mandates reflect the political power of the groups involved**.** Minimum nurse staffing ratios are sponsored by nurses groups; mental health coverage mandates are promoted by mental health professionals; alternative health coverage is pushed by acupuncturists, chiropractic is supported by chiropractors, etc. There are virtually no credible outcome measures to prove that any of these increase longevity or improve patients' quality of life. But each lobbying group says it's important, and mandates generate jobs for members. To be sure, many of these medical groups provide huge benefits to patients. Many do excellent work. I do not at all want to denigrate them. But I want to suggest that mandating medical services is expensive and is largely a function of our employer based financing system and the split between finance and service provision.

[23] J. Robinson and H. Luft 'The Impact of Hospital market Structure on Patient Volume, Average Length of Stay and the Cost of Care' Journal of Health Economics 4 (1985) 333:56

[24] David Dranove, 'The Economic Evolution of American Healthcare', Princeton University Press, 2000, page 47

Many commentators think that provider payments based on outcomes would accomplish the same goal at a much lower cost. But that's the subject of a different lecture. The downside of all this is that the more the government gets involved inappropriately - fixing problems that it shouldn't be fixing - the more we raise healthcare costs. More mandates equal higher costs. Higher costs increase the need for health insurance but make it less affordable. This leads to more uninsured folks and more government subsidies. Yet there is no measurable impact of mandates on longevity or other patient outcomes.

Problems with Employer Based Healthcare Financing

So far, we have discussed goals and incentives under the Employer Based model. Let's now look at some specific problems with this form of healthcare financing.

We'll look at 5 different problems:

1. Administrative Costs
2. Coverage and Pricing Problems
3. Price Structure
4. Labor Market Distortions
5. Healthcare Market Distortions

Problem #1: Administrative Costs

Carriers generally charge around 10 or so percent of premium to cover their administration. Medicare, which is a single payer system, charges around 2%. CALPERS, the California public employee system, covers about 400,000 people with Kaiser Permanente for about a 0.5% administrative fee – that's half of one percent of premium. Other countries with single payer healthcare systems pay less for administration. So we're already at a financial disadvantage by going to the private sector to cover health insurance financially. In addition to the 10% carrier cost, providers need complex and expensive administrative capabilities to bill the appropriate carrier for each patient treatment – remember, this is a fee-for-service model. This means providers need to track prices, codes, covered services etc. by carrier. Imagine a physician office that contracts with a dozen carriers! Some researchers estimate that carrier + provider administration represents up to 30% of all healthcare spending. That's over a trillion dollars in today's healthcare system. This high administrative cost puts our employers at a competitive disadvantage internationally, which really became noticeable in our economy from 1990 or so onward.

The problem with high administrative costs is it leads to higher premiums. That leads to higher demands for insurance subsidies. In a sense, we're always chasing our tail in this, which was fine as long as our economy was strong and we could set the world price. But when Korean steel manufacturers began undercutting American steel manufacturers' prices, we lost the margins to cover high administrative fees and the related high need for insurance subsidies and we began to run into trouble.

Problem #2: Coverage Problems

The second problem with employer based coverage is medical *continuity of treatment.* If you change your job, you may change your doctors or hospitals, which may lead to a change in your treatment. The previous treatment might have been covered under your previous insurance, but is no longer covered under your new plan. Ditto for your medications. Or number of physical therapy, chiropractic, psychotherapy, etc. appointments. In other words, your treatment plan may be a function of your job, not just your medical condition. This can have negative impacts on healthcare outcomes, especially for patients unable to advocate well for themselves.

Problem #3: Price Structure

Price is a function of employer contribution plus employee contribution. The employer pays his/her bit ---- often 50 – 75% of premium, and the employee pays the rest. But if you don't qualify for the employer based side of things then you end up paying 100%. You get whacked on price. You have to pay both the employer bit plus the employee bit. If you're poor – or relatively poor – defined as earning less than 400% of the Federal Poverty Level, then you can get insurance and subsidies through an Obamacare exchange. In essence, taxpayers fund the employer's contribution because, again, we have structured our healthcare distribution system around employers. (Got a headache yet?) But if you're rich, defined as earning greater than 400% of the federal poverty level, then you get no such subsidy and are responsible for both the employer and employee contributions.

This burden leads, among other things, to labor market distortions.

Problem #4: Labor Market Distortions

Some employees – perhaps 40% of chronically ill folks – chose jobs or remain in their jobs for the benefits. The lack of health coverage is a disincentive for Americans to create new businesses. Some people don't start their own business or become an independent contractor. Remember that small business has always been our engine for economic growth. The employer-based financing system stifles the growth of small business. John Goodman, a healthcare economist, estimates that among chronically ill workers the employer-based system reduced job mobility by 40%. [25] That has an effect on all of us. We're not getting employees who are the best at their jobs – who have high job satisfaction and related job performance. Instead too many employees are stuck in their jobs, unable to move, generating poorer outputs and potentially facing other problems. We get a poorer economic return from these employees. That's simultaneously sad and economically inefficient.

Problem #5: Healthcare Market Distortions

The employer contribution has a negative impact on carriers' efforts to control healthcare costs. Sounds contradictory, doesn't it? But let's go through the reasoning. In this example, let's assume that an employer offers plans from two competing carriers and pays 75% of the premium. The employee sees only 25% of any efficiency gains generated by carriers or providers, because the employee only pays 25% of the premium. (Actually only about 15% of the gains, assuming the employee is in the 40% combined state and federal tax bracket.) In other words, if the carrier can reduce costs by $1000/year, the employee only sees $250 in savings – closer to $150 after the tax benefits. To receive that $150 savings, the employee might need to complete complicated paperwork,

[25] Goodman, Employer Sponsored, Personal and Portable Health Insurance, Health Affairs, Nov/Dec 2006

change physician or hospital, or agree to a different type of treatment. Probably too much effort for many employees.

But generating that $150 employee savings also creates too much burden for the carrier; it's simply too difficult to cut $1000 of cost. Stanford's Enthoven summarizes the problem of sizeable employer healthcare contributions:

They do not provide an incentive for employees to choose the economical alternative and it is not possible for the efficient systems [carriers] to gain market share by superior efficiency.[26] Unlike most sectors of our economy, there is no huge incentive on the part of insurance carriers to become more efficient. 'Let's reduce cost by 4%. We'll get more market share.' This doesn't work because of the employer contribution plus the tax incentives. Why would a carrier knock itself out to reduce cost? Cost reduction doesn't buy much. So carriers compete on other factors: marketing, pizzazz, gym membership, network size. They don't compete on value because they can't win at that game. Instead, carriers say "We can get our share of the market as long as we've priced it where the competition prices it. Then we'll do some marketing." There's no great competitive incentive to cut costs and improve quality. A similar situation occurs when only one carrier offers plans in a particular business. The employer is likely hesitant to switch the entire company – all the employees - to a different carrier for a small savings. That might create more employee problems than it solves. The carriers know this. So they keep prices in line with the competition, and provide the appropriate marketing pizzazz and gizmos, like network size and gym membership – neither of which apparently adds much to longevity.

Other sectors of our economy compete on value – a combination of price and outcomes. They compete by offering better products or lower priced products.

But not healthcare --- largely, though not entirely, because of our employer based financial structure.

The Medicare Modernization Act of 2003 and Health Savings Accounts

The George W. Bush administration passed a large and complex Medicare Act in 2003 that did several things, only some of which directly affected employer based health insurance. The Act, among non-employer based things, introduced drug coverage to Medicare and invented Medicare Part C, also known as Medicare Advantage. While both were important, neither directly impacted employer based insurance so are outside this current story. For that reason (only!) I'll pass over them here and only discuss Health Savings Accounts. Health Savings Accounts or HSAs have two basic components: a tax preferred savings account that allows account holders to pay medical costs in a tax advantaged way, and a high deductible health plan. In 2020 the minimum deductible for an HSA qualified plan is $1400 for an individual and $2800 for a family plan. These amounts vary annually.

Also in 2020, the maximum contributions to an HSA savings account are $3,550 for an individual and $7,100 for a family. Again, these amounts vary annually. There are, of course, lots of regulations defining appropriate HSA utilization. Uniquely in our tax code, HSAs offer triple tax benefits to owners. First, contributions are tax deductible to the individual and not taxable income if made by an employer. Second, HSA accounts grow tax free. Third, withdrawals made to pay qualified medical

[26] Enthoven, op. cit.

expenses are not taxable. This obviously benefits account holders substantially and expands on the 1953 IRS ruling that fringe benefits are tax deductible to the employer and not taxable income to the employee.

HSAs also theoretically benefit employers by allowing them to purchase health insurance with higher deductibles and consequently lower premiums. Again, see how this fits the history of employer based health insurance: as employers had increasing difficulty paying benefits post 1990 or so, the government stepped in to reduce benefit costs to employers. HSAs allowed employers to shift costs to employees and thus purchase less robust benefits.

We can understand HSAs, and their cousins Health Reimbursement Accounts, in history as efforts to maintain the employer based health insurance system structure, a structure under increasing financial pressure post 1990.

What else did the government do to support this increasingly unwieldy system?

The Affordable Care Act

Passed in 2010, the ACA is the latest – and last? - attempt to prop up the employer based insurance financing system. President Barak Obama introduced the Affordable Care Act (a.k.a. the Personal Protection and Affordable Care Act or Obamacare) in 2010. It's a huge piece of legislation, vast in scope and complexity, more or less a business plan for our $3.5 trillion healthcare economy. At $3.8 trillion, our healthcare economy is about the size of France or Britain's total economy, half again as big as Russia's or India's total, and twice as big as Korea's or Spain's. Our healthcare economy only serves the medical needs of our 310 million people, while India's total economy serves all the needs – medical, transportation, education, defense, foreign aid etc – of its 1 billion people. Ditto for Russia with 140 million people. Consider the Affordable Care Act's size and magnitude as roughly equivalent to developing or fixing the entire economic program for Russia and Saudi Arabia, or Iran, Israel, Argentina, Poland and Mexico together. It's that huge and complicated and, I would guess, about equally unsuited to glib slogans or simplistic approaches.

The Act itself is huge, 2409 pages of text, consisting of 10 different chapters and having as its main thrust, better access to health services for Americans. Chapter 1, 374 pages, explains how health insurance becomes a guaranteed issue product (meaning you cannot be denied coverage) with an individual mandate covering all Americans. Coverage is, in other words, both available and required. Chapter 1 also introduces subsidies, exchanges and employer's responsibilities under the Act. Chapter 2 addresses the role of public programs like Medicaid, the Children's Health Insurance Program and the Indian Health Services. This Chapter discusses subsidies and enrollment standards and extends the CHIP program through 2019. Chapter 3 consists of 501 pages that improve healthcare quality and efficiency. This Chapter addresses the process of changing from a fee-for-service financing model to quality based payments through Medical Homes, Accountable Care Organizations and similar. It also reduces Medicare spending via efficiency gains and seems to assume that private health insurance carriers will follow Medicare's model.

Chapter 4, Prevention of Chronic Disease and Improving Health, spends 130 pages discussing how our healthcare system will transform in order to treat chronic illnesses, like obesity. It mandates food labels in restaurants and elevates the US Preventive Services Task Force's role in determining which preventive tests will be covered at no out-of-pocket cost to patients.

Chapter 5, 256 pages, tells how our healthcare work force will evolve. It addresses the lack of primary care physicians, creates the Ready Reserve Corp and increases the Public Health Service Corp of first responders to deal with healthcare emergencies like epidemics and terrorism.

Chapter 6 aims to reduce systemic fraud and abuse and expand nursing home transparency.

Chapter 7, a short chapter called 'Improving Access to Innovative Therapies' is basically dedicated to improving access to generic drugs.

Chapter 8, Senator Ted Kennedy's baby, is the CLASS act or Community Living Assistance Services and Support, or federally funded long term care insurance. This was put on the back burner as it proved so difficult to implement.

Chapter 9 explains how we pay for all this, including fees on health insurers, drug manufacturers and medical device manufacturers and the "Cadillac" Tax on high cost health plans, among other things.

Chapter 10, Strengthening Quality Affordable Health Care for All Americans, 372 pages, is a bucket list of programs that various politicians wanted to include, like gun owner's rights and Nebraska's cornhusker kickback. Some commentators, including Princeton Professor Uwe Reinhardt, suggested that much of Chapter 10 was designed to be included in either House or Senate drafts for political reasons, then cut during the conference committee's 'cleansing' process. Scott Brown's election to replace Ted Kennedy scuttled that idea by depriving the Democrats of a filibuster-proof senate majority and effectively leaving all these programs in the final bill.

Why healthcare reform in 2009

President Obama decided to move aggressively on healthcare because of several disturbing trends. From 2000 – 2006

- Health insurance premiums rose by about 80% while
- Overall inflation only rose by 20%, but
- Median household income was actually down 3% in real (after inflation) terms.

Obama and his aides worried about two different health insurance death spirals affecting the individual and small group markets primarily.

The first kind of 'death spiral' would occur when healthy people decide not to purchase health insurance, thus leaving only sick people in the insurance pool. Premiums would rise quickly forcing 'healthier' sick people opt out, leaving only the sickest of the sick still in. Health insurance then would become a payment program for sick people, not its traditional role of protection against catastrophic financial calamity due to an unexpected illness for the vast majority of Americans.

The second, separate though somewhat related death spiral would occur when young people decide that health insurance is too expensive to purchase. Young 'invincibles' – so called because they don't think they'll get sick – exit the market, leaving only older and more expensive participants in the pool. Again premiums rise, causing more and more young, healthy people to leave the pool and thus depriving the insurance pool of this healthy, inexpensive population.

Obama worried that continued economic stagnation - as began with the stock market crash in 2007 - would exacerbate both of these situations. Indeed, the number of uninsured had risen in this country from under 44 million in 2002 to over 50 million in 2009.

In addition to potential insurance death spirals, Obama saw two kinds of healthcare waste consuming vast amounts of healthcare spending.

The first kind – geographic treatment variation tracked extensively by researchers at the Dartmouth Institute for Healthcare and Health Policy – alone represented about a third of all spending. Here's Dartmouth researcher Dr. Elliott Fisher after completing a massive study of Medicare treatment utilization rates:

a large fraction – perhaps a third – of medical care is devoted to services that do not necessarily improve health outcomes or the quality of care …

care in the U.S. could be just as good or better and cost a lot less — perhaps as much as 30 percent less — if all U.S. regions could safely adopt the more conservative practice patterns of lower-cost regions

Many other studies and research organizations, including the Congressional Budget Office, have arrived at similar overspending conclusions.

The second kind of waste – non-evidence based care - was quantified by a research team led by Dr.Vinay Prasad, senior fellow at the US National Cancer Institute. This team reviewed every article published in the New England Journal of Medicine over a 10 year period (2000 – 2010) then identified those that tested and overturned 'common' or routine medical practices. It's a fascinating though not a terribly easy-to-read study.

Prasad's conclusion:

Of all those things we're doing that lack good evidence, probably about half of them are incorrect.

Or, as Nicholas Balakar summarized Prasad's work in the New York Times

Many doctors persist in using practices that have been shown to be useless or harmful

Obama and his team worried that our healthcare system had no systematic, routinized mechanism for identifying such useless, ineffective or harmful practices and of informing doctors. We lacked a national, comprehensive data base of treatment outcomes and metrics. The economic and personal costs of failing to develop such a data base were probably both incalculable and huge.

In 2009, thus, Obama perceived the following about our healthcare system:

- Cost trend for past 30 to 40 yrs averaged our GDP growth rate + 3 to 5%, economically unsustainable
- Coverage trend
  - Increasing numbers and rates of uninsured
  - Possible death spirals in the small group and individual markets

- Tremendous medical test and treatment inefficiency when defined by
  - Geographic variation and
  - Effectiveness
- Mediocre outcomes when measured by longevity, disease morbidity, infant mortality as compared to other developed countries

Obama's concern: the private sector, mainly health insurance carriers, physicians, hospitals, pharmaceutical companies, medical device manufacturers and similar, could not alone solve these healthcare problems. The government had a role and responsibility to help also.

As an analogy, consider the relationship between a city's zoning regulations and private construction companies. The city says 'build industrial buildings here and residences there', then leaves the private companies to do the actual work. The public sector's responsibility is organizational; the private sector's is fill in and implementation. This imperfect analogy may shed some light on Obama's orientation and thinking.

A different way of saying the same thing: Obama did not trust markets to solve our healthcare problems. He thought our healthcare system needed some extra-market inputs.

Two Key ACA Impacts:
Obamacare's carrot and stick

As with the Medicare Modernization Act of 2003, Obamacare affected our healthcare system dramatically, in many ways unrelated to employer based insurance. I will here only outline a two major impacts on the employer based model here.

First, the ACA mandated that employers provide health insurance to employees or face financial penalties. This is interesting historically: remember how employers wanted to provide benefits in World War II to attract the best employees and how employers followed this pattern for decades after.

But the economic difficulties employers had funding benefits post 1990 or so, even with the introduction of HSAs, forced some to abandon the system. Employers went from *wanting to supply* benefits in the 1940s to *wanting to avoid supplying them* in the early 2000s. As a consequence, the number of uninsured Americans rose from about 44 million between 2002 – 2005 to 50 million in 2009. The HSA carrot of lower premiums by shifting costs to employees failed and the Obama administration decided they needed a stick to keep employers from fleeing.

That stick was the employer mandate.

Second, the ACA subsidized health insurance policies for people earning less than 400% of the federal poverty level along a sliding scale: the lower your income, the more your subsidy. Here are the 2020 federal poverty levels and the ACA limits (400%).

Household size	Federal Poverty Level	400% of the FPL
1	$12,490	$49,960
2	$16,910	$67,640

3	$21,330	$85,320
4	$25,750	$103,000

These subsidies were, again, essentially an attempt to prop up the now economically inefficient employer based system.

Even with the HSA carrot and Obamacare stick, however, some 27 million Americans still lacked health insurance by 2018. In addition, many Americans were 'underinsured' meaning they had health insurance but had difficulty paying their deductibles and skipped care as a result. By one estimate, 29% of insured people were underinsured in 2018 with the rate growing. [27]

Clearly, the employer based model was failing. Health insurance experts from across the political divide understood this by the mid 2010s. Not unsurprisingly, they proposed very different solutions to this problem.

Maybe the employer based model is on its wane. But it's in place today and many groups have an interest in maintaining it.

So let's discuss briefly what employers do to cope with this fundamentally unsound system.

First, cost sharing. That's a fancy way of saying 'make the employees – or the sick people - pay more.' It is not sustainable because we don't address the root causes of the problem. It's a band-aid that employees will only tolerate for a while. Then they start to rebel. They move out of state. They'll find some way to get out of it because they can't afford it.

I don't know what the tipping point is but I suspect that a $700/month employee contribution with a $5000 annual deductible for a single mother earing $80,000 with two kids is pretty close. And that's about the average household size and income in the US today: 2.6 people with $80,000 in annual income. 'Average' of course, means 'half are below this'. I wonder how a similar household earning $55,000 copes.

A variation on this is cost sharing with insurance carriers. Under various creative programs, employers who spend less during a plan year can get a rebate from the carrier.

The fundamental idea remains the same: working within a fundamentally unsound system, employers seek band-aids to get through the next year or two. Shift costs to employees: check. Get a rebate from carriers who overestimate one year's utilization and costs: check. Band-aid after band-aid, year after year.

The **second** thing employers try to do to improve this system - employee wellness programs. This seems a perennial hot button.

Changing employee lifestyles is very difficult and we get the benefits 20 or 30 or 40 years in the future but we pay for the program now. It's not going to reduce our current health insurance costs.

[27] Commonwealth Fund February 7, 2019, Underinsured Rate Rose From 2014-2018

Maybe people will live longer, maybe they'll be healthier in the future, but somebody else will get the savings.

But more fundamentally, the 'prevention will reduce healthcare costs' argument rests on a faulty assumption according to a couple of very clever economists, Bob Galvin of Yale and Suzanne Delbanco of the Leapfrog Group.[28]

Let's say employers offer great wellness programs that actually work. They reduce the need for hospitalizations and hospitals practice wonderfully safe medicine so nobody gets readmitted within 30 days. In other words, let's assume we decrease demand for healthcare. Will that reduce healthcare costs? Will that save us money?

The answer these guys put forward in, again, our fundamentally unsound system, is 'No'. No, it won't save us any money because doctors will stay in business. Hospitals will find ways to keep their beds full. They'll come up with new diseases. New technologies will develop to treat new (or old) problems. 40 years ago, how many people had sleep studies? None. We hadn't invented the technologies then. But today, lots of people have sleep studies and use CPAPs. A new medical industry.

According to Galvin and Delbanco, if we eliminate heart disease we're going to have a whole bunch of doctors treating other diseases. Galvin and Delbanco argue that healthcare is a super good in which the demand to live without pain and 'feel better' is continuous and robust. There are all kinds of life quality improvement procedures and treatments available to help people accomplish these goals.

Doctors and hospitals will find ways to maintain their income. This is kind of depressing because no matter what we do on the prevention side and the demand side, healthcare costs won't go down.

I'm not sure that I buy this argument completely. But I think it shows a problem with employer based health insurance. No matter what employers do, they won't be able to significantly lower their health insurance bills. They'll still face the same expense problems. They'll still have trouble competing with foreign firms.

Cost shifting and Wellness Programs won't save this flawed system. We'll need to look elsewhere for means to fix our healthcare financing structure. The incentive structure established by the employer based insurance model leads us to pay too much for the wrong kinds of treatments. Rather than investing in foot therapies or sophisticated podiatric remote reporting thermometers, we invest in foot amputations. Rather than investing in exercise programs, we invest in open heart surgeries. This serves the financial interests of the medical provider communities, that have, over time, solidified their financial and political power. But it doesn't serve the interests of the medical service payer communities. Our insurance cost problem is not primarily that some providers earn too much money or that others order unnecessary or duplicative tests. It is, rather, that we provide the wrong services to our population because we have institutionalized the wrong set of incentives. I hope you

[28] Robert Galvin and Suzanne Delbanco 'Between a Rock and a Hard Place: Understanding the Employer Mind-Set' Health Affairs, November / December, 2006

can see how our 90-year history of employer based health insurance included both the dynamic growth of this model and its demise:

- First, starting in 1929, employers began to provide health coverage to employees.
- Second, especially during World War II, the employer based system dramatically expanded.
- Third, post World War II, US firms dominated the world economy so could afford to provide generous insurance benefits to employees.
- Fourth, in the 1960s, Medicare and Medicaid took potential political threats to the system off the table.
- Fifth, post 2000, the government provided tax benefits and subsidies to prop up the increasingly economically inefficient employer based system.
- Sixth, post 2018 or so, the Medicare for All (Democratic) folks attacked the increasingly unwieldy system head on with a 'throw it out and base our entire healthcare system on Medicare' approach. The (Republican) reaction was to slice and dice our existing payment system and focus on individual health insurance buyer decision making. Let's explore these 2 very different directions.

Democratic reformers, led by Bernie Sanders and Elizabeth Warren, propose Medicare for All to eliminate employer based health insurance entirely. These folks say, in essence, that the employer based system has run its course and lived beyond its useful life. Instead of the currently convoluted system of subsidies, tax advantages and policy confusion they say, we should adopt one national health insurance program, funded by the government and equally available to all Americans. They propose using Medicare as the model.

Republican reformers, however, see history evolving in a different direction. Americans, they say, want health insurance choices. They have developed proposals to expand choice among Americans and increasingly these days support 'defined contribution' programs over the traditional employer funded 'defined benefit' plans.

In defined benefit plans, the employer makes all insurance policy decisions and offers the same benefits to all employees.

In defined contribution plans, the employer pays all employees a specific amount and the employees then purchase their own benefits.

Building on the defined contribution idea, Republicans want fewer health insurance requirements and more options available to Americans. Why, they ask, should an employer or even the government, choose your health insurance for you? Their answer: neither should but both together can provide funds for individuals and families to use for their health insurance purchases.

Republicans favor market solutions, arguing that efficiency comes from the unfettered relationship between a product buyer (patient) and seller (physician, hospital, pharmaceutical, etc.). Republicans see high healthcare costs, rather than high uninsured rates, as the fundamental problem and they believe that the best way to lower costs is through competitive markets.

- The market also stimulates medical innovation far better than any government program can.
- Activities that suppress the market do more harm than good for our healthcare system according to Republicans.
- As costs come down, so will rates of uninsured folks, since many would like to purchase health insurance policies but simply can't afford to.
- The market mechanism promotes efficiency, meaning the best outcomes at the lowest cost, far better than any other mechanism.

Democrats believe that healthcare is a right. Americans, they say, are entitled to clean air, clean water, elementary school education and access to medical care. Extending coverage to all Americans is simply the right thing for a just, enlightened society to do. The logical extension of the Democratic position is a national single payer system, sometimes called Medicare for All. Indeed, here is Senator Barak Obama, speaking in 2008: If I were designing a system from scratch, I would probably go ahead with a single payer system. Democrats believe that we need more governmental involvement in healthcare, more oversight, more regulation, more programs to protect people against systemic abuse, and, most importantly, more programs to ensure equity and expand coverage rates. Coverage, according to them, is the primary healthcare systemic problem right now. It's both morally wrong and economically inefficient to continue having 50 million uninsured Americans.

Our healthcare problems, say the Democrats, are fundamentally caused by having insufficient governmental involvement in healthcare, largely on the payment front.

Single payer healthcare systems cost less, argue Democrats: Medicare's administrative budget runs about 2% of total program costs, while private health insurers average around 10%. That difference, about 8% of $4 trillion in total annual healthcare spending, approaches $320 billion annually.

Single payer healthcare systems also generate better results, say the Democrats: Western European countries, Canada, Japan and other developed countries that have embraced single payer healthcare enjoy longer life spans and lower infant mortality rates than we do. Our private sector based healthcare financing system generates poorer value, meaning poorer results at higher costs. One key reason for this, according to Democrats: our overly expensive healthcare system deprives our various social programs of resources. In fact, Americans spend less on social support programs like housing subsidies, nutrition programs, job training and retraining and public health as a percent of GDP than do most other developed countries.

Democrats point to people like Joe described below, as needing far more social supports than exist today.[29] By medicalizing Joe's problems – meaning treat what are fundamentally social problems with expensive medical care – we end with poorer outcomes at higher costs. Joe, 28 years old, suffers from type I diabetes. He works only occasionally, has little cash available and consumes a poor diet consisting mainly of processed food with few fresh fruits or vegetables. Joe's shoes have holes in them so his feet are constantly damp. Last year he had 2 toes removed from his right foot due to poor circulation, costing $7,100 though he didn't pay any of this on his own. His doctor admonishes him

[29] This discussion comes from The American Healthcare Paradox by Elizabeth Bradley and Lauren Taylor

to keep his feet dry, eat better food and take his insulin but Joe can't afford to do any of these sufficiently regularly. He will likely lose toes on his left foot costing $14,000 and faces a potential below-the-knee amputation ($17,000) leading both to total medical expenses exceeding $30,000 and a lifetime existence on social benefits. Post-amputation, it's unlikely that Joe will earn enough to pay very much in taxes – one standard measure of contribution to our society - if he pays anything at all.

The first tragedy in Joe's story: new shoes cost $50 and apples about $1/day. We, as a society, could solve many of Joe's medical problems for a few hundred dollars annually and help turn him from an economic 'taker' into an economic contributor. The second tragedy is that we already spend enough on healthcare + social services combined to treat problems like Joe's. In fact, according to Bradley and Taylor's research published in their book The American Paradox, the US already spends at about the OECD average for healthcare and social services together. But we misallocate those resources. We're 1 of only three countries that spends the majority of [medical + social] on 'medical'; most other countries spend about 2/3 on 'social'. We have, thus, medicalized our social problems, very expensively and inefficiently. That's why single payer systems generate better results at lower medical costs than we do: by controlling medical spending more tightly, they allow societies to invest more in social programs.

This resource misallocation harms everyone in our society, claim Democrats, not just the poor. They cite research studies to back up this line of reasoning. Elizabeth Gudrais, for example, summarizing research by Harvard Professor Majid Ezzati, finds that Americans at top income levels live longer than people at bottom income levels, but less long than people at top income levels of other countriesBradley and Taylor find, in The American Paradox, that American health outcomes among insured populations lag substantially behind those of other countries. Our entire system needs, according to Democrats, a complete overhaul with Medicare for All or something similar as the ultimate goal.

Republicans see healthcare very differently from Democrats. They see healthcare provision as a product, not a human right. As a product, it will respond to market forces that demand efficiencies. Republicans believe that the suppliers of healthcare will develop new products to capture markets, that the best of the suppliers will succeed, the worst i.e. least efficient will fail and that our system will be better for it.

The key element in the Republican's vision is stimulating consumer demand for services by getting money into patient's hands. They favor tax credits – refundable or otherwise - that allow people to purchase their own insurance policies rather than having their employer do this for them, and higher deductibles so consumers have 'skin in the game' when making medical care decisions. Republicans think our uninsured problem is caused primarily by the high cost of medical insurance. Their efficiency-oriented programs will reduce costs they say, thereby making insurance affordable to more people and reducing our rate of uninsured to a more reasonable number, one that public programs can, realistically, address. Mitt Romney, in an early draft of RomneyCare in Massachusetts, aimed for individual monthly premiums of $200. Though never passed, that is the type of low cost insurance option Republicans would like to offer.

Republicans worry about market inefficiencies causing US hip replacements to average about $40,000 while Spanish cost about $8000, or New York City colonoscopy prices to range from $2000 to $8700 depending on the hospital, for exactly the same service. These discrepancies exist because

market forces are suppressed in our healthcare system by regulations and public programs claim the Republicans.

Our healthcare problems, they say, are fundamentally caused by having too much governmental involvement in healthcare. Today's 'health insurance', say Republicans, actually combines two different financial products, 'insurance' traditionally defined as protection against catastrophic financial harm from unexpected events, and 'routine medical financing' or payments for normal, expected medical activities. Suppressing market financing for routine, predicted medical activities like flu shots, child deliveries and knee replacements decreases efficiency and raises costs. Better financial tools exist. Using insurance to finance all medical activities opens the system to moral hazard abuse. 'Moral hazard' means people spend insurance money less judiciously than they would spend their own and get more medical care because it appears 'free' to them. An insurance- based healthcare financing system is, virtually by definition, one that promotes excessive care and waste.

Republicans sometimes point to Switzerland and Singapore as two countries that have organized their healthcare financing systems 'efficiently'. Other times they point out specific examples of efficient healthcare providers like Shouldice Hernia Hospital in Canada that generates outstanding outcomes for about half the normal US cost. This hospital is so fascinating that the Harvard Business School case study on it was, when last I checked, the 4th best seller of all its case studies. Apollo Hospitals in India, subject of another Harvard Business School case study, and Bumrumgrad in Thailand, compete for international patients by providing outstanding outcomes at relatively low costs. Republicans would like to see the efficiencies of Shouldice, Apollo and Bumrumgrad copied throughout the US.

Which direction will we take as the employer based system winds down? Market based or government supported? Decide, as you read on, which type of solution seems most appropriate to you.

Part 3: Impacts and Implications of Insurance Payment Programs
The Context of Fee Based Health Insurance

Perceptive writers have waxed poetic about the failings of healthcare financing for centuries. Moliere, an articulate French playwright wrote about his own healthcare system faults eloquently in the 1600s. Arguably his most famous play, The Imaginary Invalid, describes how a hypochondriacal gentleman plots to marry his daughter off to a physician for the resulting free medical care. Fee-for-service medical costs, it appears, were too expensive even for the wealthy in the 1600s.

Perceptive writers like Moliere have entertained audiences with gallows humor about their shared tribulations for some 400 years.

More recently George Bernard Shaw wrote The Doctor's Dilemma in 1909 to skewer the private, fee-based healthcare financing system of the time. His analysis of the then-healthcare system mirrored Moliere's from 3 centuries earlier, showing that, unfortunately, some things never change. Shaw's Preface, reproduced below, 'is an extensive tirade against the … medical profession, as being excessively given to protestations of the public good and the actual pursuit of private interest' according to the Wikipedia summary. Shaw saw physicians as professionals who claimed to do well

for themselves by doing good for others, but in the end, always did well for themselves and only sometimes did good for others.

Since Shaw is far more articulate than me, I decided to include his Preface to the Doctor's Dilemma here. As you read this, consider how Shaw's complaints about his healthcare system in 1909 mirror many of our own today and ask yourself how much has changed over the past 113 years. (If you really want to depress yourself, read Moliere's Imaginary Invalid and ask yourself the same questions.) Then ask yourself how much – if at all – our healthcare reforms since 2003 have changed the incentive structure and underlying operation of the system. Yes, I understand that technology has improved. But I wonder if the system itself has.

We'll now hear from George Bernard Shaw himself.

The Doctor's Dilemma
Preface
On Doctors, 1909

It is not the fault of our doctors that the medical service of the community, as at present provided for, is a murderous absurdity.

That any sane nation, having observed that you could provide for the supply of bread by giving bakers a pecuniary interest in baking for you, should go on to give a surgeon a pecuniary interest in cutting off your leg, is enough to make one despair of political humanity.

But that is precisely what we have done. And the more appalling the mutilation, the more the mutilator is paid. He who corrects the ingrowing toe-nail receives a few shillings: he who cuts your inside out receives hundreds of guineas, except when he does it to a poor person for practice.

Scandalized voices murmur that these operations are necessary. They may be. It may also be necessary to hang a man or pull down a house. But we take good care not to make the hangman and

the housebreaker the judges of that. If we did, no man's neck would be safe and no man's house stable. But we do make the doctor the judge, and fine him anything from sixpence to several hundred guineas if he decides in our favor.

I cannot knock my shins severely without forcing on some surgeon the difficult question, "Could I not make a better use of a pocketful of guineas than this man is making of his leg? Could he not write as well—or even better—on one leg than on two? And the guineas would make all the difference in the world to me just now. My wife—my pretty ones—the leg may mortify—it is always safer to operate—he will be well in a fortnight—artificial legs are now so well made that they are really better than natural ones—evolution is towards motors and leglessness, etc., etc., etc."

Now there is no calculation that an engineer can make as to the behavior of a girder under a strain, or an astronomer as to the recurrence of a comet, more certain than the calculation that under such circumstances we shall be dismembered unnecessarily in all directions by surgeons who believe the operations to be necessary solely because they want to perform them. The process metaphorically called bleeding the rich man is performed not only metaphorically but literally every day by surgeons who are quite as honest as most of us. After all, what harm is there in it? The surgeon need not take off the rich man's (or woman's) leg or arm: he can remove the appendix or the uvula, and leave the patient none the worse after a fortnight or so in bed, whilst the nurse, the general practitioner, the apothecary, and the surgeon will be the better.

DOUBTFUL CHARACTER BORNE BY THE MEDICAL PROFESSION

Again I hear the voices indignantly muttering old phrases about the high character of a noble profession and the honor and conscience of its members. I must reply that the medical profession has not a high character: it has an infamous character. I do not know a single thoughtful and well-informed person who does not feel that the tragedy of illness at present is that it delivers you helplessly into the hands of a profession which you deeply mistrust, because it not only advocates and practices the most revolting cruelties in the pursuit of knowledge, and justifies them on grounds which would equally justify practicing the same cruelties on yourself or your children, or burning down London to test a patent fire extinguisher, but, when it has shocked the public, tries to reassure it with lies of breath-bereaving brazenness. That is the character the medical profession has got just now. It may be deserved or it may not: there it is at all events, and the doctors who have not realized this are living in a fool's paradise.

As to the humor and conscience of doctors, they have as much as any other class of men, no more and no less.

And what other men dare pretend to be impartial where they have a strong pecuniary interest on one side? Nobody supposes that doctors are less virtuous than judges; but a judge whose salary and reputation depended on whether the verdict was for plaintiff or defendant, prosecutor or prisoner, would be as little trusted as a general in the pay of the enemy.

To offer me a doctor as my judge, and then weight his decision with a bribe of a large sum of money and a virtual guarantee that if he makes a mistake it can never be proved against him, is to go wildly beyond the ascertained strain which human nature will bear. It is simply unscientific to allege or

believe that doctors do not under existing circumstances perform unnecessary operations and manufacture and prolong lucrative illnesses.

The only ones who can claim to be above suspicion are those who are so much sought after that their cured patients are immediately replaced by fresh ones. And there is this curious psychological fact to be remembered: a serious illness or a death advertizes the doctor exactly as a hanging advertizes the barrister who defended the person hanged.

Suppose, for example, a royal personage gets something wrong with his throat, or has a pain in his inside. If a doctor effects some trumpery cure with a wet compress or a peppermint lozenge nobody takes the least notice of him. But if he operates on the throat and kills the patient, or extirpates an internal organ and keeps the whole nation palpitating for days whilst the patient hovers in pain and fever between life and death, his fortune is made: every rich man who omits to call him in when the same symptoms appear in his household is held not to have done his utmost duty to the patient. The wonder is that there is a king or queen left alive in Europe.

DOCTOR'S CONSCIENCES

There is another difficulty in trusting to the honor and conscience of a doctor. Doctors are just like other Englishmen: most of them have no honor and no conscience: what they commonly mistake for these is sentimentality and an intense dread of doing anything that everybody else does not do, or omitting to do anything that everybody else does. This of course does amount to a sort of working or rule-of-thumb conscience; but it means that you will do anything, good or bad, provided you get enough people to keep you in countenance by doing it also. It is the sort of conscience that makes it possible to keep order on a pirate ship, or in a troop of brigands. It may be said that in the last analysis there is no other sort of honor or conscience in existence—that the assent of the majority is the only sanction known to ethics. No doubt this holds good in political practice. If mankind knew the facts, and agreed with the doctors, then the doctors would be in the right; and any person who thought otherwise would be a lunatic. But mankind does not agree, and does not know the facts. All that can be said for medical popularity is that until there is a practicable alternative to blind trust in the doctor, the truth about the doctor is so terrible that we dare not face it. Moliere saw through the doctors; but he had to call them in just the same. Napoleon had no illusions about them; but he had to die under their treatment just as much as the most credulous ignoramus that ever paid sixpence for a bottle of strong medicine. In this predicament most people, to save themselves from unbearable mistrust and misery, or from being driven by their conscience into actual conflict with the law, fall back on the old rule that if you cannot have what you believe in you must believe in what you have. When your child is ill or your wife dying, and you happen to be very fond of them, or even when, if you are not fond of them, you are human enough to forget every personal grudge before the spectacle of a fellow creature in pain or peril, what you want is comfort, reassurance, something to clutch at, were it but a straw. This the doctor brings you. You have a wildly urgent feeling that something must be done; and the doctor does something. Sometimes what he does kills the patient; but you do not know that; and the doctor assures you that all that human skill could do has been done. And nobody has the brutality to say to the newly bereft father, mother, husband, wife, brother, or sister, "You have killed your lost darling by your credulity."

THE PECULIAR PEOPLE

Besides, the calling in of the doctor is now compulsory except in cases where the patient is an adult—and not too ill to decide the steps to be taken. We are subject to prosecution for manslaughter or for criminal neglect if the patient dies without the consolations of the medical profession. This menace is kept before the public by the Peculiar People. The Peculiars, as they are called, have gained their name by believing that the Bible is infallible, and taking their belief quite seriously. The Bible is very clear as to the treatment of illness. The Epistle of James; chapter v., contains the following explicit directions:

14. Is any sick among you? let him call for the elders of the Church; and let them pray over him, anointing him with oil in the name of the Lord:

15. And the prayer of faith shall save the sick, and the Lord shall raise him up; and if he have committed sins, they shall be forgiven him.

The Peculiars obey these instructions and dispense with doctors. They are therefore prosecuted for manslaughter when their children die.

When I was a young man, the Peculiars were usually acquitted. The prosecution broke down when the doctor in the witness box was asked whether, if the child had had medical attendance, it would have lived. It was, of course, impossible for any man of sense and honor to assume divine omniscience by answering this in the affirmative, or indeed pretending to be able to answer it at all. And on this the judge had to instruct the jury that they must acquit the prisoner. Thus a judge with a keen sense of law (a very rare phenomenon on the Bench, by the way) was spared the possibility of leaving to sentence one prisoner (under the Blasphemy laws) for questioning the authority of Scripture, and another for ignorantly and superstitiously accepting it as a guide to conduct. To-day all this is changed. The doctor never hesitates to claim divine omniscience, nor to clamor for laws to punish any scepticism on the part of laymen. A modern doctor thinks nothing of signing the death certificate of one of his own diphtheria patients, and then going into the witness box and swearing a peculiar into prison for six months by assuring the jury, on oath, that if the prisoner's child, dead of diphtheria, had been placed under his treatment instead of that of St. James, it would not have lived. And he does so not only with impunity, but with public applause, though the logical course would be to prosecute him either for the murder of his own patient or for perjury in the case of St. James. Yet no barrister, apparently, dreams of asking for the statistics of the relative case-mortality in diphtheria among the Peculiars and among the believers in doctors, on which alone any valid opinion could be founded. The barrister is as superstitious as the doctor is infatuated; and the Peculiar goes unpitied to his cell, though nothing whatever has been proved except that his child does without the interference of a doctor as effectually as any of the hundreds of children who die every day of the same diseases in the doctor's care.

RECOIL OF THE DOGMA OF MEDICAL INFALLIBILITY ON THE DOCTOR

On the other hand, when the doctor is in the dock, or is the defendant in an action for malpractice, he has to struggle against the inevitable result of his former pretences to infinite knowledge and unerring skill. He has taught the jury and the judge, and even his own counsel, to believe that every doctor can, with a glance at the tongue, a touch on the pulse, and a reading of the clinical thermometer, diagnose with absolute certainty a patient's complaint, also that on dissecting a dead body he can

infallibly put his finger on the cause of death, and, in cases where poisoning is suspected, the nature of the poison used. Now all this supposed exactness and infallibility is imaginary; and to treat a doctor as if his mistakes were necessarily malicious or corrupt malpractices (an inevitable deduction from the postulate that the doctor, being omniscient, cannot make mistakes) is as unjust as to blame the nearest apothecary for not being prepared to supply you with sixpenny-worth of the elixir of life, or the nearest motor garage for not having perpetual motion on sale in gallon tins. But if apothecaries and motor car makers habitually advertized elixir of life and perpetual motion, and succeeded in creating a strong general belief that they could supply it, they would find themselves in an awkward position if they were indicted for allowing a customer to die, or for burning a chauffeur by putting petrol into his car. That is the predicament the doctor finds himself in when he has to defend himself against a charge of malpractice by a plea of ignorance and fallibility. His plea is received with flat credulity; and he gets little sympathy, even from laymen who know, because he has brought the incredulity on himself. If he escapes, he can only do so by opening the eyes of the jury to the facts that medical science is as yet very imperfectly differentiated from common curemongering witchcraft; that diagnosis, though it means in many instances (including even the identification of pathogenic bacilli under the microscope) only a choice among terms so loose that they would not be accepted as definitions in any really exact science, is, even at that, an uncertain and difficult matter on which doctors often differ; and that the very best medical opinion and treatment varies widely from doctor to doctor, one practitioner prescribing six or seven scheduled poisons for so familiar a disease as enteric fever where another will not tolerate drugs at all; one starving a patient whom another would stuff; one urging an operation which another would regard as unnecessary and dangerous; one giving alcohol and meat which another would sternly forbid, etc., etc., etc.: all these discrepancies arising not between the opinion of good doctors and bad ones (the medical contention is, of course, that a bad doctor is an impossibility), but between practitioners of equal eminence and authority. Usually it is impossible to persuade the jury that these facts are facts. Juries seldom notice facts; and they have been taught to regard any doubts of the omniscience and omnipotence of doctors as blasphemy. Even the fact that doctors themselves die of the very diseases they profess to cure passes unnoticed. We do not shoot out our lips and shake our heads, saying, "They save others: themselves they cannot save": their reputation stands, like an African king's palace, on a foundation of dead bodies; and the result is that the verdict goes against the defendant when the defendant is a doctor accused of malpractice.

Fortunately for the doctors, they very seldom find themselves in this position, because it is so difficult to prove anything against them. The only evidence that can decide a case of malpractice is expert evidence: that is, the evidence of other doctors; and every doctor will allow a colleague to decimate a whole countryside sooner than violate the bond of professional etiquet by giving him away. It is the nurse who gives the doctor away in private, because every nurse has some particular doctor whom she likes; and she usually assures her patients that all the others are disastrous noodles, and soothes the tedium of the sick-bed by gossip about their blunders. She will even give a doctor away for the sake of making the patient believe that she knows more than the doctor. But she dare not, for her livelihood, give the doctor away in public. And the doctors stand by one another at all costs. Now and then some doctor in an unassailable position, like the late Sir William Gull, will go into the witness box and say what he really thinks about the way a patient has been treated; but such behavior is considered little short of infamous by his colleagues.

WHY DOCTORS DO NOT DIFFER

The truth is, there would never be any public agreement among doctors if they did not agree to agree on the main point of the doctor being always in the right. Yet the two guinea man never thinks that the five shilling man is right: if he did, he would be understood as confessing to an overcharge of one pound seventeen shillings; and on the same ground the five shilling man cannot encourage the notion that the owner of the sixpenny surgery round the corner is quite up to his mark. Thus even the layman has to be taught that infallibility is not quite infallible, because there are two qualities of it to be had at two prices.

But there is no agreement even in the same rank at the same price. During the first great epidemic of influenza towards the end of the nineteenth century a London evening paper sent round a journalist-patient to all the great consultants of that day, and published their advice and prescriptions; a proceeding passionately denounced by the medical papers as a breach of confidence of these eminent physicians. The case was the same; but the prescriptions were different, and so was the advice. Now a doctor cannot think his own treatment right and at the same time think his colleague right in prescribing a different treatment when the patient is the same. Anyone who has ever known doctors well enough to hear medical shop talked without reserve knows that they are full of stories about each other's blunders and errors, and that the theory of their omniscience and omnipotence no more holds good among themselves than it did with Moliere and Napoleon. But for this very reason no doctor dare accuse another of malpractice. He is not sure enough of his own opinion to ruin another man by it. He knows that if such conduct were tolerated in his profession no doctor's livelihood or reputation would be worth a year's purchase. I do not blame him: I would do the same myself. But the effect of this state of things is to make the medical profession a conspiracy to hide its own shortcomings. No doubt the same may be said of all professions. They are all conspiracies against the laity; and I do not suggest that the medical conspiracy is either better or worse than the military conspiracy, the legal conspiracy, the sacerdotal conspiracy, the pedagogic conspiracy, the royal and aristocratic conspiracy, the literary and artistic conspiracy, and the innumerable industrial, commercial, and financial conspiracies, from the trade unions to the great exchanges, which make up the huge conflict which we call society. But it is less suspected. The Radicals who used to advocate, as an indispensable preliminary to social reform, the strangling of the last king with the entrails of the last priest, substituted compulsory vaccination for compulsory baptism without a murmur.

THE CRAZE FOR OPERATIONS

Thus everything is on the side of the doctor. When men die of disease they are said to die from natural causes. When they recover (and they mostly do) the doctor gets the credit of curing them. In surgery all operations are recorded as successful if the patient can be got out of the hospital or nursing home alive, though the subsequent history of the case may be such as would make an honest surgeon vow never to recommend or perform the operation again.

The large range of operations which consist of amputating limbs and extirpating organs admits of no direct verification of their necessity. There is a fashion in operations as there is in sleeves and skirts: the triumph of some surgeon who has at last found out how to make a once desperate operation fairly safe is usually followed by a rage for that operation not only among the doctors, but actually among their patients. There are men and women whom the operating table seems to fascinate; half-alive people who through vanity, or hypochondria, or a craving to be the constant objects of anxious

attention or what not, lose such feeble sense as they ever had of the value of their own organs and limbs. They seem to care as little for mutilation as lobsters or lizards, which at least have the excuse that they grow new claws and new tails if they lose the old ones. Whilst this book was being prepared for the press a case was tried in the Courts, of a man who sued a railway company for damages because a train had run over him and amputated both his legs. He lost his case because it was proved that he had deliberately contrived the occurrence himself for the sake of getting an idler's pension at the expense of the railway company, being too dull to realize how much more he had to lose than to gain by the bargain even if he had won his case and received damages above his utmost hopes.

Thus amazing case makes it possible to say, with some prospect of being believed, that there is in the classes who can afford to pay for fashionable operations a sprinkling of persons so incapable of appreciating the relative importance of preserving their bodily integrity, (including the capacity for parentage) and the pleasure of talking about themselves and hearing themselves talked about as the heroes and heroines of sensational operations, that they tempt surgeons to operate on them not only with large fees, but with personal solicitation. Now it cannot be too often repeated that when an operation is once performed, nobody can ever prove that it was unnecessary. If I refuse to allow my leg to be amputated, its mortification and my death may prove that I was wrong; but if I let the leg go, nobody can ever prove that it would not have mortified had I been obstinate. Operation is therefore the safe side for the surgeon as well as the lucrative side. The result is that we hear of "conservative surgeons" as a distinct class of practitioners who make it a rule not to operate if they can possibly help it, and who are sought after by the people who have vitality enough to regard an operation as a last resort. But no surgeon is bound to take the conservative view. If he believes that an organ is at best a useless survival, and that if he extirpates it the patient will be well and none the worse in a fortnight, whereas to await the natural cure would mean a month's illness, then he is clearly justified in recommending the operation even if the cure without operation is as certain as anything of the kind ever can be. Thus the conservative surgeon and the radical or extirpatory surgeon may both be right as far as the ultimate cure is concerned; so that their consciences do not help them out of their differences.

CREDULITY AND CHLOROFORM

There is no harder scientific fact in the world than the fact that belief can be produced in practically unlimited quantity and intensity, without observation or reasoning, and even in defiance of both, by the simple desire to believe founded on a strong interest in believing. Everybody recognizes this in the case of the amatory infatuations of the adolescents who see angels and heroes in obviously (to others) commonplace and even objectionable maidens and youths. But it holds good over the entire field of human activity. The hardest-headed materialist will become a consulter of table-rappers and slate-writers if he loses a child or a wife so beloved that the desire to revive and communicate with them becomes irresistible. The cobbler believes that there is nothing like leather. The Imperialist who regards the conquest of England by a foreign power as the worst of political misfortunes believes that the conquest of a foreign power by England would be a boon to the conquered. Doctors are no more proof against such illusions than other men. Can anyone then doubt that under existing conditions a great deal of unnecessary and mischievous operating is bound to go on, and that patients are encouraged to imagine that modern surgery and anesthesia have made operations much less serious matters than they really are? When doctors write or speak to the public about operations, they imply, and often say in so many words, that chloroform has made surgery painless. People who have been

operated on know better. The patient does not feel the knife, and the operation is therefore enormously facilitated for the surgeon; but the patient pays for the anesthesia with hours of wretched sickness; and when that is over there is the pain of the wound made by the surgeon, which has to heal like any other wound. This is why operating surgeons, who are usually out of the house with their fee in their pockets before the patient has recovered consciousness, and who therefore see nothing of the suffering witnessed by the general practitioner and the nurse, occasionally talk of operations very much as the hangman in Barnaby Rudge talked of executions, as if being operated on were a luxury in sensation as well as in price.

MEDICAL POVERTY

To make matters worse, doctors are hideously poor. The Irish gentleman doctor of my boyhood, who took nothing less than a guinea, though he might pay you four visits for it, seems to have no equivalent nowadays in English society. Better be a railway porter than an ordinary English general practitioner. A railway porter has from eighteen to twenty-three shillings a week from the Company merely as a retainer; and his additional fees from the public, if we leave the third-class twopenny tip out of account (and I am by no means sure that even this reservation need be made), are equivalent to doctor's fees in the case of second-class passengers, and double doctor's fees in the case of first. Any class of educated men thus treated tends to become a brigand class, and doctors are no exception to the rule. They are offered disgraceful prices for advice and medicine. Their patients are for the most part so poor and so ignorant that good advice would be resented as impracticable and wounding. When you are so poor that you cannot afford to refuse eighteenpence from a man who is too poor to pay you any more, it is useless to tell him that what he or his sick child needs is not medicine, but more leisure, better clothes, better food, and a better drained and ventilated house.

It is kinder to give him a bottle of something almost as cheap as water, and tell him to come again with another eighteenpence if it does not cure him. When you have done that over and over again every day for a week, how much scientific conscience have you left? If you are weak-minded enough to cling desperately to your eighteenpence as denoting a certain social superiority to the sixpenny doctor, you will be miserably poor all your life; whilst the sixpenny doctor, with his low prices and quick turnover of patients, visibly makes much more than you do and kills no more people.

A doctor's character can no more stand out against such conditions than the lungs of his patients can stand out against bad ventilation. The only way in which he can preserve his self-respect is by forgetting all he ever learnt of science, and clinging to such help as he can give without cost merely by being less ignorant and more accustomed to sick-beds than his patients. Finally, he acquires a certain skill at nursing cases under poverty-stricken domestic conditions, just as women who have been trained as domestic servants in some huge institution with lifts, vacuum cleaners, electric lighting, steam heating, and machinery that turns the kitchen into a laboratory and engine house combined, manage, when they are sent out into the world to drudge as general servants, to pick up their business in a new way, learning the slatternly habits and wretched makeshifts of homes where even bundles of kindling wood are luxuries to be anxiously economized.

THE SUCCESSFUL DOCTOR

The doctor whose success blinds public opinion to medical poverty is almost as completely demoralized. His promotion means that his practice becomes more and more confined to the idle

rich. The proper advice for most of their ailments is typified in Abernethy's "Live on sixpence a day and earn it." But here, as at the other end of the scale, the right advice is neither agreeable nor practicable. And every hypochondriacal rich lady or gentleman who can be persuaded that he or she is a lifelong invalid means anything from fifty to five hundred pounds a year for the doctor. Operations enable a surgeon to earn similar sums in a couple of hours; and if the surgeon also keeps a nursing home, he may make considerable profits at the same time by running what is the most expensive kind of hotel. These gains are so great that they undo much of the moral advantage which the absence of grinding pecuniary anxiety gives the rich doctor over the poor one. It is true that the temptation to prescribe a sham treatment because the real treatment is too dear for either patient or doctor does not exist for the rich doctor. He always has plenty of genuine cases which can afford genuine treatment; and these provide him with enough sincere scientific professional work to save him from the ignorance, obsolescence, and atrophy of scientific conscience into which his poorer colleagues sink. But on the other hand his expenses are enormous. Even as a bachelor, he must, at London west end rates, make over a thousand a year before he can afford even to insure his life. His house, his servants, and his equipage (or autopage) must be on the scale to which his patients are accustomed, though a couple of rooms with a camp bed in one of them might satisfy his own requirements. Above all, the income which provides for these outgoings stops the moment he himself stops working. Unlike the man of business, whose managers, clerks, warehousemen and laborers keep his business going whilst he is in bed or in his club, the doctor cannot earn a farthing by deputy. Though he is exceptionally exposed to infection, and has to face all weathers at all hours of the night and day, often not enjoying a complete night's rest for a week, the money stops coming in the moment he stops going out; and therefore illness has special terrors for him, and success no certain permanence. He dare not stop making hay while the sun shines; for it may set at any time. Men do not resist pressure of this intensity. When they come under it as doctors they pay unnecessary visits; they write prescriptions that are as absurd as the rub of chalk with which an Irish tailor once charmed away a wart from my father's finger; they conspire with surgeons to promote operations; they nurse the delusions of the malade imaginaire (who is always really ill because, as there is no such thing as perfect health, nobody is ever really well); they exploit human folly, vanity, and fear of death as ruthlessly as their own health, strength, and patience are exploited by selfish hypochondriacs. They must do all these things or else run pecuniary risks that no man can fairly be asked to run. And the healthier the world becomes, the more they are compelled to live by imposture and the less by that really helpful activity of which all doctors get enough to preserve them from utter corruption. For even the most hardened humbug who ever prescribed ether tonics to ladies whose need for tonics is of precisely the same character as the need of poorer women for a glass of gin, has to help a mother through child-bearing often enough to feel that he is not living wholly in vain.

THE PSYCHOLOGY OF SELF-RESPECT IN SURGEONS

The surgeon, though often more unscrupulous than the general practitioner, retains his self-respect more easily. The human conscience can subsist on very questionable food. No man who is occupied in doing a very difficult thing, and doing it very well, ever loses his self-respect. The shirk, the duffer, the malingerer, the coward, the weakling, may be put out of countenance by his own failures and frauds; but the man who does evil skilfully, energetically, masterfully, grows prouder and bolder at every crime. The common man may have to found his self-respect on sobriety, honesty and industry; but a Napoleon needs no such props for his sense of dignity. If Nelson's conscience whispered to him at all in the silent watches of the night, you may depend on it it whispered about the Baltic and the

Nile and Cape St. Vincent, and not about his unfaithfulness to his wife. A man who robs little children when no one is looking can hardly have much self-respect or even self-esteem; but an accomplished burglar must be proud of himself. In the play to which I am at present preluding I have represented an artist who is so entirely satisfied with his artistic conscience, even to the point of dying like a saint with its support, that he is utterly selfish and unscrupulous in every other relation without feeling at the smallest disadvantage. The same thing may be observed in women who have a genius for personal attractiveness: they expend more thought, labor, skill, inventiveness, taste and endurance on making themselves lovely than would suffice to keep a dozen ugly women honest; and this enables them to maintain a high opinion of themselves, and an angry contempt for unattractive and personally careless women, whilst they lie and cheat and slander and sell themselves without a blush. The truth is, hardly any of us have ethical energy enough for more than one really inflexible point of honor. Andrea del Sarto, like Louis Dubedat in my play, must have expended on the attainment of his great mastery of design and his originality in fresco painting more conscientiousness and industry than go to the making of the reputations of a dozen ordinary mayors and churchwardens; but (if Vasari is to be believed) when the King of France entrusted him with money to buy pictures for him, he stole it to spend on his wife. Such cases are not confined to eminent artists. Unsuccessful, unskilful men are often much more scrupulous than successful ones. In the ranks of ordinary skilled labor many men are to be found who earn good wages and are never out of a job because they are strong, indefatigable, and skilful, and who therefore are bold in a high opinion of themselves; but they are selfish and tyrannical, gluttonous and drunken, as their wives and children know to their cost.

Not only do these talented energetic people retain their self-respect through shameful misconduct: they do not even lose the respect of others, because their talents benefit and interest everybody, whilst their vices affect only a few. An actor, a painter, a composer, an author, may be as selfish as he likes without reproach from the public if only his art is superb; and he cannot fulfil his condition without sufficient effort and sacrifice to make him feel noble and martyred in spite of his selfishness. It may even happen that the selfishness of an artist may be a benefit to the public by enabling him to concentrate himself on their gratification with a recklessness of every other consideration that makes him highly dangerous to those about him. In sacrificing others to himself he is sacrificing them to the public he gratifies; and the public is quite content with that arrangement. The public actually has an interest in the artist's vices.

It has no such interest in the surgeon's vices. The surgeon's art is exercised at its expense, not for its gratification. We do not go to the operating table as we go to the theatre, to the picture gallery, to the concert room, to be entertained and delighted: we go to be tormented and maimed, lest a worse thing should befall us. It is of the most extreme importance to us that the experts on whose assurance we face this horror and suffer this mutilation should leave no interests but our own to think of; should judge our cases scientifically; and should feel about them kindly. Let us see what guarantees we have: first for the science, and then for the kindness.

ARE DOCTORS MEN OF SCIENCE?

I presume nobody will question the existence of widely spread popular delusion that every doctor is a titan of science. It is escaped only in the very small class which understands by science something more than conjuring with retorts and spirit lamps, magnets and microscopes, and discovering magical cures for disease. To a sufficiently ignorant man every captain of a trading schooner is a Galileo, every organ-grinder a Beethoven, every piano-tuner a Hemholtz, every Old Bailey barrister a Solon,

every Seven Dials pigeon dealer a Darwin, every scrivener a Shakespear, every locomotive engine a miracle, and its driver no less wonderful than George Stephenson. As a matter of fact, the rank and file of doctors are no more scientific than their tailors; or, if you prefer to put it the reverse way, their tailors are no less scientific than they. Doctoring is an art, not a science: any layman who is interested in science sufficiently to take in one of the scientific journals and follow the literature of the scientific movement, knows more about it than those doctors (probably a large majority) who are not interested in it, and practise only to earn their bread. Doctoring is not even the art of keeping people in health (no doctor seems able to advise you what to eat any better than his grandmother or the nearest quack): it is the art of curing illnesses.

It does happen exceptionally that a practising doctor makes a contribution to science (my play describes a very notable one); but it happens much oftener that he draws disastrous conclusions from his clinical experience because he has no conception of scientific method, and believes, like any rustic, that the handling of evidence and statistics needs no expertness. The distinction between a quack doctor and a qualified one is mainly that only the qualified one is authorized to sign death certificates, for which both sorts seem to have about equal occasion. Unqualified practitioners now make large incomes as hygienists, and are resorted to as frequently by cultivated amateur scientists who understand quite well what they are doing as by ignorant people who are simply dupes. Bone-setters make fortunes under the very noses of our greatest surgeons from educated and wealthy patients; and some of the most successful doctors on the register use quite heretical methods of treating disease, and have qualified themselves solely for convenience. Leaving out of account the village witches who prescribe spells and sell charms, the humblest professional healers in this country are the herbalists. These men wander through the fields on Sunday seeking for herbs with magic properties of curing disease, preventing childbirth, and the like. Each of them believes that he is on the verge of a great discovery, in which Virginia Snake Root will be an ingredient, heaven knows why! Virginia Snake Root fascinates the imagination of the herbalist as mercury used to fascinate the alchemists. On week days he keeps a shop in which he sells packets of pennyroyal, dandelion, etc., labelled with little lists of the diseases they are supposed to cure, and apparently do cure to the satisfaction of the people who keep on buying them. I have never been able to perceive any distinction between the science of the herbalist and that of the duly registered doctor. A relative of mine recently consulted a doctor about some of the ordinary symptoms which indicate the need for a holiday and a change. The doctor satisfied himself that the patient's heart was a little depressed. Digitalis being a drug labelled as a heart specific by the profession, he promptly administered a stiff dose. Fortunately the patient was a hardy old lady who was not easily killed. She recovered with no worse result than her conversion to Christian Science, which owes its vogue quite as much to public despair of doctors as to superstition. I am not, observe, here concerned with the question as to whether the dose of digitalis was judicious or not; the point is, that a farm laborer consulting a herbalist would have been treated in exactly the same way.

BACTERIOLOGY AS A SUPERSTITION

The smattering of science that all—even doctors—pick up from the ordinary newspapers nowadays only makes the doctor more dangerous than he used to be. Wise men used to take care to consult doctors qualified before 1860, who were usually contemptuous of or indifferent to the germ theory and bacteriological therapeutics; but now that these veterans have mostly retired or died, we are left in the hands of the generations which, having heard of microbes much as St. Thomas Aquinas heard

of angels, suddenly concluded that the whole art of healing could be summed up in the formula: Find the microbe and kill it. And even that they did not know how to do. The simplest way to kill most microbes is to throw them into an open street or river and let the sun shine on them, which explains the fact that when great cities have recklessly thrown all their sewage into the open river the water has sometimes been cleaner twenty miles below the city than thirty miles above it. But doctors instinctively avoid all facts that are reassuring, and eagerly swallow those that make it a marvel that anyone could possibly survive three days in an atmosphere consisting mainly of countless pathogenic germs. They conceive microbes as immortal until slain by a germicide administered by a duly qualified medical man. All through Europe people are adjured, by public notices and even under legal penalties, not to throw their microbes into the sunshine, but to collect them carefully in a handkerchief; shield the handkerchief from the sun in the darkness and warmth of the pocket; and send it to a laundry to be mixed up with everybody else's handkerchiefs, with results only too familiar to local health authorities.

In the first frenzy of microbe killing, surgical instruments were dipped in carbolic oil, which was a great improvement on not dipping them in anything at all and simply using them dirty; but as microbes are so fond of carbolic oil that they swarm in it, it was not a success from the anti-microbe point of view. Formalin was squirted into the circulation of consumptives until it was discovered that formalin nourishes the tubercle bacillus handsomely and kills men. The popular theory of disease is the common medical theory: namely, that every disease had its microbe duly created in the garden of Eden, and has been steadily propagating itself and producing widening circles of malignant disease ever since. It was plain from the first that if this had been even approximately true, the whole human race would have been wiped out by the plague long ago, and that every epidemic, instead of fading out as mysteriously as it rushed in, would spread over the whole world. It was also evident that the characteristic microbe of a disease might be a symptom instead of a cause. An unpunctual man is always in a hurry; but it does not follow that hurry is the cause of unpunctuality: on the contrary, what is the matter with the patient is sloth. When Florence Nightingale said bluntly that if you overcrowded your soldiers in dirty quarters there would be an outbreak of smallpox among them, she was snubbed as an ignorant female who did not know that smallpox can be produced only by the importation of its specific microbe.

If this was the line taken about smallpox, the microbe of which has never yet been run down and exposed under the microscope by the bacteriologist, what must have been the ardor of conviction as to tuberculosis, tetanus, enteric fever, Maltese fever, diphtheria, and the rest of the diseases in which the characteristic bacillus had been identified! When there was no bacillus it was assumed that, since no disease could exist without a bacillus, it was simply eluding observation. When the bacillus was found, as it frequently was, in persons who were not suffering from the disease, the theory was saved by simply calling the bacillus an impostor, or pseudobacillus. The same boundless credulity which the public exhibit as to a doctor's power of diagnosis was shown by the doctors themselves as to the analytic microbe hunters. These witch finders would give you a certificate of the ultimate constitution of anything from a sample of the water from your well to a scrap of your lungs, for seven-and-sixpense. I do not suggest that the analysts were dishonest. No doubt they carried the analysis as far as they could afford to carry it for the money. No doubt also they could afford to carry it far enough to be of some use. But the fact remains that just as doctors perform for half-a-crown, without the least misgiving, operations which could not be thoroughly and safely performed with due scientific rigor and the requisite apparatus by an unaided private practitioner for less than some thousands of pounds,

so did they proceed on the assumption that they could get the last word of science as to the constituents of their pathological samples for a two hours cab fare.

ECONOMIC DIFFICULTIES OF IMMUNIZATION

I have heard doctors affirm and deny almost every possible proposition as to disease and treatment. I can remember the time when doctors no more dreamt of consumption and pneumonia being infectious than they now dream of sea-sickness being infectious, or than so great a clinical observer as Sydenham dreamt of smallpox being infectious. I have heard doctors deny that there is such a thing as infection. I have heard them deny the existence of hydrophobia as a specific disease differing from tetanus. I have heard them defend prophylactic measures and prophylactic legislation as the sole and certain salvation of mankind from zymotic disease; and I have heard them denounce both as malignant spreaders of cancer and lunacy. But the one objection I have never heard from a doctor is the objection that prophylaxis by the inoculatory methods most in vogue is an economic impossibility under our private practice system. They buy some stuff from somebody for a shilling, and inject a pennyworth of it under their patient's skin for half-a-crown, concluding that, since this primitive rite pays the somebody and pays them, the problem of prophylaxis has been satisfactorily solved. The results are sometimes no worse than the ordinary results of dirt getting into cuts; but neither the doctor nor the patient is quite satisfied unless the inoculation "takes"; that is, unless it produces perceptible illness and disablement. Sometimes both doctor and patient get more value in this direction than they bargain for. The results of ordinary private-practice-inoculation at their worst are bad enough to be indistinguishable from those of the most discreditable and dreaded disease known; and doctors, to save the credit of the inoculation, have been driven to accuse their patient or their patient's parents of having contracted this disease independently of the inoculation, an excuse which naturally does not make the family any more resigned, and leads to public recriminations in which the doctors, forgetting everything but the immediate quarrel, naively excuse themselves by admitting, and even claiming as a point in their favor, that it is often impossible to distinguish the disease produced by their inoculation and the disease they have accused the patient of contracting. And both parties assume that what is at issue is the scientific soundness of the prophylaxis. It never occurs to them that the particular pathogenic germ which they intended to introduce into the patient's system may be quite innocent of the catastrophe, and that the casual dirt introduced with it may be at fault. When, as in the case of smallpox or cowpox, the germ has not yet been detected, what you inoculate is simply undefined matter that has been scraped off an anything but chemically clean calf suffering from the disease in question. You take your chance of the germ being in the scrapings, and, lest you should kill it, you take no precautions against other germs being in it as well. Anything may happen as the result of such an inoculation. Yet this is the only stuff of the kind which is prepared and supplied even in State establishments: that is, in the only establishments free from the commercial temptation to adulterate materials and scamp precautionary processes.

Even if the germ were identified, complete precautions would hardly pay. It is true that microbe farming is not expensive. The cost of breeding and housing two head of cattle would provide for the breeding and housing of enough microbes to inoculate the entire population of the globe since human life first appeared on it. But the precautions necessary to insure that the inoculation shall consist of nothing else but the required germ in the proper state of attenuation are a very different matter from the precautions necessary in the distribution and consumption of beefsteaks. Yet people expect to

find vaccines and antitoxins and the like retailed at "popular prices" in private enterprise shops just as they expect to find ounces of tobacco and papers of pins.

THE PERILS OF INOCULATION

The trouble does not end with the matter to be inoculated. There is the question of the condition of the patient. The discoveries of Sir Almroth Wright have shown that the appalling results which led to the hasty dropping in 1894 of Koch's tuberculin were not accidents, but perfectly orderly and inevitable phenomena following the injection of dangerously strong "vaccines" at the wrong moment, and reinforcing the disease instead of stimulating the resistance to it. To ascertain the right moment a laboratory and a staff of experts are needed. The general practitioner, having no such laboratory and no such experience, has always chanced it, and insisted, when he was unlucky, that the results were not due to the inoculation, but to some other cause: a favorite and not very tactful one being the drunkenness or licentiousness of the patient. But though a few doctors have now learnt the danger of inoculating without any reference to the patient's "opsonic index" at the moment of inoculation, and though those other doctors who are denouncing the danger as imaginary and opsonin as a craze or a fad, obviously do so because it involves an operation which they have neither the means nor the knowledge to perform, there is still no grasp of the economic change in the situation. They have never been warned that the practicability of any method of extirpating disease depends not only on its efficacy, but on its cost. For example, just at present the world has run raving mad on the subject of radium, which has excited our credulity precisely as the apparitions at Lourdes excited the credulity of Roman Catholics. Suppose it were ascertained that every child in the world could be rendered absolutely immune from all disease during its entire life by taking half an ounce of radium to every pint of its milk. The world would be none the healthier, because not even a Crown Prince—no, not even the son of a Chicago Meat King, could afford the treatment. Yet it is doubtful whether doctors would refrain from prescribing it on that ground. The recklessness with which they now recommend wintering in Egypt or at Davos to people who cannot afford to go to Cornwall, and the orders given for champagne jelly and old port in households where such luxuries must obviously be acquired at the cost of stinting necessaries, often make one wonder whether it is possible for a man to go through a medical training and retain a spark of common sense. This sort of inconsiderateness gets cured only in the classes where poverty, pretentious as it is even at its worst, cannot pitch its pretences high enough to make it possible for the doctor (himself often no better off than the patient) to assume that the average income of an English family is about 2,000 pounds a year, and that it is quite easy to break up a home, sell an old family seat at a sacrifice, and retire into a foreign sanatorium devoted to some "treatment" that did not exist two years ago and probably will not exist (except as a pretext for keeping an ordinary hotel) two years hence. In a poor practice the doctor must find cheap treatments for cheap people, or humiliate and lose his patients either by prescribing beyond their means or sending them to the public hospitals. When it comes to prophylactic inoculation, the alternative lies between the complete scientific process, which can only be brought down to a reasonable cost by being very highly organized as a public service in a public institution, and such cheap, nasty, dangerous and scientifically spurious imitations as ordinary vaccination, which seems not unlikely to be ended, like its equally vaunted forerunner, XVIII. century inoculation, by a purely reactionary law making all sorts of vaccination, scientific or not, criminal offences. Naturally, the poor doctor (that is, the average doctor) defends ordinary vaccination frantically, as it means to him the bread of his children. To secure the vehement and practically unanimous support of the rank and file of the medical profession for any sort of treatment or operation, all that is necessary is that it can be easily

practised by a rather shabbily dressed man in a surgically dirty room in a surgically dirty house without any assistance, and that the materials for it shall cost, say, a penny, and the charge for it to a patient with 100 pounds a year be half-a-crown. And, on the other hand, a hygienic measure has only to be one of such refinement, difficulty, precision and costliness as to be quite beyond the resources of private practice, to be ignored or angrily denounced as a fad.

TRADE UNIONISM AND SCIENCE

Here we have the explanation of the savage rancor that so amazes people who imagine that the controversy concerning vaccination is a scientific one. It has really nothing to do with science. The medical profession, consisting for the most part of very poor men struggling to keep up appearances beyond their means, find themselves threatened with the extinction of a considerable part of their incomes: a part, too, that is easily and regularly earned, since it is independent of disease, and brings every person born into the nation, healthy or not, to the doctors. To boot, there is the occasional windfall of an epidemic, with its panic and rush for revaccination. Under such circumstances, vaccination would be defended desperately were it twice as dirty, dangerous, and unscientific in method as it actually is. The note of fury in the defence, the feeling that the anti-vaccinator is doing a cruel, ruinous, inconsiderate thing in a mood of indignant folly: all this, so puzzling to the observer who knows nothing of the economic side of the question, and only sees that the anti-vaccinator, having nothing whatever to gain and a good deal to lose by placing himself in opposition to the law and to the outcry that adds private persecution to legal penalties, can have no interest in the matter except the interest of a reformer in abolishing a corrupt and mischievous superstition, becomes intelligible the moment the tragedy of medical poverty and the lucrativeness of cheap vaccination is taken into account.

In the face of such economic pressure as this, it is silly to expect that medical teaching, any more than medical practice, can possibly be scientific. The test to which all methods of treatment are finally brought is whether they are lucrative to doctors or not. It would be difficult to cite any proposition less obnoxious to science, than that advanced by Hahnemann: to wit, that drugs which in large doses produce certain symptoms, counteract them in very small doses, just as in more modern practice it is found that a sufficiently small inoculation with typhoid rallies our powers to resist the disease instead of prostrating us with it. But Hahnemann and his followers were frantically persecuted for a century by generations of apothecary-doctors whose incomes depended on the quantity of drugs they could induce their patients to swallow. These two cases of ordinary vaccination and homeopathy are typical of all the rest. Just as the object of a trade union under existing conditions must finally be, not to improve the technical quality of the work done by its members, but to secure a living wage for them, so the object of the medical profession today is to secure an income for the private doctor; and to this consideration all concern for science and public health must give way when the two come into conflict. Fortunately they are not always in conflict. Up to a certain point doctors, like carpenters and masons, must earn their living by doing the work that the public wants from them; and as it is not in the nature of things possible that such public want should be based on unmixed disutility, it may be admitted that doctors have their uses, real as well as imaginary. But just as the best carpenter or mason will resist the introduction of a machine that is likely to throw him out of work, or the public technical education of unskilled laborers' sons to compete with him, so the doctor will resist with all his powers of persecution every advance of science that threatens his income. And as the advance of scientific hygiene tends to make the private doctor's visits rarer, and the public inspector's frequenter,

whilst the advance of scientific therapeutics is in the direction of treatments that involve highly organized laboratories, hospitals, and public institutions generally, it unluckily happens that the organization of private practitioners which we call the medical profession is coming more and more to represent, not science, but desperate and embittered antiscience: a statement of things which is likely to get worse until the average doctor either depends upon or hopes for an appointment in the public health service for his livelihood.

So much for our guarantees as to medical science. Let us now deal with the more painful subject of medical kindness.

DOCTORS AND VIVISECTION

The importance to our doctors of a reputation for the tenderest humanity is so obvious, and the quantity of benevolent work actually done by them for nothing (a great deal of it from sheer good nature) so large, that at first sight it seems unaccountable that they should not only throw all their credit away, but deliberately choose to band themselves publicly with outlaws and scoundrels by claiming that in the pursuit of their professional knowledge they should be free from the restraints of law, of honor, of pity, of remorse, of everything that distinguishes an orderly citizen from a South Sea buccaneer, or a philosopher from an inquisitor. For here we look in vain for either an economic or a sentimental motive. In every generation fools and blackguards have made this claim; and honest and reasonable men, led by the strongest contemporary minds, have repudiated it and exposed its crude rascality. From Shakespear and Dr. Johnson to Ruskin and Mark Twain, the natural abhorrence of sane mankind for the vivisector's cruelty, and the contempt of able thinkers for his imbecile casuistry, have been expressed by the most popular spokesmen of humanity. If the medical profession were to outdo the Anti-Vivisection Societies in a general professional protest against the practice and principles of the vivisectors, every doctor in the kingdom would gain substantially by the immense relief and reconciliation which would follow such a reassurance of the humanity of the doctor. Not one doctor in a thousand is a vivisector, or has any interest in vivisection, either pecuniary or intellectual, or would treat his dog cruelly or allow anyone else to do it. It is true that the doctor complies with the professional fashion of defending vivisection, and assuring you that people like Shakespear and Dr. Johnson and Ruskin and Mark Twain are ignorant sentimentalists, just as he complies with any other silly fashion: the mystery is, how it became the fashion in spite of its being so injurious to those who follow it. Making all possible allowance for the effect of the brazen lying of the few men who bring a rush of despairing patients to their doors by professing in letters to the newspapers to have learnt from vivisection how to cure certain diseases, and the assurances of the sayers of smooth things that the practice is quite painless under the law, it is still difficult to find any civilized motive for an attitude by which the medical profession has everything to lose and nothing to gain.

THE PRIMITIVE SAVAGE MOTIVE

I say civilized motive advisedly; for primitive tribal motives are easy enough to find. Every savage chief who is not a Mahomet learns that if he wishes to strike the imagination of his tribe—and without doing that he can rule them—he must terrify or revolt them from time to time by acts of hideous cruelty or disgusting unnaturalness. We are far from being as superior to such tribes as we imagine. It is very doubtful indeed whether Peter the Great could have effected the changes he made in Russia if he had not fascinated and intimidated his people by his monstrous cruelties and grotesque

escapades. Had he been a nineteenth-century king of England, he would have had to wait for some huge accidental calamity: a cholera epidemic, a war, or an insurrection, before waking us up sufficiently to get anything done. Vivisection helps the doctor to rule us as Peter ruled the Russians. The notion that the man who does dreadful things is superhuman, and that therefore he can also do wonderful things either as ruler, avenger, healer, or what not, is by no means confined to barbarians. Just as the manifold wickednesses and stupidities of our criminal code are supported, not by any general comprehension of law or study of jurisprudence, not even by simple vindictiveness, but by the superstition that a calamity of any sort must be expiated by a human sacrifice; so the wickednesses and stupidities of our medicine men are rooted in superstitions that have no more to do with science than the traditional ceremony of christening an ironclad has to do with the effectiveness of its armament. We have only to turn to Macaulay's description of the treatment of Charles II in his last illness to see how strongly his physicians felt that their only chance of cheating death was by outraging nature in tormenting and disgusting their unfortunate patient. True, this was more than two centuries ago; but I have heard my own nineteenth-century grandfather describe the cupping and firing and nauseous medicines of his time with perfect credulity as to their beneficial effects; and some more modern treatments appear to me quite as barbarous. It is in this way that vivisection pays the doctor. It appeals to the fear and credulity of the savage in us; and without fear and credulity half the private doctor's occupation and seven-eighths of his influence would be gone.

THE HIGHER MOTIVE. THE TREE OF KNOWLEDGE.

But the greatest force of all on the side of vivisection is the mighty and indeed divine force of curiosity. Here we have no decaying tribal instinct which men strive to root out of themselves as they strive to root out the tiger's lust for blood. On the contrary, the curiosity of the ape, or of the child who pulls out the legs and wings of a fly to see what it will do without them, or who, on being told that a cat dropped out of the window will always fall on its legs, immediately tries the experiment on the nearest cat from the highest window in the house (I protest I did it myself from the first floor only), is as nothing compared to the thirst for knowledge of the philosopher, the poet, the biologist, and the naturalist. I have always despised Adam because he had to be tempted by the woman, as she was by the serpent, before he could be induced to pluck the apple from the tree of knowledge. I should have swallowed every apple on the tree the moment the owner's back was turned. When Gray said "Where ignorance is bliss, 'tis folly to be wise," he forgot that it is godlike to be wise; and since nobody wants bliss particularly, or could stand more than a very brief taste of it if it were attainable, and since everybody, by the deepest law of the Life Force, desires to be godlike, it is stupid, and indeed blasphemous and despairing, to hope that the thirst for knowledge will either diminish or consent to be subordinated to any other end whatsoever. We shall see later on that the claim that has arisen in this way for the unconditioned pursuit of knowledge is as idle as all dreams of unconditioned activity; but none the less the right to knowledge must be regarded as a fundamental human right. The fact that men of science have had to fight so hard to secure its recognition, and are still so vigorously persecuted when they discover anything that is not quite palatable to vulgar people, makes them sorely jealous for that right; and when they hear a popular outcry for the suppression of a method of research which has an air of being scientific, their first instinct is to rally to the defence of that method without further consideration, with the result that they sometimes, as in the case of vivisection, presently find themselves fighting on a false issue.

THE FLAW IN THE ARGUMENT

I may as well pause here to explain their error. The right to know is like the right to live. It is fundamental and unconditional in its assumption that knowledge, like life, is a desirable thing, though any fool can prove that ignorance is bliss, and that "a little knowledge is a dangerous thing" (a little being the most that any of us can attain), as easily as that the pains of life are more numerous and constant than its pleasures, and that therefore we should all be better dead. The logic is unimpeachable; but its only effect is to make us say that if these are the conclusions logic leads to, so much the worse for logic, after which curt dismissal of Folly, we continue living and learning by instinct: that is, as of right. We legislate on the assumption that no man may be killed on the strength of a demonstration that he would be happier in his grave, not even if he is dying slowly of cancer and begs the doctor to despatch him quickly and mercifully. To get killed lawfully he must violate somebody else's right to live by committing murder. But he is by no means free to live unconditionally. In society he can exercise his right to live only under very stiff conditions. In countries where there is compulsory military service he may even have to throw away his individual life to save the life of the community.

It is just so in the case of the right to knowledge. It is a right that is as yet very imperfectly recognized in practice. But in theory it is admitted that an adult person in pursuit of knowledge must not be refused it on the ground that he would be better or happier without it. Parents and priests may forbid knowledge to those who accept their authority; and social taboo may be made effective by acts of legal persecution under cover of repressing blasphemy, obscenity, and sedition; but no government now openly forbids its subjects to pursue knowledge on the ground that knowledge is in itself a bad thing, or that it is possible for any of us to have too much of it.

LIMITATIONS OF THE RIGHT TO KNOWLEDGE

But neither does any government exempt the pursuit of knowledge, any more than the pursuit of life, liberty, and happiness (as the American Constitution puts it), from all social conditions. No man is allowed to put his mother into the stove because he desires to know how long an adult woman will survive at a temperature of 500 degrees Fahrenheit, no matter how important or interesting that particular addition to the store of human knowledge may be. A man who did so would have short work made not only of his right to knowledge, but of his right to live and all his other rights at the same time. The right to knowledge is not the only right; and its exercise must be limited by respect for other rights, and for its own exercise by others. When a man says to Society, "May I torture my mother in pursuit of knowledge?" Society replies, "No." If he pleads, "What! Not even if I have a chance of finding out how to cure cancer by doing it?" Society still says, "Not even then." If the scientist, making the best of his disappointment, goes on to ask may he torture a dog, the stupid and callous people who do not realize that a dog is a fellow-creature and sometimes a good friend, may say Yes, though Shakespear, Dr. Johnson and their like may say No. But even those who say "You may torture A dog" never say "You may torture MY dog." And nobody says, "Yes, because in the pursuit of knowledge you may do as you please." Just as even the stupidest people say, in effect, "If you cannot attain to knowledge without burning your mother you must do without knowledge," so the wisest people say, "If you cannot attain to knowledge without torturing a dog, you must do without knowledge."

But in practice you cannot persuade any wise man that this alternative can ever be forced on anyone but a fool, or that a fool can be trusted to learn anything from any experiment, cruel or humane. The Chinaman who burnt down his house to roast his pig was no doubt honestly unable to conceive any less disastrous way of cooking his dinner; and the roast must have been spoiled after all (a perfect type of the average vivisectionist experiment); but this did not prove that the Chinaman was right: it only proved that the Chinaman was an incapable cook and, fundamentally, a fool.

Take another celebrated experiment: one in sanitary reform. In the days of Nero Rome was in the same predicament as London to-day. If some one would burn down London, and it were rebuilt, as it would now have to be, subject to the sanitary by-laws and Building Act provisions enforced by the London County Council, it would be enormously improved; and the average lifetime of Londoners would be considerably prolonged. Nero argued in the same way about Rome. He employed incendiaries to set it on fire; and he played the harp in scientific raptures whilst it was burning. I am so far of Nero's way of thinking that I have often said, when consulted by despairing sanitary reformers, that what London needs to make her healthy is an earthquake. Why, then, it may be asked, do not I, as a public-spirited man, employ incendiaries to set it on fire, with a heroic disregard of the consequences to myself and others? Any vivisector would, if he had the courage of his opinions. The reasonable answer is that London can be made healthy without burning her down; and that as we have not enough civic virtue to make her healthy in a humane and economical way, we should not have enough to rebuild her in that way. In the old Hebrew legend, God lost patience with the world as Nero did with Rome, and drowned everybody except a single family. But the result was that the progeny of that family reproduced all the vices of their predecessors so exactly that the misery caused by the flood might just as well have been spared: things went on just as they did before. In the same way, the lists of diseases which vivisection claims to have cured is long; but the returns of the Registrar-General show that people still persist in dying of them as if vivisection had never been heard of. Any fool can burn down a city or cut an animal open; and an exceptionally foolish fool is quite likely to promise enormous benefits to the race as the result of such activities. But when the constructive, benevolent part of the business comes to be done, the same want of imagination, the same stupidity and cruelty, the same laziness and want of perseverance that prevented Nero or the vivisector from devising or pushing through humane methods, prevents him from bringing order out of the chaos and happiness out of the misery he has made. At one time it seemed reasonable enough to declare that it was impossible to find whether or not there was a stone inside a man's body except by exploring it with a knife, or to find out what the sun is made of without visiting it in a balloon. Both these impossibilities have been achieved, but not by vivisectors. The Rontgen rays need not hurt the patient; and spectrum analysis involves no destruction. After such triumphs of humane experiment and reasoning, it is useless to assure us that there is no other key to knowledge except cruelty. When the vivisector offers us that assurance, we reply simply and contemptuously, "You mean that you are not clever or humane or energetic enough to find one."

CRUELTY FOR ITS OWN SAKE

It will now, I hope, be clear why the attack on vivisection is not an attack on the right to knowledge: why, indeed, those who have the deepest conviction of the sacredness of that right are the leaders of the attack. No knowledge is finally impossible of human attainment; for even though it may be beyond our present capacity, the needed capacity is not unattainable. Consequently no method of

investigation is the only method; and no law forbidding any particular method can cut us off from the knowledge we hope to gain by it. The only knowledge we lose by forbidding cruelty is knowledge at first hand of cruelty itself, which is precisely the knowledge humane people wish to be spared.

But the question remains: Do we all really wish to be spared that knowledge? Are humane methods really to be preferred to cruel ones? Even if the experiments come to nothing, may not their cruelty be enjoyed for its own sake, as a sensational luxury? Let us face these questions boldly, not shrinking from the fact that cruelty is one of the primitive pleasures of mankind, and that the detection of its Protean disguises as law, education, medicine, discipline, sport and so forth, is one of the most difficult of the unending tasks of the legislator.

OUR OWN CRUELTIES

At first blush it may seem not only unnecessary, but even indecent, to discuss such a proposition as the elevation of cruelty to the rank of a human right. Unnecessary, because no vivisector confesses to a love of cruelty for its own sake or claims any general fundamental right to be cruel. Indecent, because there is an accepted convention to repudiate cruelty; and vivisection is only tolerated by the law on condition that, like judicial torture, it shall be done as mercifully as the nature of the practice allows. But the moment the controversy becomes embittered, the recriminations bandied between the opposed parties bring us face-to-face with some very ugly truths. On one occasion I was invited to speak at a large Anti-Vivisection meeting in the Queen's Hall in London. I found myself on the platform with fox hunters, tame stag hunters, men and women whose calendar was divided, not by pay days and quarter days, but by seasons for killing animals for sport: the fox, the hare, the otter, the partridge and the rest having each its appointed date for slaughter. The ladies among us wore hats and cloaks and head-dresses obtained by wholesale massacres, ruthless trappings, callous extermination of our fellow creatures. We insisted on our butchers supplying us with white veal, and were large and constant consumers of pate de foie gras; both comestibles being obtained by revolting methods. We sent our sons to public schools where indecent flogging is a recognized method of taming the young human animal. Yet we were all in hysterics of indignation at the cruelties of the vivisectors. These, if any were present, must have smiled sardonically at such inhuman humanitarians, whose daily habits and fashionable amusements cause more suffering in England in a week than all the vivisectors of Europe do in a year. I made a very effective speech, not exclusively against vivisection, but against cruelty; and I have never been asked to speak since by that Society, nor do I expect to be, as I should probably give such offence to its most affluent subscribers that its attempts to suppress vivisection would be seriously hindered. But that does not prevent the vivisectors from freely using the "youre another" retort, and using it with justice.

We must therefore give ourselves no airs of superiority when denouncing the cruelties of vivisection. We all do just as horrible things, with even less excuse. But in making that admission we are also making short work of the virtuous airs with which we are sometimes referred to the humanity of the medical profession as a guarantee that vivisection is not abused—much as if our burglars should assure us that they arc too honest to abuse the practice of burgling. We are, as a matter of fact, a cruel nation; and our habit of disguising our vices by giving polite names to the offences we are determined to commit does not, unfortunately for my own comfort, impose on me. Vivisectors can hardly pretend to be better than the classes from which they are drawn, or those above them; and if these classes are capable of sacrificing animals in various cruel ways under cover of sport, fashion, education,

discipline, and even, when the cruel sacrifices are human sacrifices, of political economy, it is idle for the vivisector to pretend that he is incapable of practising cruelty for pleasure or profit or both under the cloak of science. We are all tarred with the same brush; and the vivisectors are not slow to remind us of it, and to protest vehemently against being branded as exceptionally cruel and its devisors of horrible instruments of torture by people whose main notion of enjoyment is cruel sport, and whose requirements in the way of villainously cruel traps occupy pages of the catalogue of the Army and Navy Stores.

THE SCIENTIFIC INVESTIGATION OF CRUELTY

There is in man a specific lust for cruelty which infects even his passion of pity and makes it savage. Simple disgust at cruelty is very rare. The people who turn sick and faint and those who gloat are often alike in the pains they take to witness executions, floggings, operations or any other exhibitions of suffering, especially those involving bloodshed, blows, and laceration. A craze for cruelty can be developed just as a craze for drink can; and nobody who attempts to ignore cruelty as a possible factor in the attraction of vivisection and even of antivivisection, or in the credulity with which we accept its excuses, can be regarded as a scientific investigator of it. Those who accuse vivisectors of indulging the well-known passion of cruelty under the cloak of research are therefore putting forward a strictly scientific psychological hypothesis, which is also simple, human, obvious, and probable. It may be as wounding to the personal vanity of the vivisector as Darwin's Origin of Species was to the people who could not bear to think that they were cousins to the monkeys (remember Goldsmith's anger when he was told that he could not move his upper jaw); but science has to consider only the truth of the hypothesis, and not whether conceited people will like it or not. In vain do the sentimental champions of vivisection declare themselves the most humane of men, inflicting suffering only to relieve it, scrupulous in the use of anesthetics, and void of all passion except the passion of pity for a disease-ridden world. The really scientific investigator answers that the question cannot be settled by hysterical protestations, and that if the vivisectionist rejects deductive reasoning, he had better clear his character by his own favorite method of experiment.

SUGGESTED LABORATORY TESTS OF THE VIVISECTOR'S EMOTIONS

Take the hackneyed case of the Italian who tortured mice, ostensibly to find out about the effects of pain rather less than the nearest dentist could have told him, and who boasted of the ecstatic sensations (he actually used the word love) with which he carried out his experiments. Or the gentleman who starved sixty dogs to death to establish the fact that a dog deprived of food gets progressively lighter and weaker, becoming remarkably emaciated, and finally dying: an undoubted truth, but ascertainable without laboratory experiments by a simple enquiry addressed to the nearest policeman, or, failing him, to any sane person in Europe. The Italian is diagnosed as a cruel voluptuary: the dog-starver is passed over as such a hopeless fool that it is impossible to take any interest in him. Why not test the diagnosis scientifically? Why not perform a careful series of experiments on persons under the influence of voluptuous ecstasy, so as to ascertain its physiological symptoms? Then perform a second series on persons engaged in mathematical work or machine designing, so as to ascertain the symptoms of cold scientific activity? Then note the symptoms of a vivisector performing a cruel experiment; and compare them with the voluptuary symptoms and the mathematical symptoms? Such experiments would be quite as interesting and important as any yet undertaken by the vivisectors. They might open a line of investigation which would finally make, for instance, the ascertainment of the guilt or innocence of an accused person a much exacter process

than the very fallible methods of our criminal courts. But instead of proposing such an investigation, our vivisectors offer us all the pious protestations and all the huffy recriminations that any common unscientific mortal offers when he is accused of unworthy conduct.

ROUTINE

Yet most vivisectors would probably come triumphant out of such a series of experiments, because vivisection is now a routine, like butchering or hanging or flogging; and many of the men who practise it do so only because it has been established as part of the profession they have adopted. Far from enjoying it, they have simply overcome their natural repugnance and become indifferent to it, as men inevitably become indifferent to anything they do often enough. It is this dangerous power of custom that makes it so difficult to convince the common sense of mankind that any established commercial or professional practice has its root in passion. Let a routine once spring from passion, and you will presently find thousands of routineers following it passionlessly for a livelihood. Thus it always seems strained to speak of the religious convictions of a clergyman, because nine out of ten clergymen have no religions convictions: they are ordinary officials carrying on a routine of baptizing, marrying, and churching; praying, reciting, and preaching; and, like solicitors or doctors, getting away from their duties with relief to hunt, to garden, to keep bees, to go into society, and the like. In the same way many people do cruel and vile things without being in the least cruel or vile, because the routine to which they have been brought up is superstitiously cruel and vile. To say that every man who beats his children and every schoolmaster who flogs a pupil is a conscious debauchee is absurd: thousands of dull, conscientious people beat their children conscientiously, because they were beaten themselves and think children ought to be beaten. The ill-tempered vulgarity that instinctively strikes at and hurts a thing that annoys it (and all children are annoying), and the simple stupidity that requires from a child perfection beyond the reach of the wisest and best adults (perfect truthfulness coupled with perfect obedience is quite a common condition of leaving a child unwhipped), produce a good deal of flagellation among people who not only do not lust after it, but who hit the harder because they are angry at having to perform an uncomfortable duty. These people will beat merely to assert their authority, or to carry out what they conceive to be a divine order on the strength of the precept of Solomon recorded in the Bible, which carefully adds that Solomon completely spoilt his own son and turned away from the god of his fathers to the sensuous idolatry in which he ended his days.

In the same way we find men and women practising vivisection as senselessly as a humane butcher, who adores his fox terrier, will cut a calf's throat and hang it up by its heels to bleed slowly to death because it is the custom to eat veal and insist on its being white; or as a German purveyor nails a goose to a board and stuffs it with food because fashionable people eat pate de foie gras; or as the crew of a whaler breaks in on a colony of seals and clubs them to death in wholesale massacre because ladies want sealskin jackets; or as fanciers blind singing birds with hot needles, and mutilate the ears and tails of dogs and horses. Let cruelty or kindness or anything else once become customary and it will be practised by people to whom it is not at all natural, but whose rule of life is simply to do only what everybody else does, and who would lose their employment and starve if they indulged in any peculiarity. A respectable man will lie daily, in speech and in print, about the qualities of the article he lives by selling, because it is customary to do so. He will flog his boy for telling a lie, because it is customary to do so. He will also flog him for not telling a lie if the boy tells inconvenient or disrespectful truths, because it is customary to do so. He will give the same boy a present on his

birthday, and buy him a spade and bucket at the seaside, because it is customary to do so, being all the time neither particularly mendacious, nor particularly cruel, nor particularly generous, but simply incapable of ethical judgment or independent action.

Just so do we find a crowd of petty vivisectionists daily committing atrocities and stupidities, because it is the custom to do so. Vivisection is customary as part of the routine of preparing lectures in medical schools. For instance, there are two ways of making the action of the heart visible to students. One, a barbarous, ignorant, and thoughtless way, is to stick little flags into a rabbit's heart and let the students see the flags jump. The other, an elegant, ingenious, well-informed, and instructive way, is to put a sphygmograph on the student's wrist and let him see a record of his heart's action traced by a needle on a slip of smoked paper. But it has become the custom for lecturers to teach from the rabbit; and the lecturers are not original enough to get out of their groove. Then there are the demonstrations which are made by cutting up frogs with scissors. The most humane man, however repugnant the operation may be to him at first, cannot do it at lecture after lecture for months without finally—and that very soon—feeling no more for the frog than if he were cutting up pieces of paper. Such clumsy and lazy ways of teaching are based on the cheapness of frogs and rabbits. If machines were as cheap as frogs, engineers would not only be taught the anatomy of machines and the functions of their parts: they would also have machines misused and wrecked before them so that they might learn as much as possible by using their eyes, and as little as possible by using their brains and imaginations. Thus we have, as part of the routine of teaching, a routine of vivisection which soon produces complete indifference to it on the part even of those who are naturally humane. If they pass on from the routine of lecture preparation, not into general practice, but into research work, they carry this acquired indifference with them into the laboratory, where any atrocity is possible, because all atrocities satisfy curiosity. The routine man is in the majority in his profession always: consequently the moment his practice is tracked down to its source in human passion there is a great and quite sincere poohpoohing from himself, from the mass of the profession, and from the mass of the public, which sees that the average doctor is much too commonplace and decent a person to be capable of passionate wickedness of any kind.

Here then, we have in vivisection, as in all the other tolerated and instituted cruelties, this anti-climax: that only a negligible percentage of those who practise and consequently defend it get any satisfaction out of it. As in Mr. Galsworthy's play Justice the useless and detestable torture of solitary imprisonment is shown at its worst without the introduction of a single cruel person into the drama, so it would be possible to represent all the torments of vivisection dramatically without introducing a single vivisector who had not felt sick at his first experience in the laboratory. Not that this can exonerate any vivisector from suspicion of enjoying his work (or her work: a good deal of the vivisection in medical schools is done by women). In every autobiography which records a real experience of school or prison life, we find that here and there among the routineers there is to be found the genuine amateur, the orgiastic flogging schoolmaster or the nagging warder, who has sought out a cruel profession for the sake of its cruelty. But it is the genuine routineer who is the bulwark of the practice, because, though you can excite public fury against a Sade, a Bluebeard, or a Nero, you cannot rouse any feeling against dull Mr. Smith doing his duty: that is, doing the usual thing. He is so obviously no better and no worse than anyone else that it is difficult to conceive that the things he does are abominable. If you would see public dislike surging up in a moment against an individual, you must watch one who does something unusual, no matter how sensible it may be.

The name of Jonas Hanway lives as that of a brave man because he was the first who dared to appear in the streets of this rainy island with an umbrella.

THE OLD LINE BETWEEN MAN AND BEAST

But there is still a distinction to be clung to by those who dare not tell themselves the truth about the medical profession because they are so helplessly dependent on it when death threatens the household. That distinction is the line that separates the brute from the man in the old classification. Granted, they will plead, that we are all cruel; yet the tame-stag-hunter does not hunt men; and the sportsman who lets a leash of greyhounds loose on a hare would be horrified at the thought of letting them loose on a human child. The lady who gets her cloak by flaying a sable does not flay a negro; nor does it ever occur to her that her veal cutlet might be improved on by a slice of tender baby.

Now there was a time when some trust could be placed in this distinction. The Roman Catholic Church still maintains, with what it must permit me to call a stupid obstinacy, and in spite of St. Francis and St. Anthony, that animals have no souls and no rights; so that you cannot sin against an animal, or against God by anything you may choose to do to an animal. Resisting the temptation to enter on an argument as to whether you may not sin against your own soul if you are unjust or cruel to the least of those whom St. Francis called his little brothers, I have only to point out here that nothing could be more despicably superstitious in the opinion of a vivisector than the notion that science recognizes any such step in evolution as the step from a physical organism to an immortal soul. That conceit has been taken out of all our men of science, and out of all our doctors, by the evolutionists; and when it is considered how completely obsessed biological science has become in our days, not by the full scope of evolution, but by that particular method of it which has neither sense nor purpose nor life nor anything human, much less godlike, in it: by the method, that is, of so-called Natural Selection (meaning no selection at all, but mere dead accident and luck), the folly of trusting to vivisectors to hold the human animal any more sacred than the other animals becomes so clear that it would be waste of time to insist further on it. As a matter of fact the man who once concedes to the vivisector the right to put a dog outside the laws of honor and fellowship, concedes to him also the right to put himself outside them; for he is nothing to the vivisector but a more highly developed, and consequently more interesting-to-experiment-on vertebrate than the dog.

VIVISECTING THE HUMAN SUBJECT

I have in my hand a printed and published account by a doctor of how he tested his remedy for pulmonary tuberculosis, which was to inject a powerful germicide directly into the circulation by stabbing a vein with a syringe. He was one of those doctors who are able to command public sympathy by saying, quite truly, that when they discovered that the proposed treatment was dangerous, they experimented thenceforth on themselves. In this case the doctor was devoted enough to carry his experiments to the point of running serious risks, and actually making himself very uncomfortable. But he did not begin with himself. His first experiment was on two hospital patients. On receiving a message from the hospital to the effect that these two martyrs to therapeutic science had all but expired in convulsions, he experimented on a rabbit, which instantly dropped dead. It was then, and not until then, that he began to experiment on himself, with the germicide modified in the direction indicated by the experiments made on the two patients and the rabbit. As a good many people countenance vivisection because they fear that if the experiments are not made on rabbits they will be made on themselves, it is worth noting that in this case, where both rabbits and men were

equally available, the men, being, of course, enormously more instructive, and costing nothing, were experimented on first. Once grant the ethics of the vivisectionists and you not only sanction the experiment on the human subject, but make it the first duty of the vivisector. If a guinea pig may be sacrificed for the sake of the very little that can be learnt from it, shall not a man be sacrificed for the sake of the great deal that can be learnt from him? At all events, he is sacrificed, as this typical case shows. I may add (not that it touches the argument) that the doctor, the patients, and the rabbit all suffered in vain, as far as the hoped-for rescue of the race from pulmonary consumption is concerned.

"THE LIE IS A EUROPEAN POWER"

Now at the very time when the lectures describing these experiments were being circulated in print and discussed eagerly by the medical profession, the customary denials that patients are experimented on were as loud, as indignant, as high-minded as ever, in spite of the few intelligent doctors who point out rightly that all treatments are experiments on the patient. And this brings us to an obvious but mostly overlooked weakness in the vivisector's position: that is, his inevitable forfeiture of all claim to have his word believed. It is hardly to be expected that a man who does not hesitate to vivisect for the sake of science will hesitate to lie about it afterwards to protect it from what he deems the ignorant sentimentality of the laity. When the public conscience stirs uneasily and threatens suppression, there is never wanting some doctor of eminent position and high character who will sacrifice himself devotedly to the cause of science by coming forward to assure the public on his honor that all experiments on animals are completely painless; although he must know that the very experiments which first provoked the antivivisection movement by their atrocity were experiments to ascertain the physiological effects of the sensation of extreme pain (the much more interesting physiology of pleasure remains uninvestigated) and that all experiments in which sensation is a factor are voided by its suppression. Besides, vivisection may be painless in cases where the experiments are very cruel. If a person scratches me with a poisoned dagger so gently that I do not feel the scratch, he has achieved a painless vivisection; but if I presently die in torment I am not likely to consider that his humility is amply vindicated by his gentleness. A cobra's bite hurts so little that the creature is almost, legally speaking, a vivisector who inflicts no pain. By giving his victims chloroform before biting them he could comply with the law completely.

Here, then, is a pretty deadlock. Public support of vivisection is founded almost wholly on the assurances of the vivisectors that great public benefits may be expected from the practice. Not for a moment do I suggest that such a defence would be valid even if proved. But when the witnesses begin by alleging that in the cause of science all the customary ethical obligations (which include the obligation to tell the truth) are suspended, what weight can any reasonable person give to their testimony? I would rather swear fifty lies than take an animal which had licked my hand in good fellowship and torture it. If I did torture the dog, I should certainly not have the face to turn round and ask how any person there suspect an honorable man like myself of telling lies. Most sensible and humane people would, I hope, reply flatly that honorable men do not behave dishonorably, even to dogs. The murderer who, when asked by the chaplain whether he had any other crimes to confess, replied indignantly, "What do you take me for?" reminds us very strongly of the vivisectors who are so deeply hurt when their evidence is set aside as worthless.

The Achilles heel of vivisection, however, is not to be found in the pain it causes, but in the line of argument by which it is justified. The medical code regarding it is simply criminal anarchism at its very worst. Indeed no criminal has yet had the impudence to argue as every vivisector argues. No burglar contends that as it is admittedly important to have money to spend, and as the object of burglary is to provide the burglar with money to spend, and as in many instances it has achieved this object, therefore the burglar is a public benefactor and the police are ignorant sentimentalists. No highway robber has yet harrowed us with denunciations of the puling moralist who allows his child to suffer all the evils of poverty because certain faddists think it dishonest to garotte an alderman. Thieves and assassins understand quite well that there are paths of acquisition, even of the best things, that are barred to all men of honor. Again, has the silliest burglar ever pretended that to put a stop to burglary is to put a stop to industry? All the vivisections that have been performed since the world began have produced nothing so important as the innocent and honorable discovery of radiography; and one of the reasons why radiography was not discovered sooner was that the men whose business it was to discover new clinical methods were coarsening and stupefying themselves with the sensual villanies and cutthroat's casuistries of vivisection. The law of the conservation of energy holds good in physiology as in other things: every vivisector is a deserter from the army of honorable investigators. But the vivisector does not see this. He not only calls his methods scientific: he contends that there are no other scientific methods. When you express your natural loathing for his cruelty and your natural contempt for his stupidity, he imagines that you are attacking science. Yet he has no inkling of the method and temper of science. The point at issue being plainly whether he is a rascal or not, he not only insists that the real point is whether some hotheaded antivivisectionist is a liar (which he proves by ridiculously unscientific assumptions as to the degree of accuracy attainable in human statement), but never dreams of offering any scientific evidence by his own methods.

There are many paths to knowledge already discovered; and no enlightened man doubts that there are many more waiting to be discovered. Indeed, all paths lead to knowledge; because even the vilest and stupidest action teaches us something about vileness and stupidity, and may accidentally teach us a good deal more: for instance, a cutthroat learns (and perhaps teaches) the anatomy of the carotid artery and jugular vein; and there can be no question that the burning of St. Joan of Arc must have been a most instructive and interesting experiment to a good observer, and could have been made more so if it had been carried out by skilled physiologists under laboratory conditions. The earthquake in San Francisco proved invaluable as an experiment in the stability of giant steel buildings; and the ramming of the Victoria by the Camperdown settled doubtful points of the greatest importance in naval warfare. According to vivisectionist logic our builders would be justified in producing artificial earthquakes with dynamite, and our admirals in contriving catastrophes at naval manoeuvres, in order to follow up the line of research thus accidentally discovered.

The truth is, if the acquisition of knowledge justifies every sort of conduct, it justifies any sort of conduct, from the illumination of Nero's feasts by burning human beings alive (another interesting experiment) to the simplest act of kindness. And in the light of that truth it is clear that the exemption of the pursuit of knowledge from the laws of honor is the most hideous conceivable enlargement of anarchy; worse, by far, than an exemption of the pursuit of money or political power, since there can hardly be attained without some regard for at least the appearances of human welfare, whereas a

curious devil might destroy the whole race in torment, acquiring knowledge all the time from his highly interesting experiment. There is more danger in one respectable scientist countenancing such a monstrous claim than in fifty assassins or dynamitards. The man who makes it is ethically imbecile; and whoever imagines that it is a scientific claim has not the faintest conception of what science means. The paths to knowledge are countless. One of these paths is a path through darkness, secrecy, and cruelty. When a man deliberately turns from all other paths and goes down that one, it is scientific to infer that what attracts him is not knowledge, since there are other paths to that, but cruelty. With so strong and scientific a case against him, it is childish for him to stand on his honor and reputation and high character and the credit of a noble profession and so forth: he must clear himself either by reason or by experiment, unless he boldly contends that evolution has retained a passion of cruelty in man just because it is indispensable to the fulness of his knowledge.

THOU ART THE MAN

I shall not be at all surprised if what I have written above has induced in sympathetic readers a transport of virtuous indignation at the expense of the medical profession. I shall not damp so creditable and salutary a sentiment; but I must point out that the guilt is shared by all of us. It is not in his capacity of healer and man of science that the doctor vivisects or defends vivisection, but in his entirely vulgar lay capacity. He is made of the same clay as the ignorant, shallow, credulous, half-miseducated, pecuniarily anxious people who call him in when they have tried in vain every bottle and every pill the advertizing druggist can persuade them to buy. The real remedy for vivisection is the remedy for all the mischief that the medical profession and all the other professions are doing: namely, more knowledge. The juries which send the poor Peculiars to prison, and give vivisectionists heavy damages against humane persons who accuse them of cruelty; the editors and councillors and student-led mobs who are striving to make Vivisection one of the watchwords of our civilization, are not doctors: they are the British public, all so afraid to die that they will cling frantically to any idol which promises to cure all their diseases, and crucify anyone who tells them that they must not only die when their time comes, but die like gentlemen. In their paroxysms of cowardice and selfishness they force the doctors to humor their folly and ignorance. How complete and inconsiderate their ignorance is can only be realized by those who have some knowledge of vital statistics, and of the illusions which beset Public Health legislation.

WHAT THE PUBLIC WANTS AND WILL NOT GET

The demands of this poor public are not reasonable, but they are quite simple. It dreads disease and desires to be protected against it. But it is poor and wants to be protected cheaply. Scientific measures are too hard to understand, too costly, too clearly tending towards a rise in the rates and more public interference with the insanitary, because insufficiently financed, private house. What the public wants, therefore, is a cheap magic charm to prevent, and a cheap pill or potion to cure, all disease. It forces all such charms on the doctors.

THE VACCINATION CRAZE

Thus it was really the public and not the medical profession that took up vaccination with irresistible faith, sweeping the invention out of Jenner's hand and establishing it in a form which he himself repudiated. Jenner was not a man of science; but he was not a fool; and when he found that people who had suffered from cowpox either by contagion in the milking shed or by vaccination, were not,

as he had supposed, immune from smallpox, he ascribed the cases of immunity which had formerly misled him to a disease of the horse, which, perhaps because we do not drink its milk and eat its flesh, is kept at a greater distance in our imagination than our foster mother the cow. At all events, the public, which had been boundlessly credulous about the cow, would not have the horse on any terms; and to this day the law which prescribes Jennerian vaccination is carried out with an anti-Jennerian inoculation because the public would have it so in spite of Jenner. All the grossest lies and superstitions which have disgraced the vaccination craze were taught to the doctors by the public. It was not the doctors who first began to declare that all our old men remember the time when almost every face they saw in the street was horribly pitted with smallpox, and that all this disfigurement has vanished since the introduction of vaccination. Jenner himself alluded to this imaginary phenomenon before the introduction of vaccination, and attributed it to the older practice of smallpox inoculation, by which Voltaire, Catherine II. and Lady Mary Wortley Montagu so confidently expected to see the disease made harmless. It was not Jenner who set people declaring that smallpox, if not abolished by vaccination, had at least been made much milder: on the contrary, he recorded a pre-vaccination epidemic in which none of the persons attacked went to bed or considered themselves as seriously ill. Neither Jenner, nor any other doctor ever, as far as I know, inculcated the popular notion that everybody got smallpox as a matter of course before vaccination was invented. That doctors get infected with these delusions, and are in their unprofessional capacity as members of the public subject to them like other men, is true; but if we had to decide whether vaccination was first forced on the public by the doctors or on the doctors by the public, we should have to decide against the public.

STATISTICAL ILLUSIONS

Public ignorance of the laws of evidence and of statistics can hardly be exaggerated. There may be a doctor here and there who in dealing with the statistics of disease has taken at least the first step towards sanity by grasping the fact that as an attack of even the commonest disease is an exceptional event, apparently over-whelming statistical evidence in favor of any prophylactic can be produced by persuading the public that everybody caught the disease formerly. Thus if a disease is one which normally attacks fifteen per cent of the population, and if the effect of a prophylactic is actually to increase the proportion to twenty per cent, the publication of this figure of twenty per cent will convince the public that the prophylactic has reduced the percentage by eighty per cent instead of increasing it by five, because the public, left to itself and to the old gentlemen who are always ready to remember, on every possible subject, that things used to be much worse than they are now (such old gentlemen greatly outnumber the laudatores tempori acti), will assume that the former percentage was about 100. The vogue of the Pasteur treatment of hydrophobia, for instance, was due to the assumption by the public that every person bitten by a rabid dog necessarily got hydrophobia. I myself heard hydrophobia discussed in my youth by doctors in Dublin before a Pasteur Institute existed, the subject having been brought forward there by the scepticism of an eminent surgeon as to whether hydrophobia is really a specific disease or only ordinary tetanus induced (as tetanus was then supposed to be induced) by a lacerated wound. There were no statistics available as to the proportion of dog bites that ended in hydrophobia; but nobody ever guessed that the cases could be more than two or three per cent of the bites. On me, therefore, the results published by the Pasteur Institute produced no such effect as they did on the ordinary man who thinks that the bite of a mad dog means certain hydrophobia. It seemed to me that the proportion of deaths among the cases treated at the Institute was rather higher, if anything, than might have been expected had there been no Institute in

existence. But to the public every Pasteur patient who did not die was miraculously saved from an agonizing death by the beneficent white magic of that most trusty of all wizards, the man of science.

Even trained statisticians often fail to appreciate the extent to which statistics are vitiated by the unrecorded assumptions of their interpreters. Their attention is too much occupied with the cruder tricks of those who make a corrupt use of statistics for advertizing purposes. There is, for example, the percentage dodge. In some hamlet, barely large enough to have a name, two people are attacked during a smallpox epidemic. One dies: the other recovers. One has vaccination marks: the other has none. Immediately either the vaccinists or the antivaccinists publish the triumphant news that at such and such a place not a single vaccinated person died of smallpox whilst 100 per cent of the unvaccinated perished miserably; or, as the case may be, that 100 per cent of the unvaccinated recovered whilst the vaccinated succumbed to the last man. Or, to take another common instance, comparisons which are really comparisons between two social classes with different standards of nutrition and education are palmed off as comparisons between the results of a certain medical treatment and its neglect. Thus it is easy to prove that the wearing of tall hats and the carrying of umbrellas enlarges the chest, prolongs life, and confers comparative immunity from disease; for the statistics show that the classes which use these articles are bigger, healthier, and live longer than the class which never dreams of possessing such things. It does not take much perspicacity to see that what really makes this difference is not the tall hat and the umbrella, but the wealth and nourishment of which they are evidence, and that a gold watch or membership of a club in Pall Mall might be proved in the same way to have the like sovereign virtues. A university degree, a daily bath, the owning of thirty pairs of trousers, a knowledge of Wagner's music, a pew in church, anything, in short, that implies more means and better nurture than the mass of laborers enjoy, can be statistically palmed off as a magic-spell conferring all sorts of privileges.

In the case of a prophylactic enforced by law, this illusion is intensified grotesquely, because only vagrants can evade it. Now vagrants have little power of resisting any disease: their death rate and their case-mortality rate is always high relatively to that of respectable folk. Nothing is easier, therefore, than to prove that compliance with any public regulation produces the most gratifying results. It would be equally easy even if the regulation actually raised the death-rate, provided it did not raise it sufficiently to make the average householder, who cannot evade regulations, die as early as the average vagrant who can.

THE SURPRISES OF ATTENTION AND NEGLECT

There is another statistical illusion which is independent of class differences. A common complaint of houseowners is that the Public Health Authorities frequently compel them to instal costly sanitary appliances which are condemned a few years later as dangerous to health, and forbidden under penalties. Yet these discarded mistakes are always made in the first instance on the strength of a demonstration that their introduction has reduced the death-rate. The explanation is simple. Suppose a law were made that every child in the nation should be compelled to drink a pint of brandy per month, but that the brandy must be administered only when the child was in good health, with its digestion and so forth working normally, and its teeth either naturally or artificially sound. Probably the result would be an immediate and startling reduction in child mortality, leading to further legislation increasing the quantity of brandy to a gallon. Not until the brandy craze had been carried to a point at which the direct harm done by it would outweigh the incidental good, would an anti-brandy party be listened to. That incidental good would be the substitution of attention to the general

health of children for the neglect which is now the rule so long as the child is not actually too sick to run about and play as usual. Even if this attention were confined to the children's teeth, there would be an improvement which it would take a good deal of brandy to cancel.

This imaginary case explains the actual case of the sanitary appliances which our local sanitary authorities prescribe today and condemn tomorrow. No sanitary contrivance which the mind of even the very worst plumber can devize could be as disastrous as that total neglect for long periods which gets avenged by pestilences that sweep through whole continents, like the black death and the cholera. If it were proposed at this time of day to discharge all the sewage of London crude and untreated into the Thames, instead of carrying it, after elaborate treatment, far out into the North Sea, there would be a shriek of horror from all our experts. Yet if Cromwell had done that instead of doing nothing, there would probably have been no Great Plague of London. When the Local Health Authority forces every householder to have his sanitary arrangements thought about and attended to by somebody whose special business it is to attend to such things, then it matters not how erroneous or even directly mischievous may be the specific measures taken: the net result at first is sure to be an improvement. Not until attention has been effectually substituted for neglect as the general rule, will the statistics begin to show the merits of the particular methods of attention adopted. And as we are far from having arrived at this stage, being as to health legislation only at the beginning of things, we have practically no evidence yet as to the value of methods. Simple and obvious as this is, nobody seems as yet to discount the effect of substituting attention for neglect in drawing conclusions from health statistics. Everything is put to the credit of the particular method employed, although it may quite possibly be raising the death rate by five per thousand whilst the attention incidental to it is reducing the death rate fifteen per thousand. The net gain of ten per thousand is credited to the method, and made the excuse for enforcing more of it.

STEALING CREDIT FROM CIVILIZATION

There is yet another way in which specifics which have no merits at all, either direct or incidental, may be brought into high repute by statistics. For a century past civilization has been cleaning away the conditions which favor bacterial fevers. Typhus, once rife, has vanished: plague and cholera have been stopped at our frontiers by a sanitary blockade. We still have epidemics of smallpox and typhoid; and diphtheria and scarlet fever are endemic in the slums. Measles, which in my childhood was not regarded as a dangerous disease, has now become so mortal that notices are posted publicly urging parents to take it seriously. But even in these cases the contrast between the death and recovery rates in the rich districts and in the poor ones has led to the general conviction among experts that bacterial diseases are preventable; and they already are to a large extent prevented. The dangers of infection and the way to avoid it are better understood than they used to be. It is barely twenty years since people exposed themselves recklessly to the infection of consumption and pneumonia in the belief that these diseases were not "catching." Nowadays the troubles of consumptive patients are greatly increased by the growing disposition to treat them as lepers. No doubt there is a good deal of ignorant exaggeration and cowardly refusal to face a human and necessary share of the risk. That has always been the case. We now know that the medieval horror of leprosy was out of all proportion to the danger of infection, and was accompanied by apparent blindness to the infectiousness of smallpox, which has since been worked up by our disease terrorists into the position formerly held by leprosy. But the scare of infection, though it sets even doctors talking as if the only really scientific thing to do with a fever patient is to throw him into the nearest ditch and pump carbolic acid on him

from a safe distance until he is ready to be cremated on the spot, has led to much greater care and cleanliness. And the net result has been a series of victories over disease.

Now let us suppose that in the early nineteenth century somebody had come forward with a theory that typhus fever always begins in the top joint of the little finger; and that if this joint be amputated immediately after birth, typhus fever will disappear. Had such a suggestion been adopted, the theory would have been triumphantly confirmed; for as a matter of fact, typhus fever has disappeared. On the other hand cancer and madness have increased (statistically) to an appalling extent. The opponents of the little finger theory would therefore be pretty sure to allege that the amputations were spreading cancer and lunacy. The vaccination controversy is full of such contentions. So is the controversy as to the docking of horses' tails and the cropping of dogs' ears. So is the less widely known controversy as to circumcision and the declaring certain kinds of flesh unclean by the Jews. To advertize any remedy or operation, you have only to pick out all the most reassuring advances made by civilization, and boldly present the two in the relation of cause and effect: the public will swallow the fallacy without a wry face. It has no idea of the need for what is called a control experiment. In Shakespear's time and for long after it, mummy was a favorite medicament. You took a pinch of the dust of a dead Egyptian in a pint of the hottest water you could bear to drink; and it did you a great deal of good. This, you thought, proved what a sovereign healer mummy was. But if you had tried the control experiment of taking the hot water without the mummy, you might have found the effect exactly the same, and that any hot drink would have done as well.

BIOMETRIKA

Another difficulty about statistics is the technical difficulty of calculation. Before you can even make a mistake in drawing your conclusion from the correlations established by your statistics you must ascertain the correlations. When I turn over the pages of Biometrika, a quarterly journal in which is recorded the work done in the field of biological statistics by Professor Karl Pearson and his colleagues, I am out of my depth at the first line, because mathematics are to me only a concept: I never used a logarithm in my life, and could not undertake to extract the square root of four without misgiving. I am therefore unable to deny that the statistical ascertainment of the correlations between one thing and another must be a very complicated and difficult technical business, not to be tackled successfully except by high mathematicians; and I cannot resist Professor Karl Pearson's immense contempt for, and indignant sense of grave social danger in, the unskilled guesses of the ordinary sociologist.

Now the man in the street knows nothing of Biometrika: all he knows is that "you can prove anything by figures," though he forgets this the moment figures are used to prove anything he wants to believe. If he did take in Biometrika he would probably become abjectly credulous as to all the conclusions drawn in it from the correlations so learnedly worked out; though the mathematician whose correlations would fill a Newton with admiration may, in collecting and accepting data and drawing conclusions from them, fall into quite crude errors by just such popular oversights as I have been describing.

PATIENT-MADE THERAPEUTICS

To all these blunders and ignorances doctors are no less subject than the rest of us. They are not trained in the use of evidence, nor in biometrics, nor in the psychology of human credulity, nor in the

incidence of economic pressure. Further, they must believe, on the whole, what their patients believe, just as they must wear the sort of hat their patients wear. The doctor may lay down the law despotically enough to the patient at points where the patient's mind is simply blank; but when the patient has a prejudice the doctor must either keep it in countenance or lose his patient. If people are persuaded that night air is dangerous to health and that fresh air makes them catch cold it will not be possible for a doctor to make his living in private practice if he prescribes ventilation. We have to go back no further than the days of The Pickwick Papers to find ourselves in a world where people slept in four-post beds with curtains drawn closely round to exclude as much air as possible. Had Mr. Pickwick's doctor told him that he would be much healthier if he slept on a camp bed by an open window, Mr. Pickwick would have regarded him as a crank and called in another doctor. Had he gone on to forbid Mr. Pickwick to drink brandy and water whenever he felt chilly, and assured him that if he were deprived of meat or salt for a whole year, he would not only not die, but would be none the worse, Mr. Pickwick would have fled from his presence as from that of a dangerous madman. And in these matters the doctor cannot cheat his patient. If he has no faith in drugs or vaccination, and the patient has, he can cheat him with colored water and pass his lancet through the flame of a spirit lamp before scratching his arm. But he cannot make him change his daily habits without knowing it.

THE REFORMS ALSO COME FROM THE LAITY

In the main, then, the doctor learns that if he gets ahead of the superstitions of his patients he is a ruined man; and the result is that he instinctively takes care not to get ahead of them. That is why all the changes come from the laity. It was not until an agitation had been conducted for many years by laymen, including quacks and faddists of all kinds, that the public was sufficiently impressed to make it possible for the doctors to open their minds and their mouths on the subject of fresh air, cold water, temperance, and the rest of the new fashions in hygiene. At present the tables have been turned on many old prejudices. Plenty of our most popular elderly doctors believe that cold tubs in the morning are unnatural, exhausting, and rheumatic; that fresh air is a fad and that everybody is the better for a glass or two of port wine every day; but they no longer dare say as much until they know exactly where they are; for many very desirable patients in country houses have lately been persuaded that their first duty is to get up at six in the morning and begin the day by taking a walk barefoot through the dewy grass. He who shows the least scepticism as to this practice is at once suspected of being "an old-fashioned doctor," and dismissed to make room for a younger man.

In short, private medical practice is governed not by science but by supply and demand; and however scientific a treatment may be, it cannot hold its place in the market if there is no demand for it; nor can the grossest quackery be kept off the market if there is a demand for it.

FASHIONS AND EPIDEMICS

A demand, however, can be inculcated. This is thoroughly understood by fashionable tradesmen, who find no difficulty in persuading their customers to renew articles that are not worn out and to buy things they do not want. By making doctors tradesmen, we compel them to learn the tricks of trade; consequently we find that the fashions of the year include treatments, operations, and particular drugs, as well as hats, sleeves, ballads, and games. Tonsils, vermiform appendices, uvulas, even ovaries are sacrificed because it is the fashion to get them cut out, and because the operations are highly profitable. The psychology of fashion becomes a pathology; for the cases have every air of

being genuine: fashions, after all, are only induced epidemics, proving that epidemics can be induced by tradesmen, and therefore by doctors.

THE DOCTOR'S VIRTUES

It will be admitted that this is a pretty bad state of things. And the melodramatic instinct of the public, always demanding; that every wrong shall have, not its remedy, but its villain to be hissed, will blame, not its own apathy, superstition, and ignorance, but the depravity of the doctors. Nothing could be more unjust or mischievous. Doctors, if no better than other men, are certainly no worse. I was reproached during the performances of The Doctor's Dilemma at the Court Theatre in 1907 because I made the artist a rascal, the journalist an illiterate incapable, and all the doctors "angels." But I did not go beyond the warrant of my own experience. It has been my luck to have doctors among my friends for nearly forty years past (all perfectly aware of my freedom from the usual credulity as to the miraculous powers and knowledge attributed to them); and though I know that there are medical blackguards as well as military, legal, and clerical blackguards (one soon finds that out when one is privileged to hear doctors talking shop among themselves), the fact that I was no more at a loss for private medical advice and attendance when I had not a penny in my pocket than I was later on when I could afford fees on the highest scale, has made it impossible for me to share that hostility to the doctor as a man which exists and is growing as an inevitable result of the present condition of medical practice. Not that the interest in disease and aberrations which turns some men and women to medicine and surgery is not sometimes as morbid as the interest in misery and vice which turns some others to philanthropy and "rescue work." But the true doctor is inspired by a hatred of ill-health, and a divine impatience of any waste of vital forces. Unless a man is led to medicine or surgery through a very exceptional technical aptitude, or because doctoring is a family tradition, or because he regards it unintelligently as a lucrative and gentlemanly profession, his motives in choosing the career of a healer are clearly generous. However actual practice may disillusion and corrupt him, his selection in the first instance is not a selection of a base character.

THE DOCTOR'S HARDSHIPS

A review of the counts in the indictment I have brought against private medical practice will show that they arise out of the doctor's position as a competitive private tradesman: that is, out of his poverty and dependence. And it should be borne in mind that doctors are expected to treat other people specially well whilst themselves submitting to specially inconsiderate treatment. The butcher and baker are not expected to feed the hungry unless the hungry can pay; but a doctor who allows a fellow-creature to suffer or perish without aid is regarded as a monster. Even if we must dismiss hospital service as really venal, the fact remains that most doctors do a good deal of gratuitous work in private practice all through their careers. And in his paid work the doctor is on a different footing to the tradesman. Although the articles he sells, advice and treatment, are the same for all classes, his fees have to be graduated like the income tax. The successful fashionable doctor may weed his poorer patients out from time to time, and finally use the College of Physicians to place it out of his own power to accept low fees; but the ordinary general practitioner never makes out his bills without considering the taxable capacity of his patients.

Then there is the disregard of his own health and comfort which results from the fact that he is, by the nature of his work, an emergency man. We are polite and considerate to the doctor when there is nothing the matter, and we meet him as a friend or entertain him as a guest; but when the baby is

suffering from croup, or its mother has a temperature of 104 degrees, or its grandfather has broken his leg, nobody thinks of the doctor except as a healer and saviour. He may be hungry, weary, sleepy, run down by several successive nights disturbed by that instrument of torture, the night bell; but who ever thinks of this in the face of sudden sickness or accident? We think no more of the condition of a doctor attending a case than of the condition of a fireman at a fire. In other occupations night-work is specially recognized and provided for. The worker sleeps all day; has his breakfast in the evening; his lunch or dinner at midnight; his dinner or supper before going to bed in the morning; and he changes to day-work if he cannot stand night-work. But a doctor is expected to work day and night. In practices which consist largely of workmen's clubs, and in which the patients are therefore taken on wholesale terms and very numerous, the unfortunate assistant, or the principal if he has no assistant, often does not undress, knowing that he will be called up before he has snatched an hour's sleep. To the strain of such inhuman conditions must be added the constant risk of infection. One wonders why the impatient doctors do not become savage and unmanageable, and the patient ones imbecile. Perhaps they do, to some extent. And the pay is wretched, and so uncertain that refusal to attend without payment in advance becomes often a necessary measure of self-defence, whilst the County Court has long ago put an end to the tradition that the doctor's fee is an honorarium. Even the most eminent physicians, as such biographies as those of Paget show, are sometimes miserably, inhumanly poor until they are past their prime. In short, the doctor needs our help for the moment much more than we often need his. The ridicule of Moliere, the death of a well-informed and clever writer like the late Harold Frederic in the hands of Christian Scientists (a sort of sealing with his blood of the contemptuous disbelief in and dislike of doctors he had bitterly expressed in his books), the scathing and quite justifiable exposure of medical practice in the novel by Mr. Maarten Maartens entitled The New Religion: all these trouble the doctor very little, and are in any case well set off by the popularity of Sir Luke Fildes' famous picture, and by the verdicts in which juries from time to time express their conviction that the doctor can do no wrong. The real woes of the doctor are the shabby coat, the wolf at the door, the tyranny of ignorant patients, the work-day of 24 hours, and the uselessness of honestly prescribing what most of the patients really need: that is, not medicine, but money.

THE PUBLIC DOCTOR

What then is to be done?

Fortunately we have not to begin absolutely from the beginning: we already have, in the Medical Officer of Health, a sort of doctor who is free from the worst hardships, and consequently from the worst vices, of the private practitioner. His position depends, not on the number of people who are ill, and whom he can keep ill, but on the number of people who are well. He is judged, as all doctors and treatments should be judged, by the vital statistics of his district. When the death rate goes up his credit goes down. As every increase in his salary depends on the issue of a public debate as to the health of the constituency under his charge, he has every inducement to strive towards the ideal of a clean bill of health. He has a safe, dignified, responsible, independent position based wholly on the public health; whereas the private practitioner has a precarious, shabby-genteel, irresponsible, servile position, based wholly on the prevalence of illness.

It is true, there are grave scandals in the public medical service. The public doctor may be also a private practitioner eking out his earnings by giving a little time to public work for a mean payment. There are cases in which the position is one which no successful practitioner will accept, and where,

therefore, incapables or drunkards get automatically selected for the post, faute de mieux; but even in these cases the doctor is less disastrous in his public capacity than in his private one: besides, the conditions which produce these bad cases are doomed, as the evil is now recognized and understood. A popular but unstable remedy is to enable local authorities, when they are too small to require the undivided time of such men as the Medical Officers of our great municipalities, to combine for public health purposes so that each may share the services of a highly paid official of the best class; but the right remedy is a larger area as the sanitary unit.

MEDICAL ORGANIZATION

Another advantage of public medical work is that it admits of organization, and consequently of the distribution of the work in such a manner as to avoid wasting the time of highly qualified experts on trivial jobs. The individualism of private practice leads to an appalling waste of time on trifles. Men whose dexterity as operators or almost divinatory skill in diagnosis are constantly needed for difficult cases, are poulticing whitlows, vaccinating, changing unimportant dressings, prescribing ether drams for ladies with timid leanings towards dipsomania, and generally wasting their time in the pursuit of private fees. In no other profession is the practitioner expected to do all the work involved in it from the first day of his professional career to the last as the doctor is. The judge passes sentence of death; but he is not expected to hang the criminal with his own hands, as he would be if the legal profession were as unorganized as the medical. The bishop is not expected to blow the organ or wash the baby he baptizes. The general is not asked to plan a campaign or conduct a battle at half-past twelve and to play the drum at half-past two. Even if they were, things would still not be as bad as in the medical profession; for in it not only is the first-class man set to do third-class work, but, what is much more terrifying, the third-class man is expected to do first-class work. Every general practitioner is supposed to be capable of the whole range of medical and surgical work at a moment's notice; and the country doctor, who has not a specialist nor a crack consultant at the end of his telephone, often has to tackle without hesitation cases which no sane practitioner in a town would take in hand without assistance. No doubt this develops the resourcefulness of the country doctor, and makes him a more capable man than his suburban colleague; but it cannot develop the second-class man into a first-class one. If the practice of law not only led to a judge having to hang, but the hangman to judge, or if in the army matters were so arranged that it would be possible for the drummer boy to be in command at Waterloo whilst the Duke of Wellington was playing the drum in Brussels, we should not be consoled by the reflection that our hangmen were thereby made a little more judicial-minded, and our drummers more responsible, than in foreign countries where the legal and military professions recognized the advantages of division of labor.

Under such conditions no statistics as to the graduation of professional ability among doctors are available. Assuming that doctors are normal men and not magicians (and it is unfortunately very hard to persuade people to admit so much and thereby destroy the romance of doctoring) we may guess that the medical profession, like the other professions, consists of a small percentage of highly gifted persons at one end, and a small percentage of altogether disastrous duffers at the other. Between these extremes comes the main body of doctors (also, of course, with a weak and a strong end) who can be trusted to work under regulations with more or less aid from above according to the gravity of the case. Or, to put it in terms of the cases, there are cases that present no difficulties, and can be dealt with by a nurse or student at one end of the scale, and cases that require watching and handling by the very highest existing skill at the other; whilst between come the great mass of cases which need

visits from the doctor of ordinary ability and from the chiefs of the profession in the proportion of, say, seven to none, seven to one, three to one, one to one, or, for a day or two, none to one. Such a service is organized at present only in hospitals; though in large towns the practice of calling in the consultant acts, to some extent, as a substitute for it. But in the latter case it is quite unregulated except by professional etiquet, which, as we have seen, has for its object, not the health of the patient or of the community at large, but the protection of the doctor's livelihood and the concealment of his errors. And as the consultant is an expensive luxury, he is a last resource rather, as he should be, than a matter of course, in all cases where the general practitioner is not equal to the occasion: a predicament in which a very capable man may find himself at any time through the cropping up of a case of which he has had no clinical experience.

THE SOCIAL SOLUTION OF THE MEDICAL PROBLEM

The social solution of the medical problem, then, depends on that large, slowly advancing, pettishly resisted integration of society called generally Socialism. Until the medical profession becomes a body of men trained and paid by the country to keep the country in health it will remain what it is at present: a conspiracy to exploit popular credulity and human suffering. Already our M.O.H.s (Medical Officers of Health) are in the new position: what is lacking is appreciation of the change, not only by the public but by the private doctors. For, as we have seen, when one of the first-rate posts becomes vacant in one of the great cities, and all the leading M.O.H.s compete for it, they must appeal to the good health of the cities of which they have been in charge, and not to the size of the incomes the local private doctors are making out of the ill-health of their patients. If a competitor can prove that he has utterly ruined every sort of medical private practice in a large city except obstetric practice and the surgery of accidents, his claims are irresistible; and this is the ideal at which every M.O.H. should aim. But the profession at large should none the less welcome him and set its house in order for the social change which will finally be its own salvation. For the M.O.H. as we know him is only the beginning of that army of Public Hygiene which will presently take the place in general interest and honor now occupied by our military and naval forces. It is silly that an Englishman should be more afraid of a German soldier than of a British disease germ, and should clamor for more barracks in the same newspapers that protest against more school clinics, and cry out that if the State fights disease for us it makes us paupers, though they never say that if the State fights the Germans for us it makes us cowards. Fortunately, when a habit of thought is silly it only needs steady treatment by ridicule from sensible and witty people to be put out of countenance and perish. Every year sees an increase in the number of persons employed in the Public Health Service, who would formerly have been mere adventurers in the Private Illness Service. To put it another way, a host of men and women who have now a strong incentive to be mischievous and even murderous rogues will have a much stronger, because a much honester, incentive to be not only good citizens but active benefactors to the community. And they will have no anxiety whatever about their incomes.

THE FUTURE OF PRIVATE PRACTICE

It must not be hastily concluded that this involves the extinction of the private practitioner. What it will really mean for him is release from his present degrading and scientifically corrupting slavery to his patients. As I have already shown the doctor who has to live by pleasing his patients in competition with everybody who has walked the hospitals, scraped through the examinations, and bought a brass plate, soon finds himself prescribing water to teetotallers and brandy or champagne

jelly to drunkards; beefsteaks and stout in one house, and "uric acid free" vegetarian diet over the way; shut windows, big fires, and heavy overcoats to old Colonels, and open air and as much nakedness as is compatible with decency to young faddists, never once daring to say either "I don't know," or "I don't agree." For the strength of the doctor's, as of every other man's position when the evolution of social organization at last reaches his profession, will be that he will always have open to him the alternative of public employment when the private employer becomes too tyrannous. And let no one suppose that the words doctor and patient can disguise from the parties the fact that they are employer and employee. No doubt doctors who are in great demand can be as high-handed and independent as employees are in all classes when a dearth in their labor market makes them indispensable; but the average doctor is not in this position: he is struggling for life in an overcrowded profession, and knows well that "a good bedside manner" will carry him to solvency through a morass of illness, whilst the least attempt at plain dealing with people who are eating too much, or drinking too much, or frowsting too much (to go no further in the list of intemperances that make up so much of family life) would soon land him in the Bankruptcy Court.

Private practice, thus protected, would itself protect individuals, as far as such protection is possible, against the errors and superstitions of State medicine, which are at worst no worse than the errors and superstitions of private practice, being, indeed, all derived from it. Such monstrosities as vaccination are, as we have seen, founded, not on science, but on half-crowns. If the Vaccination Acts, instead of being wholly repealed as they are already half repealed, were strengthened by compelling every parent to have his child vaccinated by a public officer whose salary was completely independent of the number of vaccinations performed by him, and for whom there was plenty of alternative public health work waiting, vaccination would be dead in two years, as the vaccinator would not only not gain by it, but would lose credit through the depressing effects on the vital statistics of his district of the illness and deaths it causes, whilst it would take from him all the credit of that freedom from smallpox which is the result of good sanitary administration and vigilant prevention of infection. Such absurd panic scandals as that of the last London epidemic, where a fee of half-a-crown per re-vaccination produced raids on houses during the absence of parents, and the forcible seizure and re-vaccination of children left to answer the door, can be prevented simply by abolishing the half-crown and all similar follies, paying, not for this or that ceremony of witchcraft, but for immunity from disease, and paying, too, in a rational way. The officer with a fixed salary saves himself trouble by doing his business with the least possible interference with the private citizen. The man paid by the job loses money by not forcing his job on the public as often as possible without reference to its results.

THE TECHNICAL PROBLEM

As to any technical medical problem specially involved, there is none. If there were, I should not be competent to deal with it, as I am not a technical expert in medicine: I deal with the subject as an economist, a politician, and a citizen exercising my common sense. Everything that I have said applies equally to all the medical techniques, and will hold good whether public hygiene be based on the poetic fancies of Christian Science, the tribal superstitions of the druggist and the vivisector, or the best we can make of our real knowledge. But I may remind those who confusedly imagine that the medical problem is also the scientific problem, that all problems are finally scientific problems. The notion that therapeutics or hygiene or surgery is any more or less scientific than making or cleaning boots is entertained only by people to whom a man of science is still a magician who can

cure diseases, transmute metals, and enable us to live for ever. It may still be necessary for some time to come to practise on popular credulity, popular love and dread of the marvellous, and popular idolatry, to induce the poor to comply with the sanitary regulations they are too ignorant to understand. As I have elsewhere confessed, I have myself been responsible for ridiculous incantations with burning sulphur, experimentally proved to be quite useless, because poor people are convinced, by the mystical air of the burning and the horrible smell, that it exorcises the demons of smallpox and scarlet fever and makes it safe for them to return to their houses. To assure them that the real secret is sunshine and soap is only to convince them that you do not care whether they live or die, and wish to save money at their expense. So you perform the incantation; and back they go to their houses, satisfied. A religious ceremony—a poetic blessing of the threshold, for instance—would be much better; but unfortunately our religion is weak on the sanitary side. One of the worst misfortunes of Christendom was that reaction against the voluptuous bathing of the imperial Romans which made dirty habits a part of Christian piety, and in some unlucky places (the Sandwich Islands for example) made the introduction of Christianity also the introduction of disease, because the formulators of the superseded native religion, like Mahomet, had been enlightened enough to introduce as religious duties such sanitary measures as ablution and the most careful and reverent treatment of everything cast off by the human body, even to nail clippings and hairs; and our missionaries thoughtlessly discredited this godly doctrine without supplying its place, which was promptly taken by laziness and neglect. If the priests of Ireland could only be persuaded to teach their flocks that it is a deadly insult to the Blessed Virgin to place her image in a cottage that is not kept up to that high standard of Sunday cleanliness to which all her worshippers must believe she is accustomed, and to represent her as being especially particular about stables because her son was born in one, they might do more in one year than all the Sanitary Inspectors in Ireland could do in twenty; and they could hardly doubt that Our Lady would be delighted. Perhaps they do nowadays; for Ireland is certainly a transfigured country since my youth as far as clean faces and pinafores can transfigure it. In England, where so many of the inhabitants are too gross to believe in poetic faiths, too respectable to tolerate the notion that the stable at Bethany was a common peasant farmer's stable instead of a first-rate racing one, and too savage to believe that anything can really cast out the devil of disease unless it be some terrifying hoodoo of tortures and stinks, the M.O.H. will no doubt for a long time to come have to preach to fools according to their folly, promising miracles, and threatening hideous personal consequences of neglect of by-laws and the like; therefore it will be important that every M.O.H. shall have, with his (or her) other qualifications, a sense of humor, lest (he or she) should come at last to believe all the nonsense that must needs be talked. But he must, in his capacity of an expert advising the authorities, keep the government itself free of superstition. If Italian peasants are so ignorant that the Church can get no hold of them except by miracles, why, miracles there must be. The blood of St. Januarius must liquefy whether the Saint is in the humor or not. To trick a heathen into being a dutiful Christian is no worse than to trick a whitewasher into trusting himself in a room where a smallpox patient has lain, by pretending to exorcise the disease with burning sulphur. But woe to the Church if in deceiving the peasant it also deceives itself; for then the Church is lost, and the peasant too, unless he revolt against it. Unless the Church works the pretended miracle painfully against the grain, and is continually urged by its dislike of the imposture to strive to make the peasant susceptible to the true reasons for behaving well, the Church will become an instrument of his corruption and an exploiter of his ignorance, and will find itself launched upon that persecution of scientific truth of which all priesthoods are accused and none with more justice than the scientific priesthood.

And here we come to the danger that terrifies so many of us: the danger of having a hygienic orthodoxy imposed on us. But we must face that: in such crowded and poverty ridden civilizations as ours any orthodoxy is better than laisser-faire. If our population ever comes to consist exclusively of well-to-do, highly cultivated, and thoroughly instructed free persons in a position to take care of themselves, no doubt they will make short work of a good deal of official regulation that is now of life-and-death necessity to us; but under existing circumstances, I repeat, almost any sort of attention that democracy will stand is better than neglect. Attention and activity lead to mistakes as well as to successes; but a life spent in making mistakes is not only more honorable but more useful than a life spent doing nothing. The one lesson that comes out of all our theorizing and experimenting is that there is only one really scientific progressive method; and that is the method of trial and error. If you come to that, what is laisser-faire but an orthodoxy? the most tyrannous and disastrous of all the orthodoxies, since it forbids you even to learn.

THE LATEST THEORIES

Medical theories are so much a matter of fashion, and the most fertile of them are modified so rapidly by medical practice and biological research, which are international activities, that the play which furnishes the pretext for this preface is already slightly outmoded, though I believe it may be taken as a faithful record for the year (1906) in which it was begun. I must not expose any professional man to ruin by connecting his name with the entire freedom of criticism which I, as a layman, enjoy; but it will be evident to all experts that my play could not have been written but for the work done by Sir Almroth Wright in the theory and practice of securing immunization from bacterial diseases by the inoculation of "vaccines" made of their own bacteria: a practice incorrectly called vaccinetherapy (there is nothing vaccine about it) apparently because it is what vaccination ought to be and is not. Until Sir Almroth Wright, following up one of Metchnikoff's most suggestive biological romances, discovered that the white corpuscles or phagocytes which attack and devour disease germs for us do their work only when we butter the disease germs appetizingly for them with a natural sauce which Sir Almroth named opsonin, and that our production of this condiment continually rises and falls rhythmically from negligibility to the highest efficiency, nobody had been able even to conjecture why the various serums that were from time to time introduced as having effected marvellous cures, presently made such direful havoc of some unfortunate patient that they had to be dropped hastily. The quantity of sturdy lying that was necessary to save the credit of inoculation in those days was prodigious; and had it not been for the devotion shown by the military authorities throughout Europe, who would order the entire disappearance of some disease from their armies, and bring it about by the simple plan of changing the name under which the cases were reported, or for our own Metropolitan Asylums Board, which carefully suppressed all the medical reports that revealed the sometimes quite appalling effects of epidemics of revaccination, there is no saying what popular reaction might not have taken place against the whole immunization movement in therapeutics.

The situation was saved when Sir Almroth Wright pointed out that if you inoculated a patient with pathogenic germs at a moment when his powers of cooking them for consumption by the phagocytes was receding to its lowest point, you would certainly make him a good deal worse and perhaps kill him, whereas if you made precisely the same inoculation when the cooking power was rising to one of its periodical climaxes, you would stimulate it to still further exertions and produce just the opposite result. And he invented a technique for ascertaining in which phase the patient happened to

be at any given moment. The dramatic possibilities of this discovery and invention will be found in my play. But it is one thing to invent a technique: it is quite another to persuade the medical profession to acquire it. Our general practitioners, I gather, simply declined to acquire it, being mostly unable to afford either the acquisition or the practice of it when acquired. Something simple, cheap, and ready at all times for all comers, is, as I have shown, the only thing that is economically possible in general practice, whatever may be the case in Sir Almroth's famous laboratory in St. Mary's Hospital. It would have become necessary to denounce opsonin in the trade papers as a fad and Sir Almroth as a dangerous man if his practice in the laboratory had not led him to the conclusion that the customary inoculations were very much too powerful, and that a comparatively infinitesimal dose would not precipitate a negative phase of cooking activity, and might induce a positive one. And thus it happens that the refusal of our general practitioners to acquire the new technique is no longer quite so dangerous in practice as it was when The Doctor's Dilemma was written: nay, that Sir Ralph Bloomfield Boningtons way of administering inoculations as if they were spoonfuls of squills may sometimes work fairly well. For all that, I find Sir Almroth Wright, on the 23rd May, 1910, warning the Royal Society of Medicine that "the clinician has not yet been prevailed upon to reconsider his position," which means that the general practitioner ("the doctor," as he is called in our homes) is going on just as he did before, and could not afford to learn or practice a new technique even if he had ever heard of it. To the patient who does not know about it he will say nothing. To the patient who does, he will ridicule it, and disparage Sir Almroth. What else can he do, except confess his ignorance and starve?

But now please observe how "the whirligig of time brings its revenges." This latest discovery of the remedial virtue of a very, very tiny hair of the dog that bit you reminds us, not only of Arndt's law of protoplasmic reaction to stimuli, according to which weak and strong stimuli provoke opposite reactions, but of Hahnemann's homeopathy, which was founded on the fact alleged by Hahnemann that drugs which produce certain symptoms when taken in ordinary perceptible quantities, will, when taken in infinitesimally small quantities, provoke just the opposite symptoms; so that the drug that gives you a headache will also cure a headache if you take little enough of it. I have already explained that the savage opposition which homeopathy encountered from the medical profession was not a scientific opposition; for nobody seems to deny that some drugs act in the alleged manner. It was opposed simply because doctors and apothecaries lived by selling bottles and boxes of doctor's stuff to be taken in spoonfuls or in pellets as large as peas; and people would not pay as much for drops and globules no bigger than pins' heads. Nowadays, however, the more cultivated folk are beginning to be so suspicious of drugs, and the incorrigibly superstitious people so profusely supplied with patent medicines (the medical advice to take them being wrapped round the bottle and thrown in for nothing) that homeopathy has become a way of rehabilitating the trade of prescription compounding, and is consequently coming into professional credit. At which point the theory of opsonins comes very opportunely to shake hands with it.

Add to the newly triumphant homeopathist and the opsonist that other remarkable innovator, the Swedish masseur, who does not theorize about you, but probes you all over with his powerful thumbs until he finds out your sore spots and rubs them away, besides cheating you into a little wholesome exercise; and you have nearly everything in medical practice to-day that is not flat witchcraft or pure commercial exploitation of human credulity and fear of death. Add to them a good deal of vegetarian and teetotal controversy raging round a clamor for scientific eating and drinking, and resulting in little so far except calling digestion Metabolism and dividing the public between the eminent doctor

who tells us that we do not eat enough fish, and his equally eminent colleague who warns us that a fish diet must end in leprosy, and you have all that opposes with any sort of countenance the rise of Christian Science with its cathedrals and congregations and zealots and miracles and cures: all very silly, no doubt, but sane and sensible, poetic and hopeful, compared to the pseudo science of the commercial general practitioner, who foolishly clamors for the prosecution and even the execution of the Christian Scientists when their patients die, forgetting the long death roll of his own patients.

By the time this preface is in print the kaleidoscope may have had another shake; and opsonin may have gone the way of phlogiston at the hands of its own restless discoverer. I will not say that Hahnemann may have gone the way of Diafoirus; for Diafoirus we have always with us. But we shall still pick up all our knowledge in pursuit of some Will o' the Wisp or other. What is called science has always pursued the Elixir of Life and the Philosopher's Stone, and is just as busy after them to-day as ever it was in the days of Paracelsus. We call them by different names: Immunization or Radiology or what not; but the dreams which lure us into the adventures from which we learn are always at bottom the same. Science becomes dangerous only when it imagines that it has reached its goal. What is wrong with priests and popes is that instead of being apostles and saints, they are nothing but empirics who say "I know" instead of "I am learning," and pray for credulity and inertia as wise men pray for scepticism and activity. Such abominations as the Inquisition and the Vaccination Acts are possible only in the famine years of the soul, when the great vital dogmas of honor, liberty, courage, the kinship of all life, faith that the unknown is greater than the known and is only the As Yet Unknown, and resolution to find a manly highway to it, have been forgotten in a paroxysm of littleness and terror in which nothing is active except concupiscence and the fear of death, playing on which any trader can filch a fortune, any blackguard gratify his cruelty, and any tyrant make us his slaves.

Lest this should seem too rhetorical a conclusion for our professional men of science, who are mostly trained not to believe anything unless it is worded in the jargon of those writers who, because they never really understand what they are trying to say, cannot find familiar words for it, and are therefore compelled to invent a new language of nonsense for every book they write, let me sum up my conclusions as dryly as is consistent with accurate thought and live conviction.

1. Nothing is more dangerous than a poor doctor: not even a poor employer or a poor landlord.

2. Of all the anti-social vested interests the worst is the vested interest in ill-health.

3. Remember that an illness is a misdemeanor; and treat the doctor as an accessory unless he notifies every case to the Public Health authority.

4. Treat every death as a possible and under our present system a probable murder, by making it the subject of a reasonably conducted inquest; and execute the doctor, if necessary, as a doctor, by striking him off the register.

5. Make up your mind how many doctors the community needs to keep it well. Do not register more or less than this number; and let registration constitute the doctor a civil servant with a dignified living wage paid out of public funds.

6. Municipalize Harley Street.

7. Treat the private operator exactly as you would treat a private executioner.

8. Treat persons who profess to be able to cure disease as you treat fortune tellers.

9. Keep the public carefully informed, by special statistics and announcements of individual cases, of all illnesses of doctors or in their families.

10. Make it compulsory for a doctor using a brass plate to have inscribed on it, in addition to the letters indicating his qualifications, the words "Remember that I too am mortal."

11. In legislation and social organization, proceed on the principle that invalids, meaning persons who cannot keep themselves alive by their own activities, cannot, beyond reason, expect to be kept alive by the activity of others. There is a point at which the most energetic policeman or doctor, when called upon to deal with an apparently drowned person, gives up artificial respiration, although it is never possible to declare with certainty, at any point short of decomposition, that another five minutes of the exercise would not effect resuscitation. The theory that every individual alive is of infinite value is legislatively impracticable. No doubt the higher the life we secure to the individual by wise social organization, the greater his value is to the community, and the more pains we shall take to pull him through any temporary danger or disablement. But the man who costs more than he is worth is doomed by sound hygiene as inexorably as by sound economics.

12. Do not try to live for ever. You will not succeed.

13. Use your health, even to the point of wearing it out. That is what it is for. Spend all you have before you die; and do not outlive yourself.

14. Take the utmost care to get well born and well brought up. This means that your mother must have a good doctor. Be careful to go to a school where there is what they call a school clinic, where your nutrition and teeth and eyesight and other matters of importance to you will be attended to. Be particularly careful to have all this done at the expense of the nation, as otherwise it will not be done at all, the chances being about forty to one against your being able to pay for it directly yourself, even if you know how to set about it. Otherwise you will be what most people are at present: an unsound citizen of an unsound nation, without sense enough to be ashamed or unhappy about it.

Chapter 2
The Medicare Modernization Act of 2003

Public Law No: 108-173 (12/08/2003)

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 - **Title I: Medicare Prescription Drug Benefit** (Sec. 101) Amends title XVIII (Medicare) of the Social Security Act (SSA) to add a new part D (Voluntary Prescription Drug Benefit Program). Establishes a new optional Medicare prescription drug benefit program augmenting with a comprehensive, flexible, and permanent voluntary prescription drug benefit program the limited coverage of certain outpatient prescription drugs, biologicals, and vaccines currently covered under the Medicare program under its original fee-for-service component under both Medicare parts A (Hospital Insurance) and B (Supplementary Medical Insurance) and under its managed care, medical savings account (MSA), and private fee-for-service component under Medicare part C (Medicare+Choice).

Provides under this new prescription drug benefit program for offering eligible Medicare beneficiaries, regardless of income or health status, access to more coverage options, options which provide enhanced benefits, with cost-sharing, and additional beneficiary protections and assistance, such as access to negotiated prices, catastrophic coverage limits, and premium subsidies for certain low-income beneficiaries.

Provides for these options to be offered through both: (1) a new Medicare part C Medicare Advantage (MA) program that integrates basic medical coverage with added prescription drug coverage, including coverage through specialized MA plans for special needs individuals; and (2) a new separate, stand-alone Medicare Prescription Drug plan (PDP) program under Medicare part D that relies on private plans to provide coverage and to bear a portion of the financial risk for drug costs.

Makes this new program effective January 1, 2006.

Provides that until this new permanent prescription drug benefit program is effective, the Secretary of Health and Human Services (HHS) shall establish a program to endorse prescription drug discount card programs in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States and to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs. Provides that the program shall not apply to covered discount card drugs dispensed after December 31, 2005, and transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

Allows beneficiaries entitled to benefits under Medicare part A or enrolled under Medicare part B (eligible beneficiaries) to elect to enroll under new Medicare part D, and: (1) provided that they are not enrolled in an MA plan, keep their current Medicare fee-for-service coverage and receive qualified prescription drug coverage (as described below) through enrollment in Medicare part D in a new PDP that is offered in the geographic area in which the beneficiary resides; or (2) enroll in the new Medicare part C MA program in an MA plan, give up their current Medicare fee-for-service coverage, and receive qualified prescription drug coverage under the plan along with basic and possibly enhanced medical coverage through health maintenance organization (HMO) or revised MSA coverage options under the new MA program established by this Act under Medicare part C

(and as otherwise provided under Medicare+Choice under Medicare part C as discussed more fully below under title II (MedicareAdvantage) of this Act).

Provides an exception for MA enrollees: (1) enrolled in MSA plans to receive qualified coverage of prescription drugs through enrollment in a PDP; (2) enrolled in private-fee-for service plans that do not provide qualified prescription drug coverage to receive qualified coverage of prescription drugs through enrollment in PDP plans; and (3) enrolled in an MA prescription drug plan (MA-PD) to receive qualified prescription drug coverage under that plan.

Directs the Secretary to establish a process for the enrollment, disenrollment, termination, and change of enrollment of Medicare part D eligible individuals in prescription drug plans. Establishes an initial enrollment period beginning November 15, 2005 .

Directs the Secretary to conduct activities designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage under Medicare part D, including information comparing the plans offered by eligible entities under Medicare part D that are available to eligible beneficiaries in an area.

Divides qualified prescription drug coverage into either a standard coverage benefit package or an alternative prescription drug coverage with at least actuarially equivalent benefits, both with access to negotiated drug prices. Outlines the standard coverage package, which includes, for 2006, a $250 deductible, 25 percent cost-sharing for drug costs between $250 and the initial coverage limit of $2,250, then no coverage; except that the beneficiary shall have access to negotiated prices, regardless of the fact that no benefits may be payable under the coverage, until incurring out-of-pocket costs for covered drugs in a year equal $3,600, with the beneficiary thereafter to pay five percent of the cost of a prescription, or a copayment of $2 for a generic drug and $5 for any other drug, whichever is greater. Includes as negotiated prices all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations. Increases these amounts in future years by the annual percentage increase in average per capita aggregate expenditures for covered drugs for the year ending the previous July.

Includes among the out-of-pocket costs counting toward the annual $3,600 limit any costs paid by the part D eligible individual (or by another person such as a family member) under the Medicaid program or under a State pharmaceutical assistance program for which the individual (or other person) is not reimbursed.

Allows a PDP or an MA plan to provide a different prescription drug benefit design from the standard prescription drug coverage as long as the Administrator of the Medicare Benefits Administration approves of such benefit design.

Directs the Secretary to ensure that each part D eligible individual has available a choice of enrollment in at least two qualifying plans in the area in which the individual resides, at least one of which is a prescription drug plan. Provides that in such case in which such plans are not available the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

Establishes beneficiary protection requirements for qualified prescription drug plans, such as requiring each PDP sponsor offering a prescription drug plan to: (1) have a mechanism for providing specific information on a timely basis to enrollees upon request; (2) have in place with respect to

covered part D drugs a cost-effective drug utilization management program and a medication therapy management program; and (3) provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Directs the Secretary to establish, and allows the Secretary to revise PDP regions in a manner that is consistent with the requirements below for the establishment and revision of MA regions, and to the extent practicable PDP regions shall be the same as MA regions. Requires a PDP sponsor to submit to the Secretary bid and other described information with respect to each prescription drug plan it offers for review by the Secretary for the purpose of conducting negotiations concerning the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan in order for the Secretary to approve or disapprove the plan. Provides that in order to promote competition under new Medicare part D and in carrying out such part, the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponosors and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

Establishes organizational requirements for PDP sponsors, such as licenses, and requires that they enter into a contract with the Secretary to be eligible to receive payments.

Provides for premium and cost-sharing subsidies for low-income subsidy-eligible individuals.

Provides: (1) for the establishment of risk corridors for each PDP that determines the amount of risk that the PDP shall be exposed to for drug spending, and the resultant adjustment in payment attributable to this risk; and (2) that a PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits. Prohibits adjustment in payments made by reason of this paragraph from affecting the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Medicare Prescription Drug Account for payments for low-income subsidy payments, subsidy payments, payments to qualified retiree prescription drug plans, and administrative expenses. Authorizes appropriations. Requires transfers to be made to the Medicaid account for increased administrative costs. Requires amounts withheld for late penalties to be deposited into the Fund. Requires States to make payments to the Account for dual eligibles as provided for under Medicaid.

Directs the Secretary to establish requirements for PDPs to ensure the effective coordination between a part D plan and a State Pharmaceutical Assistance Program with respect to payment of premiums and coverage and payment for supplemental prescription drug benefits for part D eligible individuals enrolled under both types of plans. Requires the Secretary to apply such coordination requirements to described Rx plans, which include Medicaid programs and group health plans and the Federal Employees Health Benefit Program (FEHBP), in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

Requires the prescription drug discount program and the transitional assistance program to be implemented by the Secretary so that interim prescription drug discount cards and transitional

assistance are first available by not later than six months after the enactment of this Act in 2004 and 2005 until coverage under the new part D program becomes effective on January 1, 2006. Requires each prescription drug card sponsor that offers an endorsed discount card program to provide each discount card eligible individual entitled to benefits, or enrolled, under Medicare part A (Hospital Insurance) or part B (Supplementary Medical Insurance) with access to negotiated prices and savings on prescription drugs through enrollment in an endorsed discount card program.

Allows card sponsors to charge annual enrollment fees, not to exceed $30. Requires the fee to be uniform for all discount eligible individuals enrolled in the program. Requires a prescription drug card sponsor offering an endorsed discount card program to provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

Provides that a discount card eligible individual is an individual whose income is not more than 135 percent of the poverty line and who is entitled to have payment made of any annual enrollment fee and to have payment made, up to $600 in 2004, under such endorsed program of 90 percent of the costs incurred for covered discount card drugs.

Creates within the Federal Supplementary Medical Insurance Trust Fund the Transitional Assistance Account for payments for transitional assistance. Makes necessary appropriations.

(Sec. 103) Establishes certain requirements for States as a condition of receiving Federal Medicaid assistance, such as requiring States to provide the Secretary with Medicaid eligibility information necessary to carry out transitional prescription drug assistance verification.

Provides for: (1) Federal phase-in of the costs of premiums and cost-sharing and cost-sharing subsidies for dually eligible individuals; and (2) coordination of Medicaid with Medicare prescription drug benefits to provide that Medicare is the primary payer for covered drugs for dual eligibles.

Exempts prices negotiated from manufacturers for discount card drugs under an endorsement card program and prices negotiated by a PDP under part D, an MA-PD plan, or a qualified retiree prescription plan from the calculation of Medicaid "best price."

Extends the Qualifying-1 (Q-1) program through September 30, 2004, and expands outreach requirements for the Commissioner of Social Security to include outreach activities for transitional assistance and low-income subsidy individuals.

(Sec. 104) Prohibits, effective January 1, 2006, the selling, issuance, or renewal of Medigap Rx policies for part D enrollees, but permits the renewal of a Medigap Rx policy that was issued before January 1, 2006. Permits persons enrolling under part D during the initial enrollment period while covered under a Medigap Rx policy to enroll in a Medigap policy without prescription drug coverage or to continue the policy in effect as modified to exclude drugs. Provides that after the end of such period the individual may continue the policy in effect subject to such modification.

Guarantees issuance of a substitute Medigap policy for persons, enrolling in part D during the initial part D enrollment period, who at the time of such enrollment were enrolled in and terminated enrollment in a Medigap policy H, I, or J or a pre-standard policy that included drug coverage.

Guarantees the enrollment for any policies A, B, C, and F within the same carrier of issue. Prevents the issuer from discriminating in the pricing of such policy on the basis of such individual's health status, claims experience, receipt of health care or medical condition. Prohibits the issuer from imposing an exclusion of benefits based on a pre-existing condition under such policy. Provides that the guarantee applies for enrollments occurring in the new Medigap plan within 63 days of termination of enrollment in a Medigap plan H, I, or J.

Directs the Secretary to request the National Association of Insurance Commissioners to review and revise standards for benefit packages taking into account the changes in benefits resulting from the enactment of this Act and to otherwise update standards to reflect other changes in law included in such Act.

(Sec. 105) Includes additional provisions related to Medicare prescription drug discount cards and transitional assistance program, such as the exclusion of program costs from the calculation of the part B premium. Applies Medicare confidentiality provisions to drug pricing data.

(Sec. 106) Establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs as a result of the enactment of this Act.

(Sec. 107) Requires the Secretary to study and report to Congress on variations in per capita spending for covered part D drugs among PDP regions to determine the amount of such variation that is attributable to price variations and the differences in per capita utilization that is not taken into account in the health status risk adjustment made to PDP bids.

Requires the Secretary to conduct a review of the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings and evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care.

Directs the Secretary to enter into a contract with the Institutes of Medicine of the National Academy of Science to carry out a comprehensive study for a report to Congress on drug safety and quality issues in order to provide a blueprint for a system-wide change. Authorizes appropriations.

Directs the Secretary to provide for a study and report to Congress on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under parts C and D of title XVIII on a multi-year basis.

Requires the Comptroller General to conduct a study for a report to the Congress on the extent to which drug utilization and access to covered part D drugs by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals except for application of the assets test.

Directs the Secretary to undertake a study for a report to Congress of how to make prescription pharmaceutical information, including drug labels and usage instructions, accessible to blind and visually impaired individuals.

(Sec. 108) Authorizes the Secretary to make grants to physicians for the purpose of assisting them to implement electronic prescription drug programs that comply with appropriate standards. Authorizes appropriations.

(Sec. 109) Expands the work of quality improvement organizations to include part C and part D. Requires such organizations to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to prescription drug therapy.

Directs the Secretary to request the Institute of Medicine of the National Academy of Sciences to conduct an evaluation of the peer review program under SSA title XI.

(Sec. 110) Directs the Federal Trade Commission to conduct a study for a report to Congress on differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers.

(Sec. 111) Directs the Comptroller General of the United States to conduct an initial and final study for a report to Congress on trends in employment-based retiree health coverage, including coverage under FEHBP, and the options and incentives available under this Act which may have an effect on the voluntary provision of such coverage.

Title II: Medicare Advantage - Subtitle A: Implementation of Medicare Advantage Program - (Sec. 201) Amends SSA title XVIII part C (Medicare+Choice) to replace the current Medicare+Choice program with the Medicare Advantage (MA) program.

Subtitle B: Immediate Improvements - (Sec. 211) Revises the payment system, requiring all plans to be paid at a rate at least as high as the rate for traditional Medicare fee-for-service plans. Makes change in budget neutrality for blend. Increases minimum percentage increase to national growth rate. Includes costs of Department of Defense and Department of Veterans Affairs military facility services to Medicare-eligible beneficiaries in calculation of payment rates.

Directs the Medicare Payment Advisory Commission (MEDPAC) to conduct a study that assesses the method used for determining the adjusted average per capita cost (AAPCC).

Requires the Secretary to submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts on the availability on Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

Requires a Medicare Payment Advisory Commission (MEDPAC) study and report to Congress with respect to authority regarding disapproval of unreasonable beneficiary cost-sharing.

Subtitle C: Offering of Medicare Advantage (MA) Regional Plans; Medicare Advantage Competition - (Sec. 221) Directs the Secretary to establish regional plans to encourage private plans to serve Medicare beneficiaries in from ten to 50 regions, including in rural areas, within the 50 States and the District of Columbia beginning not later than January 1, 2005.

Prohibits the Secretary from offering a local preferred provider organization plan under Medicare part C during 2006 or 2007 in a service area unless such plan was offered under such part (including under a demonstration project under such part) in such area as of December 31, 2005. Includes risk corridors for plans during the first two years of the program in 2006 and 2007; a stabilization fund to encourage plan entry and limit plan withdrawals; a blended benchmark that will allow plan bids to

influence the benchmark amount; and network adequacy stabilization payments to assist plans in forming adequate networks, particularly in rural areas.

(Sec. 222) Provides that beginning in 2006, each MA organization shall submit to the Secretary for each MA plan for the service area in which it intends to be offered in the following year the monthly aggregate bid amount for the provision of all items and services under the plan for the type of plan and year involved.

Requires this monthly bid amount, with respect to which the Secretary has authority to negotiate, to be compared against respective benchmark amounts for MA local and MA regional plans, with plans that submit bids below the benchmark to be paid their bids, plus 75 percent of the difference between the benchmark and the bid which must be returned to beneficiaries in the form of additional benefits or reduced premiums. Provides that for plans that bid above the benchmark the government will pay the benchmark amount, and the beneficiary will pay the difference between the benchmark and the bid amount as a premium.

Requires the MA plan to provide an enrollee a monthly rebate equal to 75 percent of any average per capita savings as applicable to the plan and year involved. Allows the beneficiary rebate to be credited toward the provision of supplemental health care benefits, the prescription drug premium, or the Medicare part B premium. Requires the plan to disclose to the Secretary information on the form and amount of the rebate or the actuarial value in the case of supplemental health care benefits. Provides that for MA plans providing rebates the MA monthly basic beneficiary premium will be zero.

Provides that: (1) for MA plans with bids above the applicable benchmark, the MA monthly basic beneficiary premium will equal the amount by which the bid exceeds the benchmark; (2) the MA monthly prescription drug beneficiary premium is the base beneficiary premium less the amount of rebate credited toward such amount; and (3) the MA monthly supplemental beneficiary premium means the portion of the aggregate monthly bid amount for the year that is attributable to the provision of supplemental health benefits, less the amount of rebate credited toward such portion.

Allows enrollees to have their MA premiums deducted directly from their social security benefits, through an electronic funds transfer, or such other means as specified by the Secretary. Requires all premium payments withheld to be credited to the appropriate Trust Fund (or Account therof), as specified by the Secretary, and paid to the MA organization involved.

Subtitle D: Additional Reforms - (Sec. 231) Allows specialized MA plans for special needs individuals to be any type of coordinated care plan. Designates two specific segments of the Medicare population as special needs beneficiaries, but also provides the Secretary the authority to designate other chronically ill or disabled beneficiaries as special needs beneficiaries. Permits certain restriction on enrollment for specialized MA plans for special needs individuals. Provides authority to designate other plans as specialized MA plans.

(Sec. 232) Establishes that the MA program is a Federal program operated under Federal rules. Provides that State laws do not apply except State licensing laws or State laws relating to plan solvency.

(Sec. 233) Makes the Medicare Medical Savings Account (MSA) demonstration program a permanent program option and eliminates the capacity limit and the deadline for enrollment. Provides

that non-contract providers furnishing services to enrollees of MSAs will be subject to the same balanced billing limitations as non-contract providers furnishing services to enrolleees of coordinated care plans. Eliminates requirements for the Secretary to submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted.

(Sec. 234) Allows a reasonable cost reimbursement contract to operate indefinitely unless two other plans of the same type enter the cost contract's service area. Requires these two other plans to meet the following minimum enrollment requirements: (1) at least 5,000 enrollees for the portion of the area that is within a metropolitan statistical area having more than 250,000 people and counties contiguous to such an area; and (2) at least 1,500 enrollees for any other portion of such area.

(Sec. 235) Amends the Consolidated Omnibus Budget Reconciliation Act of 1985 to extend Municipal Health Services Demonstration projects through December 31, 2006, for beneficiaries who reside in the city in which the project is operated.

(Sec. 236) Amends SSA title XVIII to provide that protections against balance billing apply to PACE providers and beneficiaries enrolled with such PACE providers in the same manner as such protections apply to any individual enrolled with a Medicare +Choice organization under part C or with an eligible organization.

Provides that MA provisions relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under Medicare shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as provisions apply to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to under such provisions.

Amends SSA title XIX (Medicaid) to provide that, with respect to services covered under the State plan but not under Medicare that are furnished to a PACE program eligible individual enrolled with a PACE provider by a provider participating under the State plan that does not have a contract or other agreement with the PACE provider that establishes payment amounts for such services, such participating provider may not require the PACE provider to pay the participating provider an amount greater than the amount that would otherwise be payable for the service to the participating provider under the State plan.

(Sec. 237) Provides that Federally Qualified Heatlh Centers (FQHCs) will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. Raises reimbursements to FQHCs in order that when they are combined with MA payments and cost-sharing payments from beneficiaries they equal 100 percent of the reasonable costs of providing such services. Extends the safe harbor to include any remuneration between a FQHC (or entity controlled by an FQHC) and an MA organization.

(Sec. 238) Requires the Secretary to enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall conduct an evaluation (for the Secretary and Congress) of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the Medicare program.

Subtitle E: Comparative Cost Adjustment (CCA) Program - (Sec. 241) Directs the Secretary to establish a program for the application of comparative cost adjustment in CCA areas, to begin January 1, 2010, and last six years, and to test whether direct competition between private plans and the original Medicare fee-for-service program will enhance competition in Medicare.

Title III: Combatting Waste, Fraud, and Abuse - (Sec. 301) Amends SSA title XVIII to allow the Secretary to make a conditional Medicare payment if a primary plan has not made or cannot reasonably be expected to make prompt payment. Requires the payment to be contingent on reimbursement by the primary plan to the appropriate Medicare trust fund. Requires a primary plan as well as an entity that receives payment from a primary plan to reimburse the Medicare Trust Funds for any payment made by the Secretary if the primary plan was obligated to make payment. Makes other changes with regard to Medicare as a secondary payer to address the Secretary's authority to recover payment from any and all responsible entities and to bring action, including the collection of double damages, to recover payment under the Medicare secondary payer provisions.

(Sec. 302) Directs the Secretary to establish and implement quality standards for suppliers of items and services of durable medical equipment, prosthetics and orthotics, and certain other items and services. Requires the Secretary to establish standards for clinical conditions for payment for items of durable medical equipment.

Replaces the current demonstration projects for competitive acquisition of items and services with a permanent program requiring the Secretary to establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing of competitively priced described items and services (including durable medical equipment and medical supplies) for which payment is made under Medicare part B. Allows such areas to differ for different items and services.Allows the Secretary to exempt from such programs rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service and items and services for which the application of competitive acquisition is not likely to result in significant savings.Requires payment under Medicare part B for competitively priced items and services to be based on bids submitted and accepted for such items and services, and based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area. Requires Medicare payment to be equal to 80 percent of the payment amount determined, with beneficiaries paying the remaining 20 percent (after meeting the part B deductible).

Directs the Secretary to conduct a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests.

Requires the Comptroller General to conduct a study for a report to Congress on the impact of competitive acquisition of durable medical equipment on suppliers and manufacturers of such equipment and on patients.

Provides that for durable medical equipment, prosthetic devices, prosthetics and orthotics, the update will be 0 points in 2004 through 2008, and that after 2008 for those items not included in competitive bidding the update will be the consumer price index.

Provides that for 2005 the payment amount for certain items, oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses, will be reduced.

Provides that for prosthetic devices and orthotics and prosthetics in 2004, 2005, and 2006, the update will be 0 percentage points and for a subsequent year is equal to the percentage increase in the consumer price index for all urban customers for the 12-month period ending in June of the previous year.

Directs the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under Medicare are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(Sec. 303) Amends SSA title XVIII to: (1) require the Secretary, beginning in 2004, to make adjustments in practice expense relative value units for certain drug administration services when establishing the physician fee schedule; (2) require the Secretary to use the survey data submitted to the Secretary as of January 1, 2003, by a certain physician speciality organization; and (3) require the Secretary, beginning in 2005, to use supplemental survey data to adjust practice expense relative value units for certain drug administration services in the physician fee schedule if that supplemental survey data includes information on the expenses associated with administering drugs and biologicals the administration of drugs and biologicals, the survey meets criteria for acceptance, and the survey is submitted by March 1, 2004, for 2005, or March 1, 2005, for 2006. (States that this latter provision shall apply only to a speciality that receives 40 percent or more of its Medicare payments in 2002 from drugs and biologicals and shall not apply with respect to the survey submitted by a certain physician speciality organization.) Exempts the adjustments in practical expense relative value units for certain drug administration services from the budget neutrality requirements in 2004.

Requires the Secretary to: (1) promptly evaluate existing drug administration codes for physicians' services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption; (2) make adjustments to the nonphysician work pool methodology for the determination of practice expense relative value units under the physician fee schedule so that practice expense relative value units for services determined under such methodology are not affected relative to the practice expense relative value units of services not determined under such methodology; and (3) review and appropriately modify Medicare's payment policy in effect on October 1, 2003, for the administration of more than one drug or biological to an individual on a single day through the push technique. Makes the increase in expenditures resulting from this provision exempt from the budget-neutrality requirement in 2004.

Requires a transitional adjustment or additional payment for services furnished from January 1, 2004, through December 31, 2005, to be made for drug administration services. Requires the part B payment to be made to the physician and equal a percentage of the payment otherwise made.

Directs the MEDPAC to review the payment changes made under this section insofar as they affect payments under Medicare part B for items and services furnished by oncologists and for drug administration services furnished by other specialists. Requires MEDPAC to submit a report to the

Secretary and Congress and for the Secretary to make appropriate payment adjustments on the basis of such report.

Provides that the following drugs and biologicals are to be paid at 95 percent of the average wholesale price (AWP): (1) a drug or biological furnished before January 1, 2004; (2) blood clotting factors furnished during 2004; (3) a drug or biological furnished during 2004 that was not available for part B payment as of April 1, 2003; (3) pneumoccal influenza and hepatitis B vaccines furnished on or after January 1, 2004; and (4) a drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities. Provides in general that payments for other drugs furnished in 2004 will equal 85 percent of the AWP (determined as of April 1, 2003). Provides that, beginning in 2005, drugs or biologicals, except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services, will be paid using either the average sales price methodology or through the competitive acquisition program. Provides that infusion drugs furnished through covered durable medical equipment starting January 1, 2004, will be paid at 95 percent of the AWP in effect on October 1, 2003, and that those infusion drugs which may be furnished in a competitive area starting January 1, 2007, will be paid at the competitive price. Provides that intravenous immune globulin will be paid at 95 percent of the AWP in 2004 and paid according to the average sales price method in 2005.

Authorizes the Secretary to substitute a different percent of the April 1, 2003 AWP, but not less than 80 percent.

Establishes the use of the average sales price methodology for payment for drugs and biologicals (except for pneumococcal, influenza, and hepatitis B vaccines and those associated with certain renal dialysis services) that are furnished on or after January 1, 2005. Creates an exception to this methodology in the case of a physician who elects to participate in the newly established competition acquisition program.

Directs the Inspector General of the Department of Health and Human Services to conduct studies to determine the widely available market prices of drugs and biologicals.

Directs the Secretary to conduct a study for a report to Congress on sales of drugs and biologicals to large volume purchasers for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent investors.

Directs the Inspector General to conduct a study for a report to Congress on adequacy of reimbursement rate under average sales price methodology.

Directs the Secretary to establish and implement a competitive acquisition program to acquire and pay for competitively biddable drugs and biologicals through the establishment of competitive acquisition areas for the award of contracts. Gives each physician the opportunity annually to elect to obtain drugs and biologicals under the program, rather than the program above using average sales methodology. Directs the Secretary to begin to phase-in the program beginning in 2006.

(Sec. 304) Makes the amendments applicable above applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology.

(Sec. 305) Amends SSA title XVIII to provide that in the case of inhalation drugs or biologicals furnished through covered durable medical equipment that are furnished in 2004, the payment amount will be at 85 percent of AWP, and in 2005 and subsequent years, the payment amount will be the amount provided under the average sales price methodology.

Directs the Comptroller General to conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program for a report to Congress.

(Sec. 306) Requires the Secretary to conduct a demonstration project to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recoupoing overpayments under the Medicare program for services for which payment is made under Medicare part A or part B. Requires a report to Congress on the demonstration program.

(Sec. 307) Directs the Secretary to establish a pilot program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees. Makes necessary appropriations.

Title IV: Rural Provisions - Subtitle A: Provisions Relating to Part A Only - (Sec. 401) Amends SSA title XVIII part A to require Medicare, for discharges during a fiscal year beginning with FY 2004, to direct the Secretary to compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year for hospitals located in a large urban area (or, beginning with FY 2005, for all hospitals in the previous year) increased by the applicable percentage increase. Directs the Secretary to compute, for discharges occuring in a fiscal year beginning with 2004, an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed for FY 2003 for hospitals in a large urban area (or, beginning with FY 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase for the year involved.

(Sec. 402) Provides that for discharges after April 1, 2004, a hospital that is not a large urban hospital that qualifies for a disproportionate share (DSH) adjustment will receive its DSH payments using the current DSH adjustment formula for large urban hospitals, subject to a limit. Caps the DSH adjustment formula at 12 percent for any of these hospitals except rural referral centers.

(Sec. 403) Provides that for discharges on or after October 1, 2004, the Secretary is required to decrease the labor-related share to 62 percent of the standardized amount when such change results in higher total payments to the hospital. Provides that for discharges occurring on or after October 1, 2004, the Secretary is also required to decrease the labor-related share to 62 percent of the standardized amount for hospitals in Puerto Rico when such change results in higher total payments to the hospital.

(Sec. 404) Directs the Secretary, after revising the market basket weights to reflect the most current data, to establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every five years. Requires the Secretary to include in the publication of the final rule for payment for inpatient hospital services for FY 2006, an explanation of the reasons for, and options considered, in determining such frequency.

(Sec. 405) Reimburses inpatient, outpatient, and covered skilled nursing facility services provided by a critical access hospital (CAH) at 101 percent of reasonable costs of services furnished to Medicare beneficiaries.

Expands reimbursement of on-call emergency room providers to include physician's assistants, nurse practitioners, and clinical nurse specialists for the costs associated with covered Medicare services provided on or after January 1, 2005.

Allows an eligible CAH to be able to receive payments made on a periodic interim payment (PIP) basis for its inpatient services. Requires the Secretary to develop alternative methods for the timing of PIP payments to the CAHs.

Prohibits the Secretary from requiring that all physicians or practitioners providing services in a CAH assign their billing rights to the entity in order for the CAH to be paid on the basis of 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH. Prohibits a CAH from receiving payment based on 115 percent of the fee schedule for any individual physician or practitioner who did not assign billing rights to the CAH.

Allows a CAH to operate up to 25 beds while deleting the requirement that only 15 of the 25 beds be used for acute care at any time.

Establishes an authorization to award rural hospital flexibility grants at $35 million each year from FY 2005 through FY 2008 and in subsequent years requires a State to consult with the hospital association and rural hospitals in the State on the most appropriate way to use such funds. Prohibits a State from spending more than the lesser of 15 percent of the grant amount for administrative expenses or the State's federally negotiated indirect rate for administering the grant. Provides that in FY 2005 up to five percent of the total amount appropriated for grants will be available to the Health Resources and Services Administration for administering such grants.

Permits a CAH to establish a distinct part psychiatric or rehabilitation unit that meets the applicable requirements that would otherwise apply to the distinct part if the distinct part were established by a "subsection (d) hospital." Limits the total number of beds that may be established for a distinct part unit to no more than ten. Provides that if a distinct part unit does not meet the applicable requirements during a cost reporting period then no Medicare payment will be made to the CAH for services furnished in such unit during such period. Requires Medicare payments to resume only after the CAH demonstrates that the requirements have been met. Requires Medicare payments for services provided in the distinct part units to equal the amount of the payments that would otherwise be made on a prospective payment basis to distinct part units of a CAH.

Allows certain milage standards to be waived in the case of a facility that was designated as a CAH before January 1, 2006 and was certified by the State as being a necessary provider of health care services.

(Sec. 406) Requires the Secretary to provide for an additional payment amount to each low-volume hospital for discharges occurring during a fiscal year beginning with FY 2005.

(Sec. 407) Provides that in no case will a hospital be denied treatment as a sole community hospital or payment because data are unavailable for any cost reporting period due to changes in ownership,

changes in fiscal intermediaries, or other extraordinary circumstances so long as data from at least one applicable base cost reporting period is available.

(Sec. 408) Expands the definition of attending physician in hospice to include a nurse practitioner.

(Sec. 409) Directs the Secretary to conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Provides that under the project Medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs.

(Sec. 410) Excludes certain rural health clinic and Federally-qualified health center services from the prospective payment system for skilled nursing facilities.

(Sec. 410A) Directs the Secretary to establish a demonstration program to test the feasibility and advisability of the establishment of rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries.

Subtitle B: Provisions Relating to Part B Only - (Sec. 411) Extends until January 1, 2006 the hold harmless provisions governing hospital outpatient department (OPD) reimbursement for small rural hospitals and sole community hospitals.

Requires the Secretary to conduct a study to determine if the costs incurred by hospitals located in rural areas by ambulatory payment classification groups exceed those costs incurred by hospitals located in urban areas. Provides that if appropriate the Secretary is required to provide for a payment adjustment to reflect the higher costs of rural providers by January 1, 2006.

(Sec. 412) Directs the Secretary to increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00 for services furnished on or after January 1, 2004, and before January 1, 2007.

(Sec. 413) Establishes a new five percent incentive payment program designed to reward both primary care and specialist care physicians for furnishing physicians' services on or after January 1, 2005, and before January 1, 2008 in physician scarity areas.

Directs the Secretary to pay the current law ten percent Health Professional Shortage Area (HPSA) incentive payment for services furnished in full county primary care geographic area HPSAs automatically rather than having the physician identify the health professional shortage area involved.

Directs the Comptroller General to conduct a study for a report to Congress on the differences in payment amounts under the Medicare physician fee schedule for physicians' services in different geographic areas.

(Sec. 414) Revises payment for ambulance services to provide for, when phasing in the application of the payment rates under the fee schedule, for each level of ground service furnished in a year, for the portion of the payment amount that is based on the fee schedule to be the greater of the amount determined under such national fee schedule or a blended rate of the national fee schedule and the regional fee schedule for the region involved, whichever resulted in a larger payment, with the blended rate to be based 100 percent on the national fee schedule.

Requires the Secretary to establish a regional fee schedule for each of the nine census divisions. Provides for adjustment in payment for certain long trips. Directs the Secretary to provide for a percentage increase in the base rate of the fee schedule for ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010 that originate in a qualified rural area. Increases by two percent the payments for ground ambulance services orginating in a rural area or a rural census tract for services furnished on or after July 1, 2004, and before January 1, 2007. Provides that the fee schedule for ambulances in other areas will by increased by one percent. Provides that these increased payments will not affect Medicare payments for covered ambulance services after 2007.

Requires the Comptroller General to submit to Congress a report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the Medicare ambulance fee schedule.

(Sec. 415) Provides that the regulations governing the use of ambulance services will provide that, to the extent that any ambulance service (whether ground or air) may be covered, that a rural air ambulance service will be reimbursed at the air ambulance rate if: (1) the air ambulance service is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and (2) the air ambulance service complies with the equipment and crew requirements established by the Secretary.

(Sec. 416) Provides that hospitals with fewer than 50 beds in qualified rural areas will receive 100 percent reasonable cost reimbursement for clinical diagnostic laboratory tests covered under Medicare part B that are provided as outpatient hospital services during a cost reporting period beginning during the two year period beginning on July 1, 2004.

(Sec. 417) Amends the Balanced Budget Act of 1997 to extend the telemedicine demonstration project by 4 years and to increase total funding for the project.

(Sec. 418) Directs the Secretary to evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities are treated as originating sites for telehealth services for a report to Congress.

Subtitle C: Provisions Relating to Parts A and B - (Sec. 421) Provides that with respect to episodes and visits on or after April 1, 2004, and before April 1, 2005, in the case of home health services furnished in a rural area, the Secretary is required to increase the payment amount otherwise made for such services by five percent. Prevents such temporary additional payment increase from being used in calculating future home health payment amounts.

(Sec. 422) Provides that a teaching hospital's total number of Medicare-reimbursed resident positions will be reduced for cost reporting periods starting July 1, 2005, if its reference resident level is less than its applicable resident limit. Exempts rural rural hospitals with fewer than 250 acute care inpatient beds from such reduction. Provides that for such other hospitals the reduction will equal 75 percent of the difference between the hospital's limit and its reference resident level. Authorizes the Secretary to increase the applicable resident limit for each qualifying applicant hospital by such numbers as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005.

Subtitle D: Other Provisions - (Sec. 431) Amends SSA title XI to provide that any remuneration in the form of a contract, lease, grant, loan, or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to health center would not be a violation of the anti-kickback statue if such agreement contributes to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population.

(Sec. 432) Amends SSA title VII to expand the functions of the Office of Rural Health Policy to include administering grants, cooperative agreements, and contracts to provide technical assistance and other necessary activities to support activities related to improving health care in rural areas.

(Sec. 433) Directs MEDPAC to conduct a study of specified rural provisions of this title for various reports to Congress.

(Sec. 434) Directs the Secretary to waive such provisions of the Medicare program as are necessary to conduct a demonstration project under which frontier extended stay clinics in isolated rural areas are treated as providers of items and services under the Medicare program. Authorizes appropriations.

Title V: Provisions Relating to Part A - Subtitle A: Inpatient Hospital Services - (Sec. 501) Amends SSA title XVIII with respect to hospital payment updates to provide that: (1) an acute hospital will receive an update of the market basket from FY 2005 through FY 2007 if it submits data on the ten quality indicators established by the Secretary as of November 1, 2003; and (2) an acute hospital that does not submit data to the Secretary will receive an update of the market basket percentage minus 0.4 percentage points for the fiscal year in question and that the Secretary will not take this reduction into account when computing the applicable percentage increase in subsequent years.

Directs the Comptroller General to conduct a study to determine: (1) the appropriate level and distribution of Medicare payments in relation to costs for short-term general hospitals under the inpatient prospective payment system; and (2) the need for geographic adjustments to reflect legitmate differences in hospital costs across different geographic areas, kinds of hospitals, and types of cases.

(Sec. 502) Expands the formula for determining the indirect medical education adjustment percentage to cover the period from April 1, 2004 to on and after October 1, 2007.

(Sec. 503) Requires the Secretary to add new diagnosis and procedure codes in April 1 of each year without requiring the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date.

Requires the Secretary when establishing whether diagnosis related group (DRG) payment is adequate to apply a threshold that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between costs and charges) or 75 percent of one standard deviation for the diagnosis-related group involved. Requires the mechanism established to recognize the costs of new medical services and technologies under the appropriate Medicare payment system to be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under Medicare part A (Hospital Insurance).

Directs the Secretary, before establishing any add-on payment with respect to a new technology, to seek to identify one or more diagnosis-related groups associated with such technology and, within such groups, the Secretary is required to assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. Prohibits the making of an add-on payment in such case. Provides that funding for new technology will no longer be budget neutral.

(Sec. 504) Provides that hospitals in Puerto Rico will receive Medicare payments based on a 50-50 split between Federal and local amounts before April 1, 2004. Provides that starting April 1, 2004 through September 30, 2004, payment will be based on a 62.5 percent Federal amount and a 37.5 percent local amount, and that starting October 1, 2004, payment will be based on a 75 percent Federal amount and a 25 percent local amount.

(Sec. 505) Directs the Secretary to establish a process and payment adjustment to recognize commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.

(Sec. 506) Requires that hospitals that participate in Medicare and that provide Medicare covered inpatient hospital services under the contract health services program funded by the Indian Health Service and operated by the Indian Health Service, an Indian tribe, an Indian tribal organization, or an urban Indian organization be paid in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodologies, and rates of payment. Requires that these rates of payment must be accepted as payment in full for the items and services provided.

(Sec. 507) Modifies the "whole hospital" exception to the prohibition against physicians referring Medicare patients to entities in which they or their immediate family members have financial interests to provide for a period of 18 months from the date of enactment of this Act during which there is excluded from such exception (and thereby subjected to the prohibition) those circumstances in which a physician's ownership interest is in a "subsection d hospital"devoted primarily or exclusively to cardiac, orthopedic, surgical, or other specialties designated by the Secretary. Exempts from such provision speciality hospitals in operation or under development as of November 18, 2003.

Requires that, in order to maintain the exception, the speciality hospital may not increase the number of physician investors as of November 18, 2003; change or expand the field of specialization it treats; expand beyond the main campus; or increase the total number of beds in its facilities by more than the greater of five beds or 50 percent of the number of beds in the hospital as of November 18, 2003.

Makes a similar modification with respect to the rural provider exception.

Directs the Secretary in determining whether a hospital is under development as of November 18, 2003 to consider whether architectural plans have been completed, funding has been received, zoning requirements have been met, and necessary approvals from appropriate State agencies have been received, and other evidence the Secretary determines would indicate whether a hospital is under development as of such date.

Directs MEDPAC to conduct a study to determine: (1) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within specific diagnosis-related groups; (2) the

extent to which speciality hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection; (3) the financial impact of physician-owned specialty hospitals on local full-service community hospitals; (4) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and (5) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

Directs the Secretary to conduct a study of a representative sample of specialty hospitals to: (1) determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest; (2) determine the referral patterns of physician owners; (3) compare the qualty of care furnished in physician-owned speciality hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and (5) assess the differences in uncompensated care between the specialty hospital and local full-service community hospitals, and the value of any tax exemption availabble to such hospitals.

(Sec. 508) Directs the Secretary to establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State to which to be reclassified. Provides that a qualifying hospital (which must be a "subsection (d) hospital" is not eligible for a change in wage index classification on the basis of distance or commuting. Requires the qualifying hospital to meet such other criteria, such as quality, as the Secretary may specify by instruction or otherwise. Provides that if the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital, the hospital shall be reclassified to the area selected. Requires such reclassification to apply with respect to discharges occurring during the three year period beginning with April 2, 2004. Limits the total aggregate amount of additional expenditures resulting from application of this paragraph to $900 million.

Subtitle B: Other Provisions - (Sec. 511) Increases the per diem RUG payment for a skilled nursing facility (SNF) resident with acquired immune deficiency syndrome (AIDS). Provides that such payment increase will not apply on and after such date when the Secretary certifies that the SNF case mix adjustment adequately compensates for the facility's increased costs associated with caring for a resident with AIDS.

(Sec. 512) Provides coverage of certain physician's services for certain terminally ill individuals who have not elected the hospice benefit and have not previously received these physician's services.

(Sec. 513) Directs the Comptroller General to conduct a study of portable diagnostic ultrasound services furnished to Medicare beneficiaries in SNFs for a report to Congress.

Title VI: Provisions Relating to Part B - Subtitle A: Provisions Relating to Physicians' Services - Amends SSA title XVIII with respect to payment for physicians' services to: (1) provide that the update to the conversion factor for 2004 and 2005 will not be less than 1.5 percent; (2) modify the formula for calculating the sustainable growth rate to provide that the gross domestic product factor will be based on the annual average change over the preceding 10 years (a 10-year rolling average); (3) provide that in calendar years 2004 and 2005, for physicians's services provided in Alaska, the Secretary is required to increase geographic practice cost indices to a level of 1.67 for each of the work, practice expense, and malpractice cost indices that would otherwise be less than 1.67; and (4)

allow podiatrists, dentists, and optometrists to enter into private contracts with Medicare beneficiaries.

(Sec. 604) Directs the Comptroller General to conduct a study for a report to Congress on access of Medicare beneficiaries to physicians's services under the Medicare program.

(Sec. 605) Requires the Secretary to review and consider alternative data sources than those currently used to establsih the geographic index for the practice expense component under the Medicare physician fee schedule no later than January 1, 2005. Requires the Secretary to select two physician payment localties for such purposes, one to be a rural area and the other one will be a statewide locality that includes both urban and rural areas.

(Sec. 606) Directs MEDPAC to submit to Congress: (1) a report on the effect of refinements to the practice expense component of payments for physicians' services after the transition to a full resource-based payment system in 2002; and (2) a report on the extent to which increases in the volume of physicians' services under Medicare part B are a result of care that improves the health and well-being of Medicare beneficiaries.

Subtitle B: Preventive Services - (Sec. 611) Authorizes Medicare coverage of: (1) an initial preventive physical examination; (2) cardiovascular screening blood tests; and (3) diabetes screening tests.

(Sec. 614) Excludes screening mammography and diagnostic mammography from the outpatient prospective payment system (OPPS).

Subtitle C: Other Provisions - (Sec. 621) Provides that for specified covered OPD drugs and biologicals starting in 2004 payment would be made based on a percentage of the reference AWP for the drug or biological.

Directs the Comptroller General to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition costs for each specified covered outpatient drug. Requires the amount of payment for an orphan drug designated by the Secretary that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 to equal such amount as the Secretary may specify. Requires the Comptroller General not later than April 1, 2005 to furnish data from such surveys to the Secretary for use in setting payment rates for 2006.

Requires the Comptroller General, no later than 30 days after the date the Secretary promulgates the proposed rules setting forth the payment rates for 2006, to evaluate such rates and submit a report to Congress on their appropriateness.

Directs MEDPAC to submit to the Secretary a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Authorizes the Secretary to adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account appropriate recommendations to such effect in the report.

Provides that the additional expenditures that result from the previous changes will not be taken into account in establishing the conversion, weighting and other adjustment factors for 2004 and 2005, but will be taken into account for subsequent years.

Provides that with respect to payment under Medicare part B for an outpatient drug or biological covered under such part that is furnished as part of covered OPD services for which an HCPCS code has not been assigned, the amount provided for payment for such drug or biological under such part shall be equal to 95 percent of the AWP for the drug or biological.

Provides that for drugs and biologicals furnished in 2005 and 2006, the Secretary is required to reduce the threshold for establishing a separate ambulatory payment classification (APC) group for drugs or biologicals from $150 to $50 per admission. Makes these separate drug and biological APC groups ineligible for outlier payments. Provides that starting in 2004, Medicare transitional pass-through payments for drugs and biologicals covered under a competitive acquisition contract will equal the average price for the drug or biological for all competitive acquisition areas calculated and adjusted by the Secretary for that year.

Requires the Secretary to make payment for each brachytherapy device furnished under the hospital outpatient prospective payment system equal to the hospital's charges for each device furnished, adjusted to costs for all brachytherapy devices furnished on or after January 1, 2004, and before January 1, 2007. Provides that charges for such devices will not be included in determining any outlier payment.

Directs the Secretary to create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under the hospital outpatient prospective payment system in a manner reflecting the number, the radioactive isotope, and the radioactive intensity of the brachytherapy devices furnished to each patient, including the use of separate APCs for brachytherapy devices made from palladium-103 and iodine-125 devices.

Requires the Comptroller General to conduct a study for a report to Congress and the Secretary on the appropriate payment amounts needed for devices of brachytherapy. Requires the report to include specific recommendations for appropriate payments for such devices.

(Sec. 622) Prohibits the Secretary from publishing regulations that apply a functional equivalence standard to a drug or biological. Applies this prohibition to the application of a functional equivalence standard on or after the date of enactment of this Act, unless such application was made prior to enactment and the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for transitional pass-through payments.

(Sec. 623) Increases the composite rate for renal dialysis by 1.6 percent for 2005.

Provides that provisions prohibiting the Secretary from providing for an exception under provisions for Medicare coverage for end stage renal disease patients that require the Secretary to provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home, and that provisions setting a deadline of July 1, 2001, for new applications for an exception rate in the case of a facility that during 2000 did not file for an exception rate under such former provisions, shall not apply as of October 1, 2002, to pediatric facilities that do not have an exception rate in effect on such date. Requires that for purposes of this paragraph the term pediatric facility means a renal facility at least 50 percent of whose patients are individuals under 18 years of age.

Directs the Inspector General of HHS to conduct two studies for reports to the Secretary with respect to drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the Medicare program which are separately billed by end stage reneal disease facilities.

Requires the Secretary to establish a basic case-mix adjusted prospective payment system for dialysis services. Requires the basic case-mix adjusted system to begin for services furnished on January 1, 2005. Requires the system to adjust for a limited number of patient characteristics.

Provides that payments for separately billed drugs and biologicals (other than erythropoietin) will be 95 percent of the AWP for 2004, the acquisition costs in 2005 (including for 2005), and, beginning in 2006, for such drugs and biologicals (including erythropoietin), such acquisition cost or the average sales price payment methodology for the drug or biological as the Secretary may specify.

Requires drugs and biologicals (including erythropoietin) which were separately billed on the day before the enactment of this Act to continue to be separately billed on and after such date.

Directs the Secretary to establish a demonstration project for the use of a fully case-mix adjusted, bundled payment system for end stage renal disease services, beginning January 1, 2006. Authorizes appropriations.

Requires the Secretary to submit a report to Congress detailing the elements and features for the design and implementation of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundling of drugs, clinical laboratory tests, and other items that are separately billed by such facilities.

(Sec. 624) Provides for an additional two-year moratorium on therapy caps for 2004 and 2005.

Requires the Secretary to submit by March 31, 2004 overdue reports on payment and utilization of outpatient therapy services that are required by the Balanced Budget Act of 1997 and the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BIPA).

Requires the Comptroller General to identify for a report to Congress conditions or diseases that may justify waiving the application of the therapy caps with respect to such conditions or diseases.

(Sec. 625) Waives the late enrollment penalty for military retirees who did not enroll in Medicare part B upon becoming eligible for Medicare. Provides that the waiver applies to the late enrollment penalty for military retirees, 65 and over, who enrolled in the TRICARE for Life program from 2001 to 2004. Requires this waiver to apply to premiums for months beginning with January 2004. Directs the Secretary to establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such waiver provision but for which a penalty was previously collected.

Directs the Secretary to provide for a special Medicare part B enrollment period for these military retirees beginning as soon as possible after enactment of this Act and ending December 31, 2004.

(Sec. 626) Provides that in FY 2004, starting April 1, 2004, the ambulatory surgery center (ASC) update will be the Consumer Price Index for all urban consumers (U.S. city average) as estimated as of March 31, 2003, minus 3.0 percentage points. Provides that in FY 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the ASC update will be zero percent.

Provides that upon implementation of the new ASC payment system, the Secretary will no longer be required to update ASC rates based on a survey of the actual audited costs incurred by a representative sample of ASCs every five years.

Provides that subject to recommendations by the General Accounting Office, the Secretary will implement a revised payment system for payment of surgical services furnished in ASCs. Requires the new system to be implemented so that it is first effective on or after January 1, 2006, and not later than January 1, 2008.

Requires the Comptroller General to conduct a study for a report to Congress that compares the relative costs of procedures furnished in ambulatory surgical centers to the relative costs of procedures furnished in hospital outpatient departments.

(Sec. 627) Limits payment for custom molded shoes with inserts or extra-depth shoes with inserts for an individual with severe diabetic foot disease by the amount that would be paid if they were considered to be a prosthetic or orthotic device. Allows the Secretary to establish lower payment limits than these amounts if shoes and inserts of an appropriate quality are readily available at lower amounts. Requires the Secretary to establish a payment amount for an individual substituting modifications to the covered shoe that would assure that there is no net increase in Medicare expenditures.

(Sec. 628) Provides that there will be no updates to the clinical diagnostic laboratory test fee schedule for 2004 through 2008.

(Sec. 629) Keeps the Medicare part B deductible at $100 through 2004, increasing it to $110 for 2005, and providing that in subsequent years the deductible will be increased by the same percentage as the Medicare part B premium increase.

(Sec. 630) Requires the Secretary to make payment under Medicare part B to a hospital or an ambulatory care clinic (whether provider-based or free standing) that is operated by the Indian Health Service or by an Indian tribe or tribal organization for all Medicare part B covered items and services furnished during the five year period beginning on January 1, 2005.

Subtitle D: Additional Demonstrations, Studies, and Other Provisions - (Sec. 641) Requires the Secretary to conduct a demonstration project under Medicare part B under which payment is made for drugs or biologicals that are prescribed as replacements for existing covered drugs and biologicals that are furnished incident to a physician's professional service which are not usually self-administered. Requires the project to provide for cost-sharing applicable with respect to such drugs or biologicals in the same manner as the cost-sharing applicable under part D for standard prescription drug coverage.

(Sec. 642) Includes intravenous immune globulin for the treatment in the home of primary immune deficiency diseases as a covered medical service under Medicare.

(Sec. 643) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of providing for payment under Medicare part B for surgical first assisting services furnished by a certified registered nurse first assistant to Medicare beneficiaries.

(Sec. 644) Requires MEDPAC to conduct a study for a report to Congress on the practice expense relative values established by the Secretary under the Medicare physician fee schedule for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

(Sec. 645) Directs the Secretary to conduct a study for a report to Congress on the feasibility and advisability of providing for payment for vision rehabiliation services furnished by vision rehabilitation professionals.

Requires the Secretary to submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries.

(Sec. 646) Amends SSA title XVIII to direct the Secretary to establish a 5-year demonstration program under which the Secretary is required to approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care.

(Sec. 647) Directs MEDPAC to conduct a study for a report to Congress on the feasibility and advisability of allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as a comprehensive rehabilitation facility service.

(Sec. 648) Directs the Secretary to establish demonstration projects under which the Secretary is required to evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the Medicare program on behalf of such individuals for such chronic conditions. Requires the Secretary to conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under Medicare part A, and enrolled under Medicare part B, with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

(Sec. 649) Directs the Secretary to establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures

(Sec. 650) Requires the Comptroller General to conduct a study for a report to the Congress on concierge care to determine the extent to which such care is used by Medicare beneficiaries and has impacted upon the access of Medicare beneficiaries to items and services for which reimbursement is provided under the Medicare program.

(Sec. 651) Directs the Secretary to establish demonstration projects for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the Medicare program. Requires the Secretary to conduct an evaluation of the demonstration projects for a report to Congress along with such recommendations for legislation or administrative action as the Secretary determines appropriate.

Title VII: Provisions Relating to Parts A and B - Subtitle A: Home Health Services - (Sec. 701) Amends SSA title XVIII to change the time frame for the home health update from the Federal fiscal year to a calendar year basis beginning with 2004.

Increases home health agency payments by the full market basket percentage for the last quarter of 2003 (October, November, and September) and for the first quarter of 2004 (January, February, and March). Provides that the update for the remainder of 2004 and for 2005 and 2006 is the home health market basket percentage increase minus 0.8 percentage points.

(Sec. 702) Directs the Secretary to conduct a two-year demonstration project under Medicare part B under which Medicare beneficiaries with chronic conditions are deemed to be homebound for purposes of receiving home health services under the Medicare program. Authorizes appropriations.

(Sec. 703) Requires the Secretary to establish a demonstration project under which the Secretary is required, as part of a plan of an episode of care for home health services established for a Medicare beneficiary, to permit a home health agency, directly or under arrangements with a medical adult day-care facility, to provide medical adult day-care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(Sec. 704) Prohibits the Secretary during a described period of suspension from requiring a home health agency to gather or submit OASIS (Outcomes and Assessment Information Set) information that relates to an individual who is not eligible for benefits under either Medicare or Medicaid (non-Medicare/Medicaid OASIS information).

Requires the Secretary to conduct a study for a report to Congress on how non-Medicare/Medicaid OASIS information is and can be used by large home health agencies.

(Sec. 705) Directs MEDPAC to conduct a study for a report to Congress on payment margins of home health agencies under the home health prospective payment system.

(Sec. 706) Allows a religious nonmedical health care institution to provide home health services to individuals meeting conditions for coverage of religious nonmedical health care institutional services.

Subtitle B: Graduate Medical Education - (Sec. 711) Provides that hospitals with per resident amounts above 140 percent of the geographically adjusted national average amount would not get an update from FY 2004 through FY 2013.

(Sec. 712) Provides that Congress intended to provide an exception to the initial residency period for geriatric residency or fellowship programs to accomodate programs that require two years of training to initially become board eligible in the geriatric speciality.

(Sec. 713) Provides that for one year from January 1, 2004, for purposes of applying provisions for the payment of indirect medical education and direct medical education costs, the Secretary is required to allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

Requires the Inspector General of the Department of Health and Human Services to conduct a study for a report to Congress on the appropriateness of alternative payment methodologies for the costs of training residents in non-hospital settings.

Subtitle C: Chronic Care Improvement - (Sec. 721) Amends SSA title XVIII to require the Secretary to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Requires the programs to be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under Medicare for targeted beneficiaries with one or more threshold conditions. Makes necessary appropriations.

(Sec. 722) Requires each MA organization to have an ongoing quality improvement program for improving the quality of care provided to enrollees in each MA plan offered by such organization (other than an MA private fee-for-service plan or an MSA plan) effective for contract years beginning January 1, 2006. Requires as part of the quality improvement program for each MA organization to have a chronic care improvement program.

(Sec. 723) Directs the Secretary to develop a plan to improve quality of care and to reduce the cost of care for chronically ill Medicare beneficiaries. Authorizes appropriations.

Subtitle D: Other Provisions - (Sec. 731) Requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. Allows for public comment in national coverage determinations. Directs the Secretary to develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be acheived among local coverage determinations. Prohibits the Secretary in the case of an individual entitled to benefits under Medicare part A, or enrolled under part B, or both who participates in a category A clinical trial, from excluding payment for coverage of routine costs of care furnished to such individual in the trial.

Directs the Secretary to implement revised procedures for the issuance of temporary national HCPCS codes under Medicare part B.

(Sec. 732) Amends BIPA to provide that direct payment for the technical component of pathology services provided to Medicare beneficiaries who are inpatients or outpatients of acute care hospitals will be made for services furnished during 2005 and 2006.

(Sec. 733) Directs the Secretary, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, to conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries. Authorizes appropriations. Requires the Secretary to pay for the routine costs as well as transplantation and appropriate related items and services in the case of Medicare beneficiaries who are participating in such a clinical trial as if such transplantation were covered under Medicare.

(Sec. 734) Directs the Secretary to transfer to the Hospital Insurance Trust Fund an amount that would have been held by that fund if the clerical error had not occurred. Appropriates to the Trust Fund an amount determined by the Secretary of the Treasury to be equal to the interest income lost

by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

(Sec. 735) Requires MEDPAC to examine the budgetary consequences of a recommendation before making the recommendation and to review the factors affecting the efficient provision of expenditures for services in different health care sectors under Medicare fee-for-service.

Requires the Commission to conduct a study for a report to Congress on the need for current data and sources of current data available to determine the solvency and financial circumstances of hospitals and other Medicare providers of services. Requires the Commission to submit to Congress a report on investments and capital financing of hospitals participating under Medicare and access to capital financing for private and not-for-profit hospitals.

Requires the Comptroller General to appoint experts in the area of pharmaco-economics or prescription drug benefit programs to the Commission.

(Sec. 736) Makes technical corrections.

Title VIII: Cost Containment - Subtitle A: Cost Containment - Requires the Medicare Board of Trustees annual report to include information on: (1) projections of growth of general revenue Medicare spending as a percentage of the total Medicare outlays for the fiscal year and each of the succeeding six fiscal years, previous fiscal years, and 10, 50, and 75 years after such fiscal year; (2) comparisons with the growth trends for the gross domestic product, private health costs, national health expenditures, and other appropriate measures; (3) expenditures and trends in expenditures under Medicare part D; and (4) a financial analysis of the combined Medicare trust funds if general revenue funding for Medicare is limited to 45 percent of total Medicare outlays. Requires the trust fund reports to include a determination as to whether there is projected to be excess general revenue Medicare funding for any of the succeeding six fiscal years. Provides that an affirmative determination of excess general revenue funding of Medicare for two consecutive annual reports will be treated as a funding warning for Medicare in the second year for the purposes of requiring presidential submission of legislation to Congress.

(Sec. 802) Amends Federal money and finance law to provide in the event that a Medicare funding warning is made, the President is required to submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress for the succeeding year, proposed legislation to respond to such warning. Provides that if during the year in which the warning is made, legislation is enacted which eliminates excess general revenue Medicare funding for the 7-fiscal-year period, then the President is not required to make a legislative proposal.

Expresses the sense of Congress that legislation submitted in this regard should be designed to eliminate excess general revenue Medicare funding for the seven-fiscal year period that begins in such year.

(Sec. 803) Sets out the procedures for House and Senate consideration of the President's legislative proposal.

Subtitle B: Income-Related Reduction in Part B Premium Subsidy - (Sec. 811) Provides that beginning in 2007, beneficiaries with incomes over $80,000 for an individual or $160,000 for a married couple will be asked to contribute more to the cost of their Medicare benefits through

payment of a higher premium since the monthly amount of the premium subsidy applicable to the premium shall be reduced by a monthly adjustment amount that is based on the product of the sliding scale percentage and the unsubsidized part B premium amount and is phased-in beginning in 2007 through 2010.

Amends the Internal Revenue Code to direct the Secretary of the Treasury, upon written request from the Commissioner of Social Security, to make appropriate disclosure of tax return information to carry out the Medicare part B premium subsidy adjustment.

Title IX: Administrative Improvements, Regulatory Reduction, and Contracting Reform - (Sec. 900) Amends SSA title XVIII (Medicare) to establish within the Centers for Medicare & Medicaid Services (CMS) a center to administer Medicare parts C and D, provide notice of Medicare benefits and related information to beneficiaries, and perform such other duties as the Secretary may specify.

Amends SSA title XI to require that an actuary within the office of Chief Actuary of CMS have duties exclusively related to parts C and D of Medicare and related provisions.

Amends Federal civil service law to increase the pay grade for the Administrator of CMS to Executive Level III, beginning January 1, 2004.

Changes references from the Health Care Financing Administration to the Centers for Medicare and Medicaid Services.

Subtitle A: Regulatory Reform - (Sec. 901) Provides that the term "supplier" means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.

(Sec. 902) Requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. Prohibits the timeframe established from being no longer than three years except under exceptional circumstances. Provides that if the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(Sec. 903) Bars retroactive application of any substantive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines unless the Secretary determines such retroactive application is needed to comply with statutory requirements or is in the public interest. Provides that no substantive change may go into effect until 30 days after the change is issued or published unless it is needed to comply with statutory requirements or is in the public interest. Prohibits compliance action from being taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

Provides that if a provider or supplier follows written guidance provided by the Secretary or by a Medicare contractor when furnishing items or services or submitting a claim and the guidance is

inaccurate, the provider or supplier is not subject to any penalty or interest (including interest on a repayment plan).

(Sec. 904) Requires the Comptroller General to conduct a study for a report to Congress to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the Medicare program.

Requires the Secretary to periodically submit to Congress a report on the administration of Medicare and areas of inconsistency or conflict among various provisions under law and regulation.

Subtitle B: Contracting Reform - (Sec. 911) Amends SSA title XVIII to permit the Secretary to contract competitively with any eligible entity to serve as a Medicare contractor. Eliminates the distinction between Medicare part A contractors (fiscal intermediaries) and Medicare part B contractors (carriers), and merges separate authorities for fiscal intermediaries and carriers into a single authority for the new contractor. Authorizes these new contractors, called Medicare Administrative Contractors, to assume all the functions of the current fiscal intermediaries and carriers: determining payments; making payments; providing education and outreach to beneficiaries; communicating with providers and suppliers; and additional functions as are necessary.

(Sec. 912) Requires Medicare administrative contractors to implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under Medicare. Requires Medicare administrative contractors to undergo an annual independent evaluation of their information security programs.

Subtitle C: Education and Outreach - (Sec. 921) Amends SSA title XVIII to require the Secretary to: (1) coordinate the educational activities provided through Medicare administrative contractors to maximize the effectiveness of Federal education efforts for providers and suppliers; and (2) use specific claims payment error rates or similar methodology of Medicare administrative contractors in the processing or reviewing of Medicare develop and implement a methodology to measure the specific payment error rates in the processing or reviewing of Medicare claims to give such contractors an incentive to implement effective education and outreach programs for providers and suppliers.

Directs the Secretary to develop a strategy for communications with individuals entitled to benefits under Medicare part A or enrolled under Medicare part B, or both, and with providers of services and suppliers under Medicare. Requires Medicare administrative contractors, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under Medicare within 45 business days.

Directs the Secretary to ensure that Medicare administrative contractors provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals,

providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under Medicare. Requires monitoring of contractor responses. Authorizes appropriations.

Authorizes appropriations to the Secretary for enhanced provider and supplier training which are to be tailored for small providers or suppliers.

Requires the Secretary, and each Medicare contractor insofar as it provides services (including claims processing) for providers of services or suppppliers, to maintain an Internet website which provides answers in an easily accessible format to frequently asked questions, and includes other published materials of the contractractor, that relate to providers of services and suppliers under Medicare.

Prohibits a Medicare contractor from using a record of attendance at (or failutre to attend) educational activities or other information gathered during an educational program to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(Sec. 922) Directs the Secretary to establish a demonstration program under which described technical assistance is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under Medicare. Authorizes appropriations.

(Sec. 923) Requires the Secretary to appoint within HHS a Medicare Beneficiary Ombudsman to receive complaints and provide assistance with respect to such complaints and who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under Medicare. Authorizes appropriations.

Directs the Secretary to provide through the toll free telephone number 1-800-MEDICARE for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free numbers are transferred (without charge) to appropriate entities for the provision of such information or assistance.

Requires the Comptoller General to conduct a study for a report to Congress to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free telephone number.

(Sec. 924) Requires the Secretary to establish a demonstration program under which the Medicare specialists employed by HHS provide advice and assistance to individuals entitled to benefits under Medicare part A, or enrolled under part B, or both, regarding the Medicare program at the location of existing local offices of the Social Security Administration.

(Sec. 925) Directs the Secretary to provide information about the number of days of coverage remaining under the skilled nursing facility (SNF) benefit and the spell of illness involved in the explanation of Medicare benefits.

(Sec. 926) Requires the Secretary to publicly provide information that enables hospital discharge planners, Medicare beneficiaries, and the public to identify skilled nursing facilities (SNFs) that are participating in the Medicare program. Requires hospital discharge planning to evaluate a patient's need for SNF care.

Subtitle D: Appeals and Recovery - (Sec. 931) Directs the Commissioner of Social Security and the Secretary to develop and transmit to Congress and the Comptroller General a transition plan under which the functions of administrative law judges responsbile for hearing cases under the Medicare program are transferred from the responsibility of the Commissioner and Social Security Administration to the Secretary and HHS.

Directs the Commissioner and the Secretary to implement the transition plan and transfer the administrative law judge functions from the Social Security Administration to the Secretary. Requires the Secretary to: (1) assure the independence of administrative law judges performing the administrative law judge functions transferred from the Centers for Medicare & Medicaid Services and its contractors; and (2) provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred throughout the United States to ensure timely access to such judges.

Authorizes additional appropriations to increase the number of administrative law judges, improve education and training opportunities for administrative law judges, and increase the staff of the Departmental Appeals Board.

(Sec. 932) Directs the Secretary to establish a process where a provider, supplier, or a beneficiary who has filed an appeal may obtain access to judicial review when a review entity determines, within 60 days of a complete written request, that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and there is no material issue of fact in dispute. Provides that the determination by such review entity shall be considered a final decision and not be subject to review by the Secretary.

Permits expedited access to judicial review for cases where the Secretary does not enter into or renew provider agreements.

Requires the Secretary to develop and implement a process to expedite appeals of provider terminations and certain other remedies imposed on SNFs, including denial of payment for new admissions and temporary management, if imposed on an immediate basis. Allows an expedited appeal where a finding of substandard quality of care has resulted in the disapproval of a skilled nursing facility's nurse aide training program. Requires the Secretary to give priority to cases where termination has been imposed on a provider.

Allows the Secretary to waive disapproval of a nurse aide training program, upon application by a nursing facility if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility.

Provides that in addition to any amounts otherwise appropriated, such additional sums are authorized to be appropriated for FY 2004 and each subsequent fiscal year as may be necessary to reduce by 50 percent the average time for administrative determinations on appeals.

(Sec. 933) Revises the Medicare appeals process to: (1) require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QTC) unless good cause precluded the introduction of the evidence; (2) provide for the use of beneficiaries' medical records in QIC reconsiderations; (3) require that notice of decisions or determinations, redeterminations, reconsiderations, and appeals be written in a manner calculated to

be understood by a beneficiary and include reasons for the decision or determination or redetermination and the process for further appeal; (4) specify the eligibility requirements for QICs and their reviewer employees that relate to medical and legal expertise, independence, and prohibitions linked to decisions being rendered; and (5) reduce the required number of QICs from 12 to four.

(Sec. 934) Permits Medicare contractors to conduct random prepayment reviews only to develop a contractor-wide or program-wide claims payment error rate or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers. Establishes limitations on initiation of non-random prepayment review.

(Sec. 935) Provides that in situations where repaying a Medicare overpayment within 30 days creates a hardship for a provider or supplier, the Secretary is required, upon the request of the provider or supplier, to enter into an extended repayment plan of at least six months duration, but not longer than three years (or five years in the case of extreme hardship, as determined by the Secretary). Provides that if the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier.

Provides that if a provider or supplier fails to make a payment in accordance with a repayment plan, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding under the repayment plan.

Provides that if post-payment audits are conducted, the Medicare contractor is required to provide the provider or supplier with written notice of the itent to conduct the audit. Provides that if a Medicare contractor audits a provider or supplier, the contractor shall: (1) give the provider or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider or supplier and permits the development of an appropriate corrective action plan; (2) inform the provider or supplier of the appeal rights under Medicare as well as consent settlement options; (3) give the provider of services or supplier an opportunity to provide additional information to the contractor; and (4) take into account such information provided, on a timely basis, by the provider of services or supplier. Provides that such provisions shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits. Requires the Secretary to establish a standard methodology for Medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(Sec. 936) Requires the Secretary to establish by regulation a provider enrollment process with hearing rights in the case of a denial or non-renewal.

(Sec. 937) Requires the Secretary to develop a process so providers and suppliers can correct minor errors in claims that were submitted for payment without having to initiate an appeal.

(Sec. 938) Amends SSA title XVIII to direct the Secretary to establish a prior determination process where physicians and beneficiaries can request through the Medicare administrative contractor whether Medicare covers certain physicians' services before such services are provided only if the physician requestor is a participating physician, but only with respect to physicians' services to be

furnished to an individual who is entitled to benefits under Medicare and who has consented to the physician making the request for those physician services and the beneficiary is an individual entitled to benefits under Medicare, but only with respect to a physicians' service for which the individual receives an advance beneficiary notice from a physician who receives direct payment for that service.

Requires the Secretary to establish a process for the collection of information on the instances in which an advance beneficiary notice has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished. Directs the Secretary to establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advanced beneficiary notices and coverage policies under the Medicare program.

Requires the Comptroller General to submit to Congress a report on the use of advanced beneficiary notices under Medicare. Directs the Comptroller General to submit to Congress a report on the use of the prior determination process under such section.

(Sec. 939) Directs the Secretary to permit a provider of services or supplier to appeal any determination of the Secretary relating to services rendered under Medicare to an individual who subsequently dies if there is no other party available to appeal such determination.

(Sec. 940) Adds 30 days to the timeframe for deciding an appeal at the redetermination and reconsideration levels of appeal.

Indexes the amount in controversary for appeals to the consumer price index for all urban consumers, rounded to the nearest multiple of $10 beginning in 2005.

(Sec. 940A) Directs the Secretary to establish a mediation process for local coverage determinations using a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

Requires the Secretary to include in the contract with Medicare administrative contractors the performance duties expected of a medical director of a Medicare administrative contractor.

Subtitle E: Miscellaneous Provisions - (Sec. 941) Prohibits the Secretary from implementing any new or modified documentation guidelines for evaluation and management physician services under Medicare on or after the enactment of this Act unless the Secretary: (1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community; (2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines; (3) has conducted appropriate and representative pilot projects to test such guidelines; (4) finds, based on reports submitted with respect to pilot projects conducted for such or related guidelines, that described objectives for evaluation and management guidelines will be met in the implementation of such guidelines; and (5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

Directs the Secretary to carry out a study of the following for a report to Congress: (1) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under Medicare; and (2) consideration of systems other than current coding and documentation

requirements for payment for such physician services. Directs the MEDPAC to conduct an analysis of the results of the study included in the report for a report to Congress.

Requires the Secretary to conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made for a report to Congress.

(Sec. 942) Requires the Secretary to establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services to coordinate the activities of coverage, coding, and payment processes under Medicare with respect to new technologies and procedures and to coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

Directs the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005.

Requires the Comptroller General to conduct a study for a report to Congress that analyzes which external data can be collected in a shorter timeframe by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services.

(Sec. 943) Prohibits the Secretary from requiring a hospital (including a critical access hospital) to ask questions (or obtain information) relating to Medicare secondary payor provisions in the case of reference laboratory services if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

(Sec. 944) Requires emergency room services provided to screen and stabilize a Medicare beneficiary after January 1, 2004 to be evaluated for Medicare's "reasonable and necessary" requirement on the basis of the information available to the treating physician or practitioner at the time the services were ordered. Provides that except in the case where a delay would jeopardize the health or safety of individuals, the Secretary is required to request a peer review organization review before making a compliance determination that would terminate a hospital's Medicare participation because of Emergency Medical Treatment and Labor Act (EMTALA) violations.

(Sec. 945) Directs the Secretary to establish a Technical Advisory Group to review issues related to EMTALA and its implementation.

(Sec. 946) Permits a hospice to: (1) enter into arrangements with another hospice program to provide care in extraordinary, exigent or other non-routine circumstances, such as unanticipated high patient loads, staffing shortages due to illness or other events, or temporary travel by a patient outside the hospice's service area; and (2) bill and be paid for the hospice care provided under these arrangements.

(Sec. 947) Requires that public hospitals, not otherwise subject to the Occupational Safety and Health Act of 1970, comply with the Bloodborne Pathogens standard. Provides that a hospital that fails to comply with such requirement will be subject to a civil monetary penalty, but cannot be terminated from participating in Medicare.

(Sec. 948) Makes BIPA-related technical amendments and corrections.

(Sec. 949) Amends SSA title XI to permit the administrator of a Federal health care program to waive certain 5-year exclusions if the exclusion of a sole community physician or sole source of essential specialized services in a community will impose a hardship. Provides that the mandatory exclusions that can be waived are those related to convictions associated with program-related crimes; health care fraud; and controlled substances.

(Sec. 950) Amends SSA title XVIII to prohibit a group health plan providing supplemental or secondary coverage to Medicare beneficiaries from requiring dentists to obtain a claim denial from Medicare for dental benefits that are not covered by Medicare before paying the claim.

(Sec. 951) Requires the Secretary to arrange to furnish to "subsection (d)" hospitals the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage for that hospital for the current cost reporting year.

(Sec. 952) Allows physicians and non-physician practitioners to reassign payment for Medicare-covered services, regardless of where the service was provided so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such services. Allows the Secretary to provide for other enrollment qualifications to assure program integrity.

(Sec. 953) Requires the Comptroller General to report to Congress on: (1) the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate formula for 2002 and subsequently; and (2) all aspects of physician compensation for services furnished under Medicare and how those aspects interact and the effect on appropriate compensation for physician services.

Directs the Secretary to provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under Medicare in the previous year and information on how to get more information with respect to such determinations.

Requires the Comptroller General to submit to Congress a report on the implications if there were flexibility in the application of the Medicare conditions of participation for home health agencies with respect to groups or types of patients who are not Medicare beneficiaries.

Directs the Inspector General of HHS to submit a report to Congress on: (1) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days under the hospital benefit; and (2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before the completely exhaust such lifetime reserve days.

Title X: Medicaid and Miscellaneous Provisions - Subtitle A: Medicaid Provisions - (Sec. 1001) Amends SSA title XIX to establish a temporary increase in DSH allotments for FY 2004 and for certain subsequent fiscal years.

Raises the temporary floor for extremely low DSH states for FY 2004 and subsequent fiscal years.

Provides for an appropriate DSH allotment adjustment for FY 2004 and 2005 for States with statewide "Section 1115" waivers which have been revoked or terminated before the end of either such fiscal year and for which there is no DSH allotment for the State. Requires the State whose

waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State to identify and make payments to DSH hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs.

Directs the Secretary to require, with respect to FY 2004 and each fiscal year thereafter, a State as a condition of receiving Medicaid payments to submit to the Secretary an annual report identifying each DSH hospital that received a payment, the amount such hospital received, and such other information as the Secretary determines necessary to ensure the appropriateness of the DSH payments for the previous fiscal year.

Requires the State to annually submit to the Secretary an independent certified audit that verifies: (1) the extent to which hospitals have reduced their uncompensated care costs to reflect the total amount of claimed expenditures; (2) payment compliance; (3) only the uncompensated care costs of providing inpatient hospital and outpatient hospital services to described individuals are included in the calculation of the hospital-specific limits; (3) the State included all payments under Medicaid, including supplemental payments, in the calculation of such hospital-specific limits; and (4) the State has separately documented and retained a record of all of its costs and claimed expenditures under Medicare, uninsured costs in determining payment adjustments, and any payments made on behalf of the uninsured from payment adjustments.

(Sec. 1002) Permits certain high-volume DSH safety net providers to negotiate with pharmaceutical companies and to receive discounts on the prices of inpatient drugs for the lowest price they can get. (Currently such entities are only able to receive discounts on the prices of outpatient drugs because of a Center for Medicare and Medicaid Services interpretation of the best price exemption under the Medicaid drug rebate program). Provides for the application of specified auditing and recordkeeping requirements with respect to such high-volume DSH hospital safety net providers.

(Sec. 1003) Amends the Omnibus Budget Reconciliation Act of 1989, as amended by the Omnibus Budget Reconciliation Act of 1993 and the Balanced Budget Act of 1997, to permanently extend the moratorium on the determination of Saginaw Community Hospital as an institution for mental disease.

Subtitle B: Miscellaneous Provisions - (Sec. 1011) Appropriates for FY 2005 through 2008 specified funding out of any funds in the Treasury not otherwise appropriated to the Secretary for the purpose of making allotments to States for payments to eligible providers for unreimbursable costs incurred by providing emergency health care services to: (1) undocumented aliens; (2) aliens who have been parolded into the United States at a United States port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card.

(Sec. 1012) Directs the Secretary to establish the Commission on Systemic Interoperability to develop a comprehensive strategy for the adoption and implementation of health care information technology standards, that includes a timeline and prioritization for such adoption and implementation. Authorizes appropriations.

(Sec. 1013) Provides that in order to improve the quality, effectiveness, and efficiency of health care delivered pursuant to Medicare, Medicaid, and the State Children's Health Insurance Program, the Secretary is required to conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to: (1) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services; and (2) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs. Requires the Secretary to establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section. Directs the Secretary to evaluate and synthesize available scientific evidence related to health care items and services identified as priorities and to disseminate such evaluations and syntheses to various prescription drug plans to enhance patient safety and quality of health care. Authorizes appropriations.

(Sec. 1014) Directs the Secretary to establish the Citizen's Health Care Working Group to hold hearings to examine: (1) the capacity of the public and private health care systems to expand coverage options; (2) the cost of health care and the effectiveness of care provided at all stages of the disease; (3) innovative State strategies used to expand health care coverage and lower health care costs; (4) local community solutions to accessing health care coverage; (5) efforts to enroll individuals currently eligible for public or private health care coverage; (6) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and the use of technology in supporting providers in improving quality of care and lowering costs; and (7) strategies to assist purchasers of health care to become more aware of the impact of costs and to lower the costs of health care. Requires the Working Group to prepare and make available to health care consumers through the Internet and other appropriate public channels a report entitled "The Health Report to the American People." Directs the Working Group to initiate health care community meetings throughout the United States to address certain topics and to prepare and make available to the public initial recommendations on health care coverage and ways to improve and strengthen the health care system. Requires the Working Group to submit to Congress for appropriate action the final set of recommendations put together after the period of public comment. Authorizes appropriations.

(Sec. 1015) Makes appropriations to carry out this Act to be transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund: (1) not to exceed $1,000,000,000 for the Centers for Medicare and Medicaid Services; and (2) not to exceed $500,000,000 for the Social Security Administration. Provides from these latter funds for the Social Security Administration to reimburse the Internal Revenue Service for expenses in carrying out this Act. Allows the President to transfer such amounts between the Centers for Medicare and Medicaid Services and the Social Security Administration.

(Sec. 1016) Amends SSA title XVIII to direct the Secretary to establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects designed to improve the cancer-related health care infrastructure of the hospital, including construction, renovation, or other capital improvements. Makes appropriations.

Title XI: Access to Affordable Pharmaceuticals - Subtitle A: Access to Affordable Pharmaceuticals - (Sec. 1101) - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions (Hatch-Waxman Act) with respect to abbreviated new drug applications (ANDAs) to

require the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.

Requires the ANDA applicant to notify the patent holder and the brand name company (if different) of a paragraph IV certification within 20 days.

Prohibits the ANDA applicant from amending the application to include a drug different from that approved by the Food and Drug Administration (FDA), but allows the applicant to amend the application if seeking approval for a different strength of the same drug.

Authorizes the FDA to approve the ANDA on the date of an appeals court decision, the date of a settlement order or consent decree, or when a district court decision is not appealed.

Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of the notification but provides however if sued that the patent holder and the brand name company (if different) may file a counter claim to require that changes be made to correct the patient information submitted.

Disallows damages from being awarded in either case.

Provides that: (1) if a declaratory judgment is pursued, the action is to be brought in the judicial district where the defendant has its principle place of business; and; (2) in a declaratory judgment the holder of an approved new drug application may obtain access to confidential information contained in the application; and (3) the 180-day exclusivity period is to begin on the date of the first commercial marketing of the generic drug by any first ANDA applicants.

Requires a first ANDA applicant to forfeit the 180-day exclusivity period under certain circumstances including failure to market within a specified time frame, withdrawal of the application, amendment of the certification and failure to obtain tentative marketing approval.

Prohibits other subsequent ANDA applicants from being permitted the 180-day exclusivity period if all first ANDA applicants forfeit.

(Sec. 1103) Defines "bioavailability" as the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

Subtitle B: Federal Trade Commission Review - (Sec. 1112) Requires that agreements between brand name companies and generic firms regarding the manufacture or sale of a generic drug that is equivalent to the pharmaceutical marketed by the patent owner must be filed with the Assistant Attorney General and the Federal Trade Commission (FTC) for review within ten days after the agreements are executed.

(Sec. 1114) Exempts from disclosure under the Freedom of Information Act any information or documentary material filed with the Assisstant Attorney General or FTC pursuant to this subtitle, and prohibits such information or documentary material from being made public, except as may be relevant to any administrative or judicial action or proceeding.

(Sec. 1115) Subjects parties which fail to file such agreements to civil penalties.

(Sec. 1116) Allows the FTC to engage in rulemaking to carry out this subtitle.

Subtitle C: Importation of Prescription Drugs - (Sec. 1121) Directs the Secretary to promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States. Sets forth specified provisions respecting: (1) importer and foreign seller recordkeeping and information requirements; (2) qualified laboratory drug testing; (3) registration with the Secretary of Canadian sellers; and (4) approved labeling.

Declares that the Secretary should: (1) focus enforcement on cases in which individual importation poses a significant public health threat; and (2) exercise discretion to permit individuals to make such importation for non-risk personal use.

Authorizes the Secretary to grant individuals a waiver of the prohibition of importation of a prescription drug or device. Directs the Secretary to grant individuals a waiver of such prohibition for an approved prescription drug imported from Canada that is: (1) imported from a licensed pharmacy for not more than 90-day personal use; (2) accompanied by a valid prescription; (3) in a final finished dosage that was manufactured in a registered establishment; and (4) imported under such other conditions as the Secretary determines necessary to ensure public safety.

(Sec. 1122) Directs the Secretary to conduct a study on the importation of drugs into the United States for submission in a report to the Congress.

Title XII: Tax Incentives For Health And Retirement Security - (Sec. 1201) Amends the IRC to permit eligible individuals who are covered by a high deductible health plan with a deductible of at least $1,000 up to $2,250 (subject to an annual cost of living adjustment) for self-only coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $5,000, and a deductible of at least $2,000 up to $4,500 (subject to an annual cost of living adjustment) for family coverage with annual out of pocket expenses (deductibles, co-payments, not premiums) not exceeding $10,000, and not covered by any other other health plan that is not a high deductible health plan (except plans for any benefit provided by permitted insurance and plans for coverage for accidents, disability, dental care, vision care, or long-term care) to establish Health Savings Accounts (HSAs) for taxable years beginning with 2004 to pay for qualified medical expenses. Provides that: (1) contribution levels are to be determined monthly based on how many months of the year the individual is covered by a HDHP; and (2) a plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care. Prohibits Medicare-eligible individuals from participating in HSAs.

Includes as qualified medical expenses any expense for coverage under: (1) a COBRA continuation plan; (2) a qualified long-term care insurance contract; (3) a health plan during a period in which the individual is receiving unemployment compensation; and (4) health insurance premiums for individuals eligible for Medicare, other than premiums for Medigap policies program

Allows an eligible individual establishing an HSA to take a tax deduction for the taxable year of an amount equal to the aggregate contributions paid during the taxable year by or on behalf of such individual to an HSA of such individual, up to the limits specified above for self-only and family coverage. Allows the deduction whether or not the individual itemizes other deductions.

Allows contributions to remain in the HSA at the end of the year and to earn tax-exempt interest until they are withdrawn for uses other than for qualified medical expenses in which case they are to be included in the gross income of the account beneficiary and subjected to a ten percent penalty, except

in cases of disability or death or where the contributions are distributed after the account beneficiary attains Medicare eligibility. Requires contributions to be in cash, except in the case of certain rollover contributions. Allows additional "catch up" contributions for eligible individuals age 55 or older.

Allows an HSA trustee to be a bank, an insurance company, or another person.

Permits rollovers from Archer MSAs.

Prohibits any payment or distribution out of an HSA for qualified medical expenses from being treated as an expense paid for medical care.

Allows employers to contribute to the HSAs of their employees and excludes amounts contributed from the employee's income and from employment taxes.

Imposes an excise tax on: (1) the failure of employer to make comparable HSA contributions; and (2) excess contributions.

Allows HSAs to be offered under cafeteria plans.

(Sec. 1202) Excludes from gross income any special subsidy payment received under employer-sponsored qualified retiree prescription drug plan programs.

(Sec. 1203) Creates an exception to information reporting requirements relating to information at the source for flexible spending arrangements and a health reimbursement arrangement that is treated as employer-provided coverage.

Chapter 4

The Affordable Care Act of 2010

Shown Here:
Public Law No: 111-148 (03/23/2010)

(This measure has not been amended since it was passed by the Senate on December 24, 2009. The summary of that version is repeated here.)

Patient Protection and Affordable Care Act - **Title I: Quality, Affordable Health Care for All Americans - Subtitle A: Immediate Improvements in Health Care Coverage for All Americans -** (Sec. 1001, as modified by Sec. 10101) Amends the Public Health Service Act to prohibit a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from establishing lifetime limits or annual limits on the dollar value of benefits for any participant or beneficiary after January 1, 2014. Permits a restricted annual limit for plan years beginning prior to January 1, 2014. Declares that a health plan shall not be prevented from placing annual or lifetime per-beneficiary limits on covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted.

Prohibits a health plan from rescinding coverage of an enrollee except in the case of fraud or intentional misrepresentation of material fact.

Requires health plans to provide coverage for, and to not impose any cost sharing requirements for: (1) specified preventive items or services; (2) recommended immunizations; and (3) recommended preventive care and screenings for women and children.

Requires a health plan that provides dependent coverage of children to make such coverage available for an unmarried, adult child until the child turns 26 years of age.

Requires the Secretary of Health and Human Services (HHS) to develop standards for health plans (including grandfathered health plans) to provide an accurate summary of benefits and coverage explanation. Directs each such health plan, prior to any enrollment restriction, to provide such a summary of benefits and coverage explanation to: (1) the applicant at the time of application; (2) an enrollee prior to the time of enrollment or re-enrollment; and (3) a policy or certificate holder at the time of issuance of the policy or delivery of the certificate.

Requires group health plans to comply with requirements relating to the prohibition against discrimination in favor of highly compensated individuals.

Requires the Secretary to develop reporting requirements for health plans on benefits or reimbursement structures that: (1) improve health outcomes; (2) prevent hospital readmissions; (3) improve patient safety and reduce medical errors; and (4) promote wellness and health.

Prohibits: (1) a wellness and health promotion activity implemented by a health plan or any data collection activity authorized under this Act from requiring the disclosure or collection of any information relating to the lawful use, possession, or storage of a firearm or ammunition by an individual; (2) any authority provided to the Secretary under this Act from being construed to authorize the collection of such information or the maintenance of records of individual ownership or possession of a firearm or ammunition; or (3) any health insurance premium increase, denial of

coverage, or reduction of any reward for participation in a wellness program on the basis of the lawful use, possession, or storage of a firearm or ammunition.

Requires a health plan (including a grandfathered health plan) to: (1) submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums; and (2) provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended by the issuer on reimbursement for clinical services provided to enrollees and activities that improve health care quality to the total amount of premium revenue for the plan year is less than a 85% for large group markets or 80% for small group or individual markets.

Requires each U.S. hospital to establish and make public a list of its standard charges for items and services.

Requires a health plan to implement an effective process for appeals of coverage determinations and claims.

Sets forth requirements for health plans related to: (1) designation of a primary care provider; (2) coverage of emergency services; and (3) elimination of referral requirements for obstetrical or gynecological care.

(Sec. 1002) Requires the Secretary to award grants to states for offices of health insurance consumer assistance or health insurance ombudsman programs.

(Sec. 1003, as modified by Sec. 10101) Requires the Secretary to establish a process for the annual review of unreasonable increases in premiums for health insurance coverage.

(Sec. 1004) Makes this subtitle effective for plan years beginning six months after enactment of this Act, with certain exceptions.

Subtitle B: Immediate Actions to Preserve and Expand Coverage - (Sec. 1101) Requires the Secretary to establish a temporary high risk health insurance pool program to provide health insurance coverage to eligible individuals with a preexisting condition. Terminates such coverage on January 1, 2014, and provides for a transition to an American Health Benefit Exchange (Exchange).

(Sec. 1102, as modified by Sec. 10102) Requires the Secretary to establish a temporary reinsurance program to provide reimbursement to participating employment-based plans for a portion of the cost of providing health insurance coverage to early retirees before January 1, 2014.

(Sec. 1103, as modified by Sec. 10102) Requires the Secretary to establish a mechanism, including an Internet website, through which a resident of, or small business in, any state may identify affordable health insurance coverage options in that state.

(Sec. 1104) Sets forth provisions governing electronic health care transactions. Establishes penalties for health plans failing to comply with requirements.

(Sec. 1105) Makes this subtitle effective on the date of enactment of this Act.

Subtitle C: Quality Health Insurance Coverage for All Americans - Part I: Health Insurance Market Reforms - (Sec. 1201, as modified by Sec. 10103) Prohibits a health plan ("health plan" under this subtitle excludes any "grandfathered health plan" as defined in section 1251) from: (1)

imposing any preexisting condition exclusion; or (2) discriminating on the basis of any health status-related factor. Allows premium rates to vary only by individual or family coverage, rating area, age, or tobacco use.

Requires health plans in a state to: (1) accept every employer and individual in the state that applies for coverage; and (2) renew or continue coverage at the option of the plan sponsor or the individual, as applicable.

Prohibits a health plan from establishing individual eligibility rules based on health status-related factors, including medical condition, claims experience, receipt of health care, medical history, genetic information, and evidence of insurability.

Sets forth provisions governing wellness programs under the health plan, including allowing cost variances for coverage for participation in such a program.

Prohibits a health plan from discriminating with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable state law.

Requires health plans that offer health insurance coverage in the individual or small group market to ensure that such coverage includes the essential health benefits package. Requires a group health plan to ensure that any annual cost-sharing imposed under the plan does not exceed specified limitations.

Prohibits a health plan from: (1) applying any waiting period for coverage that exceeds 90 days; or (2) discriminating against individual participation in clinical trials with respect to treatment of cancer or any other life-threatening disease or condition.

Part II: Other Provisions - (Sec. 1251, as modified by Sec. 10103) Provides that nothing in this Act shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled on the date of enactment of this Act. Allows family members of individuals currently enrolled in a plan to enroll in such plan or coverage if such enrollment was permitted under the terms of the plan. Allows new employees and their families to enroll in a group health plan that provides coverage on the date of enactment of this Act.

Defines a "grandfathered health plan" as a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act.

States that this subtitle and subtitle A shall not apply to: (1) a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment of this Act, regardless of whether the individual renews such coverage after such date of enactment; (2) an existing group health plan that enrolls new employees under this section; and (3) health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this Act until the date on which the last of the collective bargaining agreements relating to the coverage terminates.

Applies provisions related to uniform coverage documents and medical loss ratios to grandfathered health plans for plan years beginning after enactment of this Act.

(Sec. 1252) Requires uniform application of standards or requirements adopted by states to all health plans in each applicable insurance market.

(Sec. 1253, as added by Sec. 10103) Directs the Secretary of Labor to prepare an annual report on self-insured group health plans and self-insured employers.

(Sec. 1254, as added by Sec. 10103) Requires the HHS Secretary to conduct a study of the fully-insured and self-insured group health plan markets related to financial solvency and the effect of insurance market reforms.

(Sec. 1255, as modified by Sec. 10103) Sets forth effective dates for specified provisions of this subtitle.

Subtitle D: Available Coverage Choices for All Americans - Part I: Establishment of Qualified Health Plans - (Sec. 1301, as modified by Sec. 10104) Defines "qualified health plan" to require that such a plan provides essential health benefits and offers at least one plan in the silver level at one plan in the gold level in each Exchange through which such plan is offered.

(Sec. 1302, as modified by Sec. 10104) Requires the essential health benefits package to provide essential health benefits and limit cost-sharing. Directs the Secretary to: (1) define essential health benefits and include emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care; (2) ensure that the scope of the essential health benefits is equal to the scope of benefits provided under a typical employer plan; and (3) provide notice and an opportunity for public comment in defining the essential health benefits. Establishes: (1) an annual limit on cost-sharing beginning in 2014; and (2) a limitation on the deductible under a small group market health plan.

Sets forth levels of coverage for health plans defined by a certain percentage of the costs paid by the plan. Allows health plans in the individual market to offer catastrophic coverage for individuals under age 30, with certain limitations.

(Sec. 1303, as modified by Sec. 10104) Sets forth special rules for abortion coverage, including: (1) permitting states to elect to prohibit abortion coverage in qualified health plans offered through an Exchange in the state; (2) prohibiting federal funds from being used for abortion services; and (3) requiring separate accounts for payments for such services. Prohibits any qualified health plan offered through an Exchange from discriminating against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(Sec. 1304, as modified by Sec. 10104) Sets forth definitions for terms used in this title.

Part II: Consumer Choices and Insurance Competition Through Health Benefit Exchanges - (Sec. 1311, as modified by Sec. 10104) Requires states to establish an American Health Benefit Exchange that: (1) facilitates the purchase of qualified health plans; and (2) provides for the establishment of a Small Business Health Options Program (SHOP Exchange) that is designed to assist qualified small employers in facilitating the enrollment of their employees in qualified health plans offered in the small group market in the state.

Requires the Secretary to establish criteria for the certification of health plans as qualified health plans, including requirements for: (1) meeting market requirements; and (2) ensuring a sufficient choice of providers.

Sets forth the requirements for an Exchange, including that an Exchange: (1) must be a governmental agency or nonprofit entity that is established by a state; (2) may not make available any health plan that is not a qualified health plan; (3) must implement procedures for certification of health plans as qualified health plans; and (4) must require health plans seeking certification to submit a justification of any premium increase prior to implementation of such increase.

Permits states to require qualified health plans to offer additional benefits. Requires states to pay for the cost of such additional benefits.

Allows a state to establish one or more subsidiary Exchanges for geographically distinct areas of a certain size.

Applies mental health parity provisions to qualified health plans.

(Sec. 1312, as modified by Sec. 10104) Allows an employer to select a level of coverage to be made available to employees through an Exchange. Allows employees to choose to enroll in any qualified health plan that offers that level of coverage.

Restricts the health plans that the federal government may make available to Members of Congress and congressional staff after the effective date of this subtitle to only those health plans that are created under this Act or offered through an Exchange.

Permits states to allow large employers to join an Exchange after 2017.

(Sec. 1313, as modified by Sec. 10104) Requires an Exchange to keep an accurate accounting of all activities, receipts, and expenditures and to submit to the Secretary, annually, a report concerning such accountings. Requires the Secretary to take certain action to reduce fraud and abuse in the administration of this title. Requires the Comptroller General to conduct an ongoing study of Exchange activities and the enrollees in qualified health plans offered through Exchanges.

Part III: State Flexibility Relating to Exchanges - (Sec. 1321) Requires the Secretary to issue regulations setting standards related to: (1) the establishment and operation of Exchanges; (2) the offering of qualified health plans through Exchanges; and (3) the establishment of the reinsurance and risk adjustment programs under part V.

Requires the Secretary to: (1) establish and operate an Exchange within a state if the state does not have one operational by January 1, 2014; and (2) presume that an Exchange operating in a state before January 1, 2010, that insures a specified percentage of its population meets the standards under this section.

(Sec. 1322, as modified by Sec. 10104) Requires the Secretary to establish the Consumer Operated and Oriented Plan (CO-OP) program to foster the creation of qualified nonprofit health insurance issuers to offer qualified health plans in the individual and small group markets. Requires the Secretary to provide for loans and grants to persons applying to become qualified nonprofit health insurance issuers. Sets forth provisions governing the establishment and operation of CO-OP program plans.

(Sec. 1323, deleted by Sec. 10104)

(Sec. 1324, as modified by Sec. 10104) Declares that health insurance coverage offered by a private health insurance issuer shall not be subject to federal or state laws if a qualified health plan offered under the CO-OP program is not subject to such law.

Part IV: State Flexibility to Establish Alternative Programs - (Sec. 1331, as modified by Sec. 10104) Requires the Secretary to establish a basic health program under which a state may enter into contracts to offer one or more standard health plans providing at least the essential health benefits to eligible individuals in lieu of offering such individuals coverage through an Exchange. Sets forth requirements for such a plan. Transfers funds that would have gone to the Exchange for such individuals to the state.

(Sec. 1332) Authorizes a state to apply to the Secretary for the waiver of specified requirements under this Act with respect to health insurance coverage within that state for plan years beginning on or after January 1, 2017. Directs the Secretary to provide for an alternative means by which the aggregate amounts of credits or reductions that would have been paid on behalf of participants in the Exchange will be paid to the state for purposes of implementing the state plan.

(Sec. 1333, as modified by Sec. 10104) Requires the Secretary to issue regulations for the creation of health care choice compacts under which two or more states may enter into an agreement that: (1) qualified health plans could be offered in the individual markets in all such states only subject to the laws and regulations of the state in which the plan was written or issued; and (2) the issuer of any qualified health plan to which the compact applies would continue to be subject to certain laws of the state in which the purchaser resides, would be required to be licensed in each state, and must clearly notify consumers that the policy may not be subject to all the laws and regulations of the state in which the purchaser resides. Sets forth provisions regarding the Secretary's approval of such compacts.

(Sec. 1334, as added by Sec. 10104) Requires the Director of the Office of Personnel Management (OPM) to: (1) enter into contracts with health insurance issuers to offer at least two multistate qualified health plans through each Exchange in each state to provide individual or group coverage; and (2) implement this subsection in a manner similar to the manner in which the Director implements the Federal Employees Health Benefits Program. Sets forth requirements for a multistate qualified health plan.

Part V: Reinsurance and Risk Adjustment - (Sec. 1341, as modified by Sec. 10104) Directs each state, not later than January 1, 2014, to establish one or more reinsurance entities to carry out the reinsurance program under this section. Requires the Secretary to establish standards to enable states to establish and maintain a reinsurance program under which: (1) health insurance issuers and third party administrators on behalf of group health plans are required to make payments to an applicable reinsurance entity for specified plan years; and (2) the applicable reinsurance entity uses amounts collected to make reinsurance payments to health insurance issuers that cover high risk individuals in the individual market. Directs the state to eliminate or modify any state high-risk pool to the extent necessary to carry out the reinsurance program established under this section.

(Sec. 1342) Requires the Secretary to establish and administer a program of risk corridors for calendar years 2014 through 2016 under which a qualified health plan offered in the individual or small group

market shall participate in a payment adjusted system based on the ratio of the allowable costs of the plan to the plan's aggregate premiums. Directs the Secretary to make payments when a plan's allowable costs exceed the target amount by a certain percentage and directs a plan to make payments to the Secretary when its allowable costs are less than target amount by a certain percentage.

(Sec. 1343) Requires each state to assess a charge on health plans and health insurance issuers if the actuarial risk of the enrollees of such plans or coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in the state for the year. Requires each state to provide a payment to health plans and health insurance issuers if the actuarial risk of the enrollees of such plan or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in the state for the year. Excludes self-insured group health plans from this section.

Subtitle E: Affordable Coverage Choices for All Americans - Part I: Premium Tax Credits and Cost-sharing Reductions - Subpart A: Premium Tax Credits and Cost-sharing Reductions - (Sec. 1401, as modified by section 10105) Amends the Internal Revenue Code to allow individual taxpayers whose household income equals or exceeds 100%, but does not exceed 400%, of the federal poverty line (as determined in the Social Security Act [SSA]) a refundable tax credit for a percentage of the cost of premiums for coverage under a qualified health plan. Sets forth formulae and rules for the calculation of credit amounts based upon taxpayer household income as a percentage of the poverty line.

Directs the Comptroller General, not later than five years after enactment of this Act, to conduct a study and report to specified congressional committees on the affordability of health insurance coverage.

(Sec. 1402) Requires reductions in the maximum limits for out-of-pocket expenses for individuals enrolled in qualified health plans whose incomes are between 100% and 400% of the poverty line.

Subpart B: Eligibility Determinations - (Sec. 1411) - Requires the Secretary to establish a program for verifying the eligibility of applicants for participation in a qualified health plan offered through an Exchange or for a tax credit for premium assistance based upon their income or their citizenship or immigration status. Requires an Exchange to submit information received from an applicant to the Secretary for verification of applicant eligibility. Provides for confidentiality of applicant information and for an appeals and redetermination process for denials of eligibility. Imposes civil penalties on applicants for providing false or fraudulent information relating to eligibility.

Requires the Secretary to study and report to Congress by January 1, 2013, on procedures necessary to ensure the protection of privacy and due process rights in making eligibility and other determinations under this Act.

(Sec. 1412) Requires the Secretary to establish a program for advance payments of the tax credit for premium assistance and for reductions of cost-sharing. Prohibits any federal payments, tax credit, or cost-sharing reductions for individuals who are not lawfully present in the United States.

(Sec. 1413) Requires the Secretary to establish a system to enroll state residents who apply to an Exchange in state health subsidy programs, including Medicaid or the Children's Health Insurance Program (CHIP, formerly known as SCHIP), if such residents are found to be eligible for such programs after screening.

(Sec. 1414) Requires the Secretary of the Treasury to disclose to HHS personnel certain taxpayer information to determine eligibility for programs under this Act or certain other social security programs.

(Sec. 1415) Disregards the premium assistance tax credit and cost-sharing reductions in determining eligibility for federal and federally-assisted programs.

(Sec. 1416, as added by section 10105) Directs the HHS Secretary to study and report to Congress by January 1, 2013, on the feasibility and implication of adjusting the application of the federal poverty level under this subtitle for different geographic areas in the United States, including its territories.

Part II: Small Business Tax Credit - (Sec. 1421, as modified by section 10105) Allows qualified small employers to elect, beginning in 2010, a tax credit for 50% of their employee health care coverage expenses. Defines "qualified small employer" as an employer who has no more than 25 employees with average annual compensation levels not exceeding $50,000. Requires a phase-out of such credit based on employer size and employee compensation.

Subtitle F: Shared Responsibility for Health Care - Part I: Individual Responsibility - (Sec. 1501, as modified by section 10106) Requires individuals to maintain minimal essential health care coverage beginning in 2014. Imposes a penalty for failure to maintain such coverage beginning in 2014, except for certain low-income individuals who cannot afford coverage, members of Indian tribes, and individuals who suffer hardship. Exempts from the coverage requirement individuals who object to health care coverage on religious grounds, individuals not lawfully present in the United States, and individuals who are incarcerated.

(Sec. 1502) Requires providers of minimum essential coverage to file informational returns providing identifying information of covered individuals and the dates of coverage. Requires the IRS to send a notice to taxpayers who are not enrolled in minimum essential coverage about services available through the Exchange operating in their state.

Part II: Employer Responsibilities - (Sec. 1511) Amends the Fair Labor Standards Act of 1938 to: (1) require employers with more than 200 full-time employees to automatically enroll new employees in a health care plan and provide notice of the opportunity to opt-out of such coverage; and (2) provide notice to employees about an Exchange, the availability of a tax credit for premium assistance, and the loss of an employer's contribution to an employer-provided health benefit plan if the employee purchases a plan through an Exchange.

(Sec. 1513, as modified by section 10106) Imposes fines on large employers (employers with more than 50 full-time employees) who fail to offer their full-time employees the opportunity to enroll in minimum essential coverage or who have a waiting period for enrollment of more than 60 days.

Requires the Secretary of Labor to study and report to Congress on whether employees' wages are reduced due to fines imposed on employers.

(Sec. 1514, as modified by section 10106) Requires large employers to file a report with the Secretary of the Treasury on health insurance coverage provided to their full-time employees. Requires such reports to contain: (1) a certification as to whether such employers provide their full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible

employer-sponsored plan; (2) the length of any waiting period for such coverage; (3) the months during which such coverage was available; (4) the monthly premium for the lowest cost option in each of the enrollment categories under the plan; (5) the employer's share of the total allowed costs of benefits provided under the plan; and (6) identifying information about the employer and full-time employees. Imposes a penalty on employers who fail to provide such report. Authorizes the Secretary of the Treasury to review the accuracy of information provided by large employers.

(Sec. 1515) Allows certain small employers to include as a benefit in a tax-exempt cafeteria plan a qualified health plan offered through an Exchange.

Subtitle G: Miscellaneous Provisions - (Sec. 1551) Applies the definitions under the Public Health Service Act related to health insurance coverage to this title.

(Sec. 1552) Requires the HHS Secretary to publish on the HHS website a list of all of the authorities provided to the Secretary under this Act.

(Sec. 1553) Prohibits the federal government, any state or local government or health care provider that receives federal financial assistance under this Act, or any health plan created under this Act from discriminating against an individual or institutional health care entity on the basis that such individual or entity does not provide a health care item or service furnished for the purpose of causing, or assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(Sec. 1554) Prohibits the Secretary from promulgating any regulation that: (1) creates an unreasonable barrier to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the health care provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principle of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

(Sec. 1555) Declares that no individual, company, business, nonprofit entity, or health insurance issuer offering group or individual health insurance coverage shall be required to participate in any federal health insurance program created by or expanded under this Act. Prohibits any penalty from being imposed upon any such issuer for choosing not to participate in any such program.

(Sec. 1556) Amends the Black Lung Benefits Act, with respect to claims filed on or after the effective date of the Black Lung Benefits Amendments of 1981, to eliminate exceptions to: (1) the applicability of certain provisions regarding rebuttable presumptions; and (2) the prohibition against requiring eligible survivors of a miner determined to be eligible for black lung benefits to file a new claim or to refile or otherwise revalidate the miner's claim.

(Sec. 1557) Prohibits discrimination by any federal health program or activity on the grounds of race, color, national origin, sex, age, or disability.

(Sec. 1558) Amends the Fair Labor Standards Act of 1938 to prohibit an employer from discharging or discriminating against any employee because the employee: (1) has received a health insurance credit or subsidy; (2) provides information relating to any violation of any provision of such Act; or

(3) objects to, or refuses to participate in, any activity, policy, practice, or assigned task that the employee reasonably believed to be in violation of such Act.

(Sec. 1559) Gives the HHS Inspector General oversight authority with respect to the administration and implementation of this title.

(Sec. 1560) Declares that nothing in this title shall be construed to modify, impair, or supersede the operation of any antitrust laws.

(Sec. 1561) Amends the Public Health Service Act to require the Secretary to: (1) develop interoperable and secure standards and protocols that facilitate enrollment of individuals in federal and state health and human services programs; and (2) award grants to develop and adapt technology systems to implement such standards and protocols.

(Sec. 1562, as added by Sec. 10107) Directs the Comptroller General to study denials by health plans of coverage for medical services and of applications to enroll in health insurance.

(Sec. 1563, as added by Sec. 10107) Disallows the waiver of laws or regulations establishing procurement requirements relating to small business concerns with respect to any contract awarded under any program or other authority under this Act.

(Sec. 1563 [*sic*], as modified by Sec. 10107) Makes technical and conforming amendments.

(Sec. 1563 [*sic*]) Expresses the sense of the Senate that: (1) the additional surplus in the Social Security trust fund generated by this Act should be reserved for Social Security; and (2) the net savings generated by the CLASS program (established under Title VIII of this Act) should be reserved for such program.

Title II: Role of Public Programs - Subtitle A: Improved Access to Medicaid - (Sec. 2001, as modified by Sec. 10201) Amends title XIX (Medicaid) of the SSA to extend Medicaid coverage, beginning in calendar 2014, to individuals under age 65 who are not entitled to or enrolled in Medicare and have incomes at or below 133% of the federal poverty line. Grants a state the option to expand Medicaid eligibility to such individuals as early as April 1, 2010. Provides that, for between 2014 and 2016, the federal government will pay 100% of the cost of covering newly-eligible individuals.

Increases the federal medical assistance percentage (FMAP): (1) with respect to newly eligible individuals; and (2) between January 1, 2014, and December 31, 2016, for states meeting certain eligibility requirements.

Requires Medicaid benchmark benefits to include coverage of prescription drugs and mental health services.

Grants states the option to extend Medicaid coverage to individuals who have incomes that exceed 133% of the federal poverty line beginning January 1, 2014.

(Sec. 2002) Requires a state to use an individual's or household's modified gross income to determine income eligibility for Medicaid for non-elderly individuals, without applying any income or expense disregards or assets or resources test.

Exempts from this requirement: (1) individuals eligible for Medicaid through another program; (2) the elderly or Social Security Disability Insurance (SSDI) program beneficiaries; (3) the medically needy; (4) enrollees in a Medicare Savings Program; and (5) the disabled.

(Sec. 2003) Revises state authority to offer a premium assistance subsidy for qualified employer-sponsored coverage to children under age 19 to extend such a subsidy to all individuals, regardless of age.

Prohibits a state from requiring, as a condition of Medicaid eligibility, that an individual (or the individual's parent) apply for enrollment in qualified employer-sponsored coverage.

(Sec. 2004, as modified by Sec. 10201) Extends Medicaid coverage to former foster care children who are under 26 years of age.

(Sec. 2005, as modified by Sec. 10201) Revises requirements for Medicaid payments to territories, including an increase in the limits on payments for FY2011 and thereafter.

(Sec. 2006, as modified by Sec. 10201) Prescribes an adjustment to the FMAP determination for certain states recovering from a major disaster.

(Sec. 2007) Rescinds any unobligated amounts available to the Medicaid Improvement Fund for FY2014-FY2018.

Subtitle B: Enhanced Support for the Children's Health Insurance Program - (Sec. 2101, as modified by Sec. 10201) Amends SSA title XXI (State Children's Health Insurance Program) (CHIP, formerly known as SCHIP) to increase the FY2016-FY2019 enhanced FMAP for states, subject to a 100% cap.

Prohibits states from applying, before the end of FY2019, CHIP eligibility standards that are more restrictive than those under this Act.

Deems ineligible for CHIP any targeted low-income children who cannot enroll in CHIP because allotments are capped, but who are therefore eligible for tax credits in the Exchanges.

Requires the Secretary to: (1) review benefits offered for children, and related cost-sharing imposed, by qualified health plans offered through an Exchange; and (2) certify those plans whose benefits and cost-sharing are at least comparable to those provided under the particular state's CHIP plan.

Prohibits enrollment bonus payments for children enrolled in CHIP after FY2013.

Requires a state CHIP plan, beginning January 1, 2014, to use modified gross income and household income to determine CHIP eligibility.

Requires a state to treat as a targeted low-income child eligible for CHIP any child determined ineligible for Medicaid as a result of the elimination of an income disregard based on expense or type of income.

(Sec. 2102) Makes technical corrections to the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA).

Subtitle C: Medicaid and CHIP Enrollment Simplification - (Sec. 2201) Amends SSA title XIX (Medicaid) to require enrollment application simplification and coordination with state health insurance Exchanges and CHIP via state-run websites.

(Sec. 2202) Permits hospitals to provide Medicaid services during a period of presumptive eligibility to members of all Medicaid eligibility categories.

Subtitle D: Improvements to Medicaid Services - (Sec. 2301) Requires Medicaid coverage of: (1) freestanding birth center services; and (2) concurrent care for children receiving hospice care.

(Sec. 2303) Gives states the option of extending Medicaid coverage to family planning services and supplies under a presumptive eligibility period for a categorically needy group of individuals.

Subtitle E: New Options for States to Provide Long-Term Services and Supports - (Sec. 2401) Authorizes states to offer home and community-based attendant services and supports to Medicaid beneficiaries with disabilities who would otherwise require care in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases.

(Sec. 2402) Gives states the option of: (1) providing home and community-based services to individuals eligible for services under a waiver; and (2) offering home and community-based services to specific, targeted populations

Creates an optional eligibility category to provide full Medicaid benefits to individuals receiving home and community-based services under a state plan amendment.

(Sec. 2403) Amends the Deficit Reduction Act of 2005 to: (1) extend through FY2016 the Money Follows the Person Rebalancing Demonstration; and (2) reduce to 90 days the institutional residency period.

(Sec. 2404) Applies Medicaid eligibility criteria to recipients of home and community-based services, during calendar 2014 through 2019, in such a way as to protect against spousal impoverishment.

(Sec. 2405) Makes appropriations for FY2010-FY2014 to the Secretary, acting through the Assistant Secretary for Aging, to expand state aging and disability resource centers.

(Sec. 2406) Expresses the sense of the Senate that: (1) during the 111th session of Congress, Congress should address long-term services and supports in a comprehensive way that guarantees elderly and disabled individuals the care they need; and (2) long-term services and supports should be made available in the community in addition to institutions.

Subtitle F: Medicaid Prescription Drug Coverage - (Sec. 2501) Amends SSA title XIX (Medicaid) to: (1) increase the minimum rebate percentage for single source drugs and innovator multiple source drugs; (2) increase the rebate for other drugs; (3) require contracts with Medicaid managed care organizations to extend prescription drug rebates (discounts) to their enrollees; (4) provide an additional rebate for new formulations of existing drugs; and (5) set a maximum rebate amount.

(Sec. 2502) Eliminates the exclusion from Medicaid coverage of, thereby extending coverage to, certain drugs used to promote smoking cessation, as well as barbiturates and benzodiazepines.

(Sec. 2503) Revises requirements with respect to pharmacy reimbursements.

Subtitle G: Medicaid Disproportionate Share Hospital (DSH) Payments - (Sec. 2551, as modified by Sec. 10201) Reduces state disproportionate share hospital (DSH) allotments, except for Hawaii, by 50% or 35% once a state's uninsured rate decreases by 45%, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Requires a reduction of only 25% or 17.5% for low DSH states, depending on whether they have spent at least or more than 99.9% of their allotments on average during FY2004-FY2008. Prescribes allotment reduction requirements for subsequent fiscal years.

Revises DSH allotments for Hawaii for the last three quarters of FY2012 and for FY2013 and succeeding fiscal years.

Subtitle H: Improved Coordination for Dual Eligible Beneficiaries - (Sec. 2601) Declares that any Medicaid waiver for individuals dually eligible for both Medicaid and Medicare may be conducted for a period of five years, with a five-year extension, upon state request, unless the Secretary determines otherwise for specified reasons.

(Sec. 2602) Directs the Secretary to establish a Federal Coordinated Health Care Office to bring together officers and employees of the Medicare and Medicaid programs at the Centers for Medicare and Medicaid Services (CMS) to: (1) integrate Medicaid and Medicare benefits more effectively; and (2) improve the coordination between the federal government and states for dual eligible individuals to ensure that they get full access to the items and services to which they are entitled.

Subtitle I: Improving the Quality of Medicaid for Patients and Providers - (Sec. 2701) Amends SSA title XI, as modified by CHIPRA, to direct the Secretary to: (1) identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults; and (2) establish a Medicaid Quality Measurement Program.

(Sec. 2702) Requires the Secretary to identify current state practices that prohibit payment for health care-acquired conditions and to incorporate them, or elements of them, which are appropriate for application in regulations to the Medicaid program. Requires such regulations to prohibit payments to states for any amounts expended for providing medical assistance for specified health care-acquired conditions.

(Sec. 2703) Gives states the option to provide coordinated care through a health home for individuals with chronic conditions. Authorizes the Secretary to award planning grants to states to develop a state plan amendment to that effect.

(Sec. 2704) Directs the Secretary to establish a demonstration project to evaluate the use of bundled payments for the provision of integrated care for a Medicaid beneficiary: (1) with respect to an episode of care that includes a hospitalization; and (2) for concurrent physicians services provided during a hospitalization.

(Sec. 2705) Requires the Secretary to establish a Medicaid Global Payment System Demonstration Project under which a participating state shall adjust payments made to an eligible safety net hospital or network from a fee-for-service payment structure to a global capitated payment model. Authorizes appropriations.

(Sec. 2706) Directs the Secretary to establish the Pediatric Accountable Care Organization Demonstration Project to authorize a participating state to allow pediatric medical providers meeting

specified requirements to be recognized as an accountable care organization for the purpose of receiving specified incentive payments. Authorizes appropriations.

(Sec. 2707) Requires the Secretary to establish a three-year Medicaid emergency psychiatric demonstration project. Makes appropriations for FY2011.

Subtitle J: Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC) - (Sec. 2801) Revises requirements with respect to the Medicaid and CHIP Payment and Access Commission (MACPAC) and the Medicare Payment Advisory Commission (MEDPAC), including those for MACPAC membership, topics to be reviewed, and MEDPAC review of Medicaid trends in spending, utilization, and financial performance.

Requires MACPAC and MEDPAC to consult with one another on related issues.

Makes appropriations to MACPAC for FY2010.

Subtitle K: Protections for American Indians and Alaska Natives - (Sec. 2901) Sets forth special rules relating to Indians.

Declares that health programs operated by the Indian Health Service (IHS), Indian tribes, tribal organizations, and Urban Indian organizations shall be the payer of last resort for services they provide to eligible individuals.

Makes such organizations Express Lane agencies for determining Medicaid and CHIP eligibility.

(Sec. 2902) Makes permanent the requirement that the Secretary reimburse certain Indian hospitals and clinics for all Medicare part B services.

Subtitle L: Maternal and Child Health Services - (Sec. 2951) Amends SSA title V (Maternal and Child Health Services) to direct the Secretary to make grants to eligible entities for early childhood home visitation programs. Makes appropriations for FY2010-FY2014.

(Sec. 2952) Encourages the Secretary to continue activities on postpartum depression or postpartum psychosis, including research to expand the understanding of their causes and treatment.

Authorizes the Secretary to make grants to eligible entities for projects to establish, operate, and coordinate effective and cost-efficient systems for the delivery of essential services to individuals with or at risk for postpartum conditions and their families. Authorizes appropriations for FY2010-FY2012.

(Sec. 2953, as modified by Sec. 10201) Directs the Secretary to allot funds to states to award grants to local organizations and other specified entities to carry out personal responsibility education programs to educate adolescents on both abstinence and contraception for the prevention of pregnancy and sexually transmitted infections, as well as on certain adulthood preparation subjects. Makes appropriations for FY2010-FY2014.

(Sec. 2954) Makes appropriations for FY2010-FY2014 for abstinence education.

(Sec. 2955) Requires the case review system for children aging out of foster care and independent living programs to include information about the importance of having a health care power of attorney in transition planning.

Title III: Improving the Quality and Efficiency of Health Care - Subtitle A: Transforming the Health Care Delivery System - Part I: Linking Payment to Quality Outcomes under the Medicare Program - (Sec. 3001) Amends SSA title XVIII (Medicare) to direct the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet specified performance standards for a certain performance period.

Directs the Secretary to establish value-based purchasing demonstration programs for: (1) inpatient critical access hospital services; and (2) hospitals excluded from the program because of insufficient numbers of measures and cases.

(Sec. 3002) Extends through 2013 the authority for incentive payments under the physician quality reporting system. Prescribes an incentive (penalty) for providers who do not report quality measures satisfactorily, beginning in 2015.

Requires the Secretary to integrate reporting on quality measures with reporting requirements for the meaningful use of electronic health records.

(Sec. 3003) Requires specified new types of reports and data analysis under the physician feedback program.

(Sec. 3004) Requires long-term care hospitals, inpatient rehabilitation hospitals, and hospices, starting in rate year 2014, to submit data on specified quality measures. Requires reduction of the annual update of entities which do not comply.

(Sec. 3005) Directs the Secretary, starting FY2014, to establish quality reporting programs for inpatient cancer hospitals exempt from the prospective payment system.

(Sec. 3006, as modified by Sec. 10301) Directs the Secretary to develop a plan to implement value-based purchasing programs for Medicare payments for skilled nursing facilities (SNFs), home health agencies, and ambulatory surgical centers.

(Sec. 3007) Directs the Secretary to establish a value-based payment modifier, under the physician fee schedule, based upon the quality of care furnished compared to cost.

(Sec. 3008) Subjects hospitals to a penalty adjustment to hospital payments for high rates of hospital acquired conditions.

Part II: National Strategy to Improve Health Care Quality - (Sec. 3011, as modified by Sec. 10302) Amends the Public Health Service Act to direct the Secretary, through a transparent collaborative process, to establish a National Strategy for Quality Improvement in health care services, patient health outcomes, and population health, taking into consideration certain limitations on the use of comparative effectiveness data.

(Sec. 3012) Directs the President to convene an Interagency Working Group on Health Care Quality.

(Sec. 3013, as modified by Sec. 10303) Directs the Secretary, at least triennially, to identify gaps where no quality measures exist as well as existing quality measures that need improvement, updating, or expansion, consistent with the national strategy for use in federal health programs.

Directs the Secretary to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding such quality measures.

Requires the Secretary to develop and update periodically provider-level outcome measures for hospitals and physicians, as well as other appropriate providers.

(Sec. 3014, as modified by Sec. 10304) Requires the convening of multi-stakeholder groups to provide input into the selection of quality and efficiency measures.

(Sec. 3015, as modified by Sec. 10305) Directs the Secretary to: (1) establish an overall strategic framework to carry out the public reporting of performance information; and (2) collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery. Authorizes the Secretary to award grants for such purpose.

Directs the Secretary to make available to the public, through standardized Internet websites, performance information summarizing data on quality measures.

Part III: Encouraging Development of New Patient Care Models - (Sec. 3021, as modified by Sec. 10306) Creates within CMS a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Makes appropriations for FY2010-FY2019.

(Sec. 3022, as modified by Sec. 10307) Directs the Secretary to establish a shared savings program that: (1) promotes accountability for a patient population; (2) coordinates items and services under Medicare parts A and B; and (3) encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(Sec. 3023, as modified by Sec. 10308) Directs the Secretary to establish a pilot program for integrated care (involving payment bundling) during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.

(Sec. 3024) Directs the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to applicable beneficiaries.

(Sec. 3025, as modified by Sec. 10309) Requires the Secretary to establish a hospital readmissions reduction program involving certain payment adjustments, effective for discharges on or after October 1, 2012, for certain potentially preventable Medicare inpatient hospital readmissions.

Directs the Secretary to make available a program for hospitals with a high severity adjusted readmission rate to improve their readmission rates through the use of patient safety organizations.

(Sec. 3026) Directs the Secretary to establish a Community-Based Care Transitions Program which provides funding to eligible entities that furnish improved care transitions services to high-risk Medicare beneficiaries.

(Sec. 3027) Amends the Deficit Reduction Act of 2005 to extend certain Gainsharing Demonstration Projects through FY2011.

Subtitle B: Improving Medicare for Patients and Providers - Part 1: Ensuring Beneficiary Access to Physician Care and Other Services - (Sec. 3101, deleted by section 10310) (Sec. 3102) Extends through calendar 2010 the floor on geographic indexing adjustments to the work portion of the physician fee schedule. Revises requirements for calculation of the practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011. Directs the Secretary to analyze current methods of establishing practice expense geographic adjustments and make appropriate further adjustments (a new methodology) to such adjustments for 2010 and subsequent years.

(Sec. 3103) Extends the process allowing exceptions to limitations on medically necessary therapy caps through December 31, 2010.

(Sec. 3104) Amends the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to extend until January 1, 2010, an exception to a payment rule that permits laboratories to receive direct Medicare reimbursement when providing the technical component of certain physician pathology services that had been outsourced by certain (rural) hospitals.

(Sec. 3105, as modified by Sec. 10311) Amends SSA title XVIII (Medicare) to extend the bonus and increased payments for ground ambulance services until January 1, 2011.

Amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to extend the payment of certain urban air ambulance services until January 1, 2011.

(Sec. 3106, as modified by Sec. 10312) Amends the Medicare, Medicaid, and SCHIP Extension Act of 2007, as modified by the American Recovery and Reinvestment Act, to extend for two years: (1) certain payment rules for long-term care hospital services; and (2) a certain moratorium on the establishment of certain hospitals and facilities.

(Sec. 3107) Amends MIPPA to extend the physician fee schedule mental health add-on payment provision through December 31, 2010.

(Sec. 3108) Allows a physician assistant who does not have an employment relationship with a SNF, but who is working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.

(Sec. 3109) Amends title XVIII, as modified by MIPPA, to exempt certain pharmacies from accreditation requirements until the Secretary develops pharmacy-specific standards.

(Sec. 3110) Creates a special part B enrollment period for military retirees, their spouses (including widows/ widowers), and dependent children, who are otherwise eligible for TRICARE (the health care plan under the Department of Defense [DOD]) and entitled to Medicare part A (Hospital Insurance) based on disability or end stage renal disease, but who have declined Medicare part B (Supplementary Medical Insurance).

(Sec. 3111) Sets payments for dual-energy x-ray absorptiometry services in 2010 and 2011 at 70% of the 2006 reimbursement rates. Directs the Secretary to arrange with the Institute of Medicine of the National Academies to study and report to the Secretary and Congress on the ramifications of Medicare reimbursement reductions for such services on beneficiary access to bone mass measurement benefits.

(Sec. 3112) Eliminates funding in the Medicare Improvement Fund FY2014.

(Sec. 3113) Directs the Secretary to conduct a demonstration project under Medicare part B of separate payments for complex diagnostic laboratory tests provided to individuals.

(Sec. 3114) Increases from 65% to 100% of the fee schedule amount provided for the same service performed by a physician the fee schedule for certified-midwife services provided on or after January 1, 2011.

Part II: Rural Protections - (Sec. 3121) Extends through 2010 hold harmless provisions under the prospective payment system for hospital outpatient department services.

Removes the 100-bed limitation for sole community hospitals so all such hospitals receive an 85% increase in the payment difference in 2010.

(Sec. 3122) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as modified by other federal law, to extend from July 1, 2010, until July 1, 2011, the reasonable cost reimbursement for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds.

(Sec. 3123, as modified by Sec. 10313) Extends the Rural Community Hospital Demonstration Program for five additional years. Expands the maximum number of participating hospitals to 30, and to 20 the number of demonstration states with low population densities.

(Sec. 3124) Extends the Medicare-dependent Hospital Program through FY2012.

(Sec. 3125, as modified by Sec. 10314) Modifies the Medicare inpatient hospital payment adjustment for low-volume hospitals for FY2011-FY2012.

(Sec. 3126) Revises requirements for the Demonstration Project on Community Health Integration Models in Certain Rural Counties to allow additional counties as well as physicians to participate.

(Sec. 3127) Directs MEDPAC to study and report to Congress on the adequacy of payments for items and services furnished by service providers and suppliers in rural areas under the Medicare program.

(Sec. 3128) Allows a critical access hospital to continue to be eligible to receive 101% of reasonable costs for providing: (1) outpatient care regardless of the eligible billing method such hospital uses; and (2) qualifying ambulance services.

(Sec. 3129) Extends through FY2012 FLEX grants under the Medicare Rural Hospital Flexibility Program. Allows the use of grant funding to assist small rural hospitals to participate in delivery system reforms.

Part III: Improving Payment Accuracy - (Sec. 3131, as modified by Sec. 10315) Requires the Secretary, starting in 2014, to rebase home health payments by an appropriate percentage, among other things, to reflect the number, mix, and level of intensity of home health services in an episode, and the average cost of providing care.

Directs the Secretary to study and report to Congress on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically

underserved areas, and in treating beneficiaries with varying levels of severity of illness. Authorizes a Medicare demonstration project based on the study results.

(Sec. 3132) Requires the Secretary, by January 1, 2011, to begin collecting additional data and information needed to revise payments for hospice care.

Directs the Secretary, not earlier than October 1, 2013, to implement, by regulation, budget neutral revisions to the methodology for determining hospice payments for routine home care and other services, which may include per diem payments reflecting changes in resource intensity in providing such care and services during the course of an entire episode of hospice care.

Requires the Secretary to impose new requirements on hospice providers participating in Medicare, including requirements for: (1) a hospice physician or nurse practitioner to have a face-to-face encounter with the individual regarding eligibility and recertification; and (2) a medical review of any stays exceeding 180 days, where the number of such cases exceeds a specified percentage of them for all hospice programs.

(Sec. 3133, as modified by Sec. 10316) Specifies reductions to Medicare DSH payments for FY2015 and ensuing fiscal years, especially to subsection (d) hospitals, to reflect lower uncompensated care costs relative to increases in the number of insured. (Generally, a subsection [d] hospital is an acute care hospital, particularly one that receives payments under Medicare's inpatient prospective payment system when providing covered inpatient services to eligible beneficiaries.)

(Sec. 3134) Directs the Secretary periodically to identify physician services as being potentially misvalued and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.

(Sec. 3135) Increases the presumed utilization rate for calculating the payment for advanced imaging equipment other than low-tech imaging such as ultrasound, x-rays and EKGs.

Increases the technical component payment "discount" for sequential imaging services on contiguous body parts during the same visit.

(Sec. 3136) Restricts the lump-sum payment option for new or replacement chairs to the complex, rehabilitative power-driven wheelchairs only. Eliminates the lump-sum payment option for all other power-driven wheelchairs. Makes the rental payment for power-driven wheelchairs 15% of the purchase price for each of the first three months (instead of 10%), and 6% of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5%).

(Sec. 3137, as modified by Sec. 10317) Amends the Tax Relief and Health Care Act of 2006, as modified by other federal law, to extend "Section 508" hospital reclassifications until September 30, 2010, with a special rule for FY2010. ("Section 508" refers to Section 508 of the Medicare Modernization Act of 2003, which allows the temporary reclassification of a hospital with a low Medicare area wage index, for reimbursement purposes, to a nearby location with a higher Medicare area wage index, so that the "Section 508 hospital" will receive the higher Medicare reimbursement rate.)

Directs the Secretary to report to Congress a plan to reform the hospital wage index system.

(Sec. 3138) Requires the Secretary to determine if the outpatient costs incurred by inpatient prospective payment system-exempt cancer hospitals, including those for drugs and biologicals, with respect to Medicare ambulatory payment classification groups, exceed those costs incurred by other hospitals reimbursed under the outpatient prospective payment system (OPPS). Requires the Secretary, if this is so, to provide for an appropriate OPPS adjustment to reflect such higher costs for services furnished on or after January 1, 2011.

(Sec. 3139) Allows a biosimilar biological product to be reimbursed at 6% of the average sales price of the brand biological product.

(Sec. 3140) Directs the Secretary to establish a Medicare Hospice Concurrent Care demonstration program under which Medicare beneficiaries are furnished, during the same period, hospice care and any other Medicare items or services from Medicare funds otherwise paid to such hospice programs.

(Sec. 3141) Requires application of the budget neutrality requirement associated with the effect of the imputed rural floor on the area wage index under the Balanced Budget Act of 1997 through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.

(Sec. 3142) Directs the Secretary to study and report to Congress on the need for an additional payment for urban Medicare-dependent hospitals for inpatient hospital services under Medicare.

(Sec. 3143) Declares that nothing in this Act shall result in the reduction of guaranteed home health benefits under the Medicare program.

Subtitle C: Provisions Relating to Part C - (Sec. 3201, as modified by Sec. 10318) Bases the MedicareAdvantage (MA) benchmark on the average of the bids from MA plans in each market.

Revises the formula for calculating the annual Medicare+Choice capitation rate to reduce the national MA per capita Medicare+Choice growth percentage used to increase benchmarks in 2011.

Increases the monthly MA plan rebates from 75% to 100% of the average per capita savings.

Requires that bid information which MA plans are required to submit to the Secretary be certified by a member of the American Academy of Actuaries and meet actuarial guidelines and rules established by the Secretary.

Directs the Secretary, acting through the CMS Chief Actuary, to establish actuarial guidelines for the submission of bid information and bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

Directs the Secretary to: (1) establish new MA payment areas for urban areas based on the Core Based Statistical Area; and (2) make monthly care coordination and management performance bonus payments, quality performance bonus payments, and quality bonuses for new and low enrollment MA plans, to MA plans that meet certain criteria.

Directs the Secretary to provide transitional rebates for the provision of extra benefits to enrollees.

(Sec. 3202) Prohibits MA plans from charging beneficiaries cost sharing for chemotherapy administration services, renal dialysis services, or skilled nursing care that is greater than what is charged under the traditional fee-for-service program.

Requires MA plans to apply the full amount of rebates, bonuses, and supplemental premiums according to the following order: (1) reduction of cost sharing, (2) coverage of preventive care and wellness benefits, and (3) other benefits not covered under the original Medicare fee-for-service program.

(Sec. 3203) Requires the Secretary to analyze the differences in coding patterns between MA and the original Medicare fee-for-service programs. Authorizes the Secretary to incorporate the results of the analysis into risk scores for 2014 and subsequent years.

(Sec. 3204) Allows beneficiaries to disenroll from an MA plan and return to the traditional Medicare fee-for-service program from January 1 to March 15 of each year.

Revises requirements for annual beneficiary election periods.

(Sec. 3205) Amends SSA title XVIII (Medicare), as modified by MIPPA, to extend special needs plan (SNP) authority through December 31, 2013.

Authorizes the Secretary to establish a frailty payment adjustment under PACE payment rules for fully-integrated, dual-eligible SNPs.

Extends authority through calendar 2012 for SNPs that do not have contracts with state Medicaid programs to continue to operate, but not to expand their service areas.

Directs the Secretary to require an MA organization offering a specialized MA plan for special needs individuals to be approved by the National Committee for Quality Assurance.

Requires the Secretary to use a risk score reflecting the known underlying risk profile and chronic health status of similar individuals, instead of the default risk score, for new enrollees in MA plans that are not specialized MA SNPs.

(Sec. 3206) Extends through calendar 2012 the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

(Sec. 3208) Creates a new type of MA plan called an MA Senior Housing Facility Plan, which would be allowed to limit its service area to a senior housing facility (continuing care retirement community) within a geographic area.

(Sec. 3209) Declares that the Secretary is not required to accept any or every bid submitted by an MA plan or Medicare part D prescription drug plan that proposes to increase significantly any beneficiary cost sharing or decrease benefits offered.

(Sec. 3210) Directs the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new standards for certain Medigap plans.

Subtitle D: Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans - (Sec. 3301) Amends Medicare part D (Voluntary Prescription Drug Benefit Program) to establish conditions for the availability of coverage for part D drugs. Requires the manufacturer to participate in the Medicare coverage gap discount program. Directs the Secretary to establish such a program.

(Sec. 3302) Excludes the MA rebate amounts and quality bonus payments from calculation of the regional low-income subsidy benchmark premium for MA monthly prescription drug beneficiaries.

(Sec. 3303) Directs the Secretary to permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is *de minimis*. Provides that, if such premium is waived, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

Authorizes the Secretary to auto-enroll subsidy eligible individuals in plans that waive *de minimis* premiums.

(Sec. 3304) Sets forth a special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an eligible couple to delay redetermination of eligibility for one year after the death of a spouse.

(Sec. 3305) Directs the Secretary, in the case of a subsidy eligible individual enrolled in one prescription drug plan but subsequently reassigned by the Secretary to a new prescription drug plan, to provide the individual with: (1) information on formulary differences between the individual's former plan and the new plan with respect to the individual's drug regimens; and (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

(Sec. 3306) Amends MIPPA to provide additional funding for FY2010-FY2012 for outreach and education activities related to specified Medicare low-income assistance programs.

(Sec. 3307) Authorizes the Secretary to identify classes of clinical concern through rulemaking, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Requires prescription drug plan sponsors to include all drugs in these classes in their formularies.

(Sec. 3308) Requires part D enrollees who exceed certain income thresholds to pay higher premiums. Revises the current authority of the IRS to disclose income information to the Social Security Administration for purposes of adjusting the part B subsidy.

(Sec. 3309) Eliminates cost sharing for certain dual eligible individuals receiving care under a home and community-based waiver program who would otherwise require institutional care.

(Sec. 3310) Directs the Secretary to require sponsors of prescription drug plans to utilize specific, uniform techniques for dispensing covered part D drugs to enrollees who reside in an long-term care facility in order to reduce waste associated with 30-day refills.

(Sec. 3311) Directs the Secretary to develop and maintain an easy to use complaint system to collect and maintain information on MA-PD plan and prescription drug complaints received by the Secretary until the complaint is resolved.

(Sec. 3312) Requires a prescription drug plan sponsor to: (1) use a single, uniform exceptions and appeals process for determination of a plan enrollee's prescription drug coverage; and (2) provide instant access to this process through a toll-free telephone number and an Internet website.

(Sec. 3313) Requires the HHS Inspector General to study and report to Congress on the inclusion in formularies of: (1) drugs commonly used by dual eligibles; and (2) prescription drug prices under Medicare part D and Medicaid.

(Sec. 3314) Allows the costs incurred by AIDS drug assistance programs and by IHS in providing prescription drugs to count toward the annual out-of-pocket threshold.

(Sec. 3315) Increases by $500 the 2010 standard initial coverage limit (thus decreasing the time that a part D enrollee would be in the coverage gap).

Subtitle E: Ensuring Medicare Sustainability - (Sec. 3401, as modified by Sec. 10319 and Sec. 10322) Revises certain market basket updates and incorporates a full productivity adjustment into any updates that do not already incorporate such adjustments, including inpatient hospitals, home health providers, nursing homes, hospice providers, inpatient psychiatric facilities, long-term care hospitals, inpatient rehabilitation facilities, and Part B providers.

Establishes a quality measure reporting program for psychiatric hospitals beginning in FY2014.

(Sec. 3402) Revises requirements for reduction of the Medicare part B premium subsidy based on income. Maintains the current 2010 income thresholds for the period of 2011 through 2019.

(Sec. 3403, as modified by Sec. 10320) Establishes an Independent Payment Advisory Board to develop and submit detailed proposals to reduce the per capita rate of growth in Medicare spending to the President for Congress to consider. Establishes a consumer advisory council to advise the Board on the impact of payment policies under this title on consumers.

Subtitle F: Health Care Quality Improvements - (Sec. 3501) Amends the Public Health Service Act to direct the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to conduct or support activities for best practices in the delivery of health care services and support research on the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Authorizes appropriations for FY2010-FY2014.

Requires the AHRQ Director, through the AHRQ Center for Quality Improvement and Patient Safety, to award grants or contracts to eligible entities to provide technical support or to implement models and practices identified in the research conducted by the Center.

(Sec. 3502, as modified by Sec. 10321) Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

(Sec. 3503) Directs the Secretary, acting through the Patient Safety Research Center, to establish a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists, as a collaborative multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such disease.

(Sec. 3504) Directs the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award at least four multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

Requires the Secretary to support federal programs administered by the National Institutes of Health (NIH), the AHRQ, the Health Resources and Services Administration (HRSA), the CMS, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine.

Directs the Secretary to support federal programs administered by the such agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine.

Authorizes appropriations for FY2010-FY2014.

(Sec. 3505) Requires the Secretary to establish three programs to award grants to qualified public, nonprofit IHS, Indian tribal, and urban Indian trauma centers to: (1) assist in defraying substantial uncompensated care costs; (2) further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer; and (3) provide emergency relief to ensure the continued and future availability of trauma services. Authorizes appropriations for FY2010-FY2015.

Directs the Secretary to provide funding to states to enable them to award grants to eligible entities for trauma services. Authorizes appropriations for FY2010-FY2015.

(Sec. 3506) Directs the Secretary to: (1) establish a program to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients; (2) establish a program to provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options; and (3) award grants for establishment and support of Shared Decisionmaking Resource Centers. Authorizes appropriations for FY2010 and subsequent fiscal years.

(Sec. 3507) Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve heath care decisionmaking by clinicians and patients and consumers.

(Sec. 3508) Authorizes the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical education of health professionals.

(Sec. 3509) Establishes an Office on Women's Health within the Office of the Secretary, the Office of the Director of the Centers for Disease Control and Prevention (CDC), the Office of the AHRQ Director, the Office of the Administrator of HRSA, and the Office of the Commissioner of Food and Drugs.

Authorizes appropriations for FY2010-FY2014 for all such Offices on Women's Health.

(Sec. 3510) Extends from three years to four years the duration of a patient navigator grant.

Prohibits the Secretary from awarding such a grant unless the recipient entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies tailored for the main focus or intervention of the navigator involved.

Authorizes appropriations for FY2010-FY2015.

(Sec. 3511) Authorizes appropriations to carry out this title, except where otherwise provided in the title.

(Sec. 3512, as added by Sec. 10201) Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any guideline or other standards under specified provisions of this Act would result in the establishment of a new cause of action or claim.

Subtitle G: Protecting and Improving Guaranteed Medicare Benefits - (Sec. 3601) Provides that nothing in this Act shall result in a reduction of guaranteed benefits under the Medicare program.

States that savings generated for the Medicare program under this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.

(Sec. 3602) Declares that nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in MA plans.

Title IV: Prevention of Chronic Disease and Improving Public Health - Subtitle A: Modernizing Disease Prevention and Public Health Systems - (Sec. 4001, as modified by Sec. 10401) Requires the President to: (1) establish the National Prevention, Health Promotion and Public Health Council; (2) establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; and (3) appoint the Surgeon General as Chairperson of the Council in order to develop a national prevention, health promotion, and public health strategy.

Requires the Secretary and the Comptroller General to conduct periodic reviews and evaluations of every federal disease prevention and health promotion initiative, program, and agency.

(Sec. 4002, as modified by Sec. 10401) Establishes a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Authorizes appropriations and appropriates money to such Fund.

(Sec. 4003) Requires (currently, allows) the Director of AHRQ to convene the Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community.

Requires the Director of CDC to convene an independent Community Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations for individuals and organizations delivering populations-based services and other policy makers

(Sec. 4004, as modified by Sec. 10401) Requires the Secretary to provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.

Requires the Secretary, acting through the Director of CDC, to: (1) establish and implement a national science-based media campaign on health promotion and disease prevention; and (2) enter into a contract for the development and operation of a federal website personalized prevention plan tool.

Subtitle B: Increasing Access to Clinical Preventive Services - (Sec. 4101, as modified by Sec. 10402) Requires the Secretary to establish a program to award grants to eligible entities to support the operation of school-based health centers.

(Sec. 4102) Requires the Secretary, acting through the Director of CDC, to carry out oral health activities, including: (1) establishing a national public education campaign that is focused on oral health care prevention and education; (2) awarding demonstration grants for research-based dental caries disease management activities; (3) awarding grants for the development of school-based dental sealant programs; and (4) entering into cooperative agreements with state, territorial, and Indian tribes or tribal organizations for oral health data collection and interpretation, a delivery system for oral health, and science-based programs to improve oral health.

Requires the Secretary to: (1) update and improve the Pregnancy Risk Assessment Monitoring System as it relates to oral health care; (2) develop oral health care components for inclusion in the National Health and Nutrition Examination Survey; and (3) ensure that the Medical Expenditures Panel Survey by AHRQ includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(Sec. 4103, as modified by Sec. 10402) Amends SSA title XVIII (Medicare) to provide coverage of personalized prevention plan services, including a health risk assessment, for individuals. Prohibits cost-sharing for such services.

(Sec. 4104, as modified by Sec. 10406) Eliminates cost-sharing for certain preventive services recommended by the United States Preventive Services Task Force.

(Sec. 4105) Authorizes the Secretary to modify Medicare coverage of any preventive service consistent with the recommendations of such Task Force.

(Sec. 4106) Amends SSA title XIX (Medicaid) to provide Medicaid coverage of preventive services and approved vaccines. Increases the FMAP for such services and vaccines.

(Sec. 4107) Provides for Medicaid coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women.

(Sec. 4108) Requires the Secretary to award grants to states to carry out initiatives to provide incentives to Medicaid beneficiaries who participate in programs to lower health risk and demonstrate changes in health risk and outcomes.

Subtitle C: Creating Healthier Communities - (Sec. 4201, as modified by Sec. 10403) Requires the Secretary, acting through the Director of CDC, to award grants to state and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base of effective prevention programming.

(Sec. 4202) Requires the Secretary, acting through the Director of CDC, to award grants to state or local health departments and Indian tribes to carry out pilot programs to provide public health community interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age.

Requires the Secretary to: (1) conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries; and (2) evaluate community prevention and wellness programs that have demonstrated potential to help Medicare beneficiaries reduce their risk of disease, disability, and injury by making healthy lifestyle choices.

(Sec. 4203) Amends the Rehabilitation Act of 1973 to require the Architectural and Transportation Barriers Compliance Board to promulgate standards setting forth the minimum technical criteria for medical diagnostic equipment used in medical settings to ensure that such equipment is accessible to, and usable by, individuals with accessibility needs.

(Sec. 4204) Authorizes the Secretary to negotiate and enter into contracts with vaccine manufacturers for the purchase and delivery of vaccines for adults. Allows a state to purchase additional quantities of adult vaccines from manufacturers at the applicable price negotiated by the Secretary. Requires the Secretary, acting through the Director of CDC, to establish a demonstration program to award grants to states to improve the provision of recommended immunizations for children and adults through the use of evidence-based, population-based interventions for high-risk populations.

Reauthorizes appropriations for preventive health service programs to immunize children and adults against vaccine-preventable diseases without charge.

Requires the Comptroller General to study the ability of Medicare beneficiaries who are 65 years or older to access routinely recommended vaccines covered under the prescription drug program since its establishment.

(Sec. 4205) Amends the Federal Food, Drug, and Cosmetic Act to require the labeling of a food item offered for sale in a retail food establishment that is part of a chain with 20 or more locations under the same name to disclose on the menu and menu board: (1) the number of calories contained in the standard menu item; (2) the suggested daily caloric intake; and (3) the availability on the premises and upon request of specified additional nutrient information. Requires self-service facilities to place adjacent to each food offered a sign that lists calories per displayed food item or per serving. Requires vending machine operators who operate 20 or more vending machines to provide a sign disclosing the number of calories contained in each article of food.

(Sec. 4206) Requires the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers an individualized wellness plan designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(Sec. 4207) Amends the Fair Labor Standards Act of 1938 to require employers to provide a reasonable break time and a suitable place, other than a bathroom, for an employee to express breast milk for her nursing child. Excludes an employer with fewer than 50 employees if such requirements would impose an undue hardship.

Subtitle D: Support for Prevention and Public Health Innovation - (Sec. 4301) Requires the Secretary, acting through the Director of CDC, to provide funding for research in the area of public health services and systems.

(Sec. 4302) Requires the Secretary to ensure that any federally conduced or supported health care or public health program, activity, or survey collects and reports specified demographic data regarding health disparities.

Requires the Secretary, acting through the National Coordinator for Health Information Technology, to develop: (1) national standards for the management of data collected; and (2) interoperability and security systems for data management.

(Sec. 4303, as modified by Sec. 10404) Requires the Director of CDC to: (1) provide employers with technical assistance, consultation, tools, and other resources in evaluating employer-based wellness programs; and (2) build evaluation capacity among workplace staff by training employers on how to evaluate such wellness programs and ensuring that evaluation resources, technical assistance, and consultation are available.

Requires the Director of CDC to conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(Sec. 4304) Requires the Secretary, acting through the Director of CDC, to establish an Epidemiology and Laboratory Capacity Grant Program to award grants to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance.

(Sec. 4305) Requires the Secretary to: (1) enter into an agreement with the Institute of Medicine to convene a Conference on Pain, the purposes of which shall include to increase the recognition of pain as a significant public health problem in the United States; and (2) establish the Interagency Pain Research Coordinating Committee.

(Sec. 4306) Appropriates funds to carry out childhood obesity demonstration projects.

Subtitle E: Miscellaneous Provisions - (Sec. 4402) Requires the Secretary to evaluate programs to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals.

Title V: Health Care Workforce - Subtitle A: Purpose and Definitions - (Sec. 5001) Declares that the purpose of this title is to improve access to and the delivery of health care services for all individuals, particularly low-income, underserved, uninsured, minority, health disparity, and rural populations.

Subtitle B: Innovations in the Health Care Workforce - (Sec. 5101, as modified by Sec. 10501) Establishes a National Health Care Workforce Commission to: (1) review current and projected health care workforce supply and demand; and (2) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies.

(Sec. 5102) Establishes a health care workforce development grant program.

(Sec. 5103) Requires the Secretary to establish the National Center for Health Care Workforce Analysis to provide for the development of information describing and analyzing the health care workforce and workforce related issues. Transfers the responsibilities and resources of the National Center for Health Workforce Analysis to the Center created under this section.

(Sec. 5104, as added by Sec. 10501) Establishes the Interagency Access to Health Care in Alaska Task Force to: (1) assess access to health care for beneficiaries of federal health care systems in Alaska; and (2) develop a strategy to improve delivery to such beneficiaries.

Subtitle C: Increasing the Supply of the Health Care Workforce - (Sec. 5201) Revises student loan repayment provisions related to the length of service requirement for the primary health care loan repayment program.

(Sec. 5202) Increases maximum amount of loans made by schools of nursing to students.

(Sec. 5203) Directs the Secretary to establish and carry out a pediatric specialty loan repayment program.

(Sec. 5204) Requires the Secretary to establish the Public Health Workforce Loan Repayment Program to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in federal, state, local, and tribal public health agencies.

(Sec. 5205) Amends the Higher Education Act of 1965 to expand student loan forgiveness to include allied health professionals employed in public health agencies.

(Sec. 5206) Includes public health workforce loan repayment programs as permitted activities under a grant program to increase the number of individuals in the public health workforce.

Authorizes the Secretary to provide for scholarships for mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(Sec. 5207) Authorizes appropriations for the National Health Service Corps Scholarship Program and the National Health Service Corps Loan Repayment Program.

(Sec. 5208) Requires the Secretary to award grants for the cost of the operation of nurse-managed health clinics.

(Sec. 5209) Eliminates the cap on the number of commissioned officers in the Public Health Service Regular Corps.

(Sec. 5210) Revises the Regular Corps and the Reserve Corps (renamed the Ready Reserve Corps) in the Public Health Service. Sets forth the uses of the Ready Reserve Corps.

Subtitle D: Enhancing Health Care Workforce Education and Training - (Sec. 5301) Sets forth provisions providing for health care professional training programs.

(Sec. 5302) Requires the Secretary to award grants for new training opportunities for direct care workers who are employed in long-term care settings.

(Sec. 5303) Sets forth provisions providing for dentistry professional training programs.

(Sec. 5304) Authorizes the Secretary to award grants for demonstration programs to establish training programs for alternative dental health care providers in order to increase access to dental health services in rural and other underserved communities.

(Sec. 5305) Requires the Secretary to award grants or contracts to entities that operate a geriatric education center to offer short-term, intensive courses that focus on geriatrics, chronic care management, and long-term care.

Expands geriatric faculty fellowship programs to make dentists eligible.

Reauthorizes and revises the geriatric education programs to allow grant funds to be used for the establishment of traineeships for individuals who are preparing for advanced education nursing degrees in areas that specialize in the care of elderly populations.

(Sec. 5306) Authorizes the Secretary to award grants to institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in, social work programs, psychology programs, child and adolescent mental health, and training of paraprofessional child and adolescent mental health workers.

(Sec. 5307) Authorizes the Secretary, acting through the Administrator of HRSA, to award grants, contracts, or cooperative agreements for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for health professions training in cultural competency, prevention, public health proficiency, reducing health disparities, and working with individuals with disabilities.

(Sec. 5308) Requires nurse-midwifery programs, in order to be eligible for advanced education nursing grants, to have as their objective the education of midwives and to be accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(Sec. 5309) Authorizes the Secretary to award grants or enter into contracts to enhance the nursing workforce by initiating and maintaining nurse retention programs.

(Sec. 5310) Makes nurse faculty at an accredited school of nursing eligible for the nursing education loan repayment program.

(Sec. 5311) Revises the nurse faculty loan repayment program, including to increase the amount of such loans.

Authorizes the Secretary, acting through the Administrator of HRSA, to enter into an agreement for the repayment of education loans in exchange for service as a member of a faculty at an accredited school of nursing.

(Sec. 5312) Authorizes appropriations for carrying out nursing workforce programs.

(Sec. 5313, as modified by Sec. 10501) Requires the Director of CDC to award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

(Sec. 5314) Authorizes the Secretary to carry out activities to address documented workforce shortages in state and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics.

(Sec. 5315) Authorizes the establishment of the United States Public Health Sciences Track, which is authorized to award advanced degrees in public health, epidemiology, and emergency preparedness and response.

Directs the Surgeon General to develop: (1) an integrated longitudinal plan for health professions continuing education; and (2) faculty development programs and curricula in decentralized venues of health care to balance urban, tertiary, and inpatient venues.

(Sec. 5316, as added by Sec. 10501) Requires the Secretary to establish a training demonstration program for family nurse practitioners to employ and provide one-year training for nurse practitioners serving as primary care providers in federally qualified health centers or nurse-managed health centers.

Subtitle E: Supporting the Existing Health Care Workforce - (Sec. 5401) Revises the allocation of funds to assist schools in supporting programs of excellence in health professions education for underrepresented minority individuals and schools designated as centers of excellence.

(Sec. 5402, as modified by Sec. 10501) Makes schools offering physician assistant education programs eligible for loan repayment for health profession faculty. Increases the amount of loan repayment for such program.

Authorizes appropriations for: (1) scholarships for disadvantaged students attending health professions or nursing schools; (2) loan repayment for health professions faculty; and (3) grants to health professions school to assist individuals from disadvantaged backgrounds.

(Sec. 5403) Requires the Secretary to: (1) make awards for area health education center programs; and (2) provide for timely dissemination of research findings using relevant resources.

(Sec. 5404) Makes revisions to the grant program to increase nursing education opportunities for individuals from disadvantaged backgrounds to include providing: (1) stipends for diploma or associate degree nurses to enter a bridge or degree completion program; (2) student scholarships or stipends for accelerated nursing degree programs; and (3) advanced education preparation.

(Sec. 5405, as modified by Sec. 10501) Requires the Secretary, acting through the Director of AHRQ, to establish a Primary Care Extension Program to provide support and assistance to educate primary care providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services, and evidence-based and evidence-informed therapies and techniques.

Requires the Secretary to award grants to states for the establishment of Primary Care Extension Program State Hubs to coordinate state health care functions with quality improvement organizations and area health education centers.

Subtitle F: Strengthening Primary Care and Other Workforce Improvements - (Sec. 5501, as modified by Sec. 10501) Requires Medicare incentive payments to: (1) primary care practitioners providing primary care services on or after January 1, 2011, and before January 1, 2016; and (2) general surgeons performing major surgical procedures on or after January 1, 2011, and before January 1, 2016, in a health professional shortage area.

(Sec. 5502, deleted by Sec. 10501)

(Sec. 5503) Reallocates unused residency positions to qualifying hospitals for primary care residents for purposes of payments to hospitals for graduate medical education costs.

(Sec. 5504) Revises provisions related to graduate medical education costs to count the time residents spend in nonprovider settings toward the full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of such residents during such time.

(Sec. 5505, as modified by Sec. 10501) Includes toward the determination of full-time equivalency for graduate medical education costs time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care in nonpatient care activities.

(Sec. 5506) Directs the Secretary, when a hospital with an approved medical residency program closes, to increase the resident limit for other hospitals based on proximity criteria.

(Sec. 5507) Requires the Secretary to: (1) award grants for demonstration projects that are designed to provide certain low-income individuals with the opportunity to obtain education and training for health care occupations that pay well and that are expected to experience labor shortages or be in high demand; and (2) award grants to states to conduct demonstration projects for purposes of developing core training competencies and certification programs for personal or home care aides.

Authorizes appropriations for FY2009-FY2012 for family-to-family health information centers.

(Sec. 5508) Authorizes the Secretary to award grants to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

Allows up to 50% of time spent teaching by a member of the National Health Service Corps to be considered clinical practice for purposes of fulfilling the service obligation.

Requires the Secretary to make payments for direct and indirect expenses to qualified teaching health centers for expansion or establishment of approved graduate medical residency training programs.

(Sec. 5509) Requires the Secretary to establish a graduate nurse education demonstration under which a hospital may receive payment for the hospital's reasonable costs for the provision of qualified clinical training to advance practice nurses.

Subtitle G: Improving Access to Health Care Services - (Sec. 5601) Reauthorizes appropriations for health centers to serve medically underserved populations.

(Sec. 5602) Requires the Secretary to establish through the negotiated rulemaking process a comprehensive methodology and criteria for designation of medically underserved populations and health professions shortage areas.

(Sec. 5603) Reauthorizes appropriations for FY2010-FY2014 for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care.

(Sec. 5604) Authorizes the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to award grants and cooperative agreements for demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

(Sec. 5605) Establishes a Commission on Key National Indicators to: (1) conduct comprehensive oversight of a newly established key national indicators system; and (2) make recommendations on how to improve such system. Directs the National Academy of Sciences to enable the establishment of such system by creating its own institutional capability or by partnering with an independent private nonprofit organization to implement such system. Directs the Comptroller General to study previous work conducted by all public agencies, private organizations, or foreign countries with respect to best practices for such systems.

(Sec. 5606, as added by Sec. 10501) Authorizes a state to award grants to health care providers who treat a high percentage of medically underserved populations or other special populations in the state.

Subtitle H: General Provisions - (Sec. 5701) Requires the Secretary to submit to the appropriate congressional committees a report on activities carried out under this title and the effectiveness of such activities.

Title VI: Transparency and Program Integrity - Subtitle A: Physician Ownership and Other Transparency - (Sec. 6001, as modified by Sec. 10601) Amends SSA title XVIII (Medicare) to prohibit physician-owned hospitals that do not have a provider agreement by August 1, 2010, to participate in Medicare. Allows their participation in Medicare under a rural provider and hospital exception to the ownership or investment prohibition if they meet certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.

(Sec. 6002) Amends SSA title XI to require drug, device, biological and medical supply manufacturers to report to the Secretary transfers of value made to a physician, physician medical practice, a physician group practice, and/or teaching hospital, as well as information on any physician ownership or investment interest in the manufacturer. Provides penalties for noncompliance. Preempts duplicative state or local laws.

(Sec. 6003) Amends SSA title XVIII (Medicare), with respect to the Medicare in-office ancillary exception to the prohibition against physician self-referrals, to require a referring physician to inform the patient in writing that the patient may obtain a specified imaging service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice. Requires the referring physician also to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

(Sec. 6004) Amends SSA title XI to require prescription drug manufacturers and authorized distributors of record to report to the Secretary specified information pertaining to drug samples.

(Sec. 6005) Amends SSA title XI to require a pharmacy benefit manager (PBM) or a health benefits plan that manages prescription drug coverage under a contract with a Medicare or Exchange health plan to report to the Secretary information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.

Subtitle B: Nursing Home Transparency and Improvement - Part I: Improving Transparency of Information - (Sec. 6101) Amends SSA title XI to require SNFs under Medicare and nursing facilities (NFs) under Medicaid to make available, upon request by the Secretary, the HHS Inspector

General, the states, or a state long-term care ombudsman, information on ownership of the SNF or NF, including a description of the facility's governing body and organizational structure, as well as information regarding additional disclosable parties.

(Sec. 6102) Requires SNFs and NFs to operate a compliance and ethics program effective in preventing and detecting criminal, civil, and administrative violations.

Directs the Secretary to establish and implement a quality assurance and performance improvement program for SNFs and NFs, including multi-unit chains of facilities.

(Sec. 6103) Amends SSA title XVIII (Medicare) to require the Secretary to publish on the Nursing Home Compare Medicare website: (1) standardized staffing data; (2) links to state websites regarding state survey and certification programs; (3) the model standardized complaint form; (4) a summary of substantiated complaints; and (5) the number of adjudicated instances of criminal violations by a facility or its employees.

(Sec. 6104) Requires SNFs to report separately expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(Sec. 6105) Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a state survey and certification agency and a state long-term care ombudsman program. Requires states to to establish complaint resolution processes.

(Sec. 6106) Amends SSA title XI to require the Secretary to develop a program for facilities to report direct care staffing information on payroll and other verifiable and auditable data in a uniform format based.

(Sec. 6107) Requires the Comptroller General to study and report to Congress on the Five-Star Quality Rating System for nursing homes of CMS.

Part II: Targeting Enforcement - (Sec. 6111) Amends SSA title XVIII (Medicare) to authorize the Secretary to reduce civil monetary penalties by 50% for certain SNFs and NFs that self-report and promptly correct deficiencies within 10 calendar days of imposition of the penalty. Directs the Secretary to issue regulations providing for an informal dispute resolution process after imposition of a penalty, as well as an escrow account for money penalties pending resolution of any appeals.

(Sec. 6112) Directs the Secretary to establish a demonstration project for developing, testing, and implementing a national independent monitor program to oversee interstate and large intrastate chains of SNFs and NFs.

(Sec. 6113) Requires the administrator of a SNF or a NF that is preparing to close to notify in writing residents, legal representatives of residents or other responsible parties, the Secretary, and the state long-term care ombudsman program in advance of the closure by at least 60 days. Requires the notice to include a plan for the transfer and adequate relocation of residents to another facility or alternative setting. Requires the state to ensure a successful relocation of residents.

(Sec. 6114) Requires the Secretary to conduct two SNF- and NF-based demonstration projects to develop best practice models in two areas: (1) one for facilities involved in the "culture change" movement; and (2) one for the use of information technology to improve resident care.

Part III: Improving Staff Training - (Sec. 6121) Requires SNFs and NFs to include dementia management and abuse prevention training as part of pre-employment initial training and, if appropriate, as part of ongoing in-service training for permanent and contract or agency staff.

Subtitle C: Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers - (Sec. 6201) Requires the Secretary to establish a nationwide program for national and state background checks on prospective direct patient access employees of long-term care facilities and providers.

Subtitle D: Patient-Centered Outcomes Research - (Sec. 6301, as modified by Sec. 10602) Amends SSA title XI to establish the Patient-Centered Outcomes Research Institute to identify priorities for, and establish, update, and carry out, a national comparative outcomes research project agenda. Provides for a peer review process for primary research.

Prohibits the Institute from allowing the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved by the Institute under a data use agreement.

Amends the Public Health Service Act to direct the Office of Communication and Knowledge Transfer at AHRQ to disseminate broadly the research findings published by the Institute and other government-funded research relevant to comparative clinical effective research.

Prohibits the Secretary from using evidence and findings from Institute research to make a determination regarding Medicare coverage unless such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

Amends the Internal Revenue Code to establish in the Treasury the Patient-Centered Outcomes Research Trust Fund. Directs the Secretary to make transfers to that Trust Fund from the Medicare Trust Funds.

Imposes annual fees of $2 times the number of insured lives on each specified health insurance policy and on self-insured health plans.

(Sec. 6302) Terminates the Federal Coordinating Council for Comparative Effectiveness Research upon enactment of this Act.

Subtitle E: Medicare, Medicaid, and CHIP Program Integrity Provisions - (Sec. 6401, as modified by Sec. 10603) Amends SSA title XVIII (Medicare) to require the Secretary to: (1) establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP; and (2) determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier.

Requires providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating

in a federal health care program; or (4) has had billing privileges revoked. Authorizes the Secretary to deny enrollment in a program if these affiliations pose an undue risk to it.

Requires providers and suppliers to establish a compliance program containing specified core elements.

Directs the CMS Administrator to establish a process for making available to each state agency with responsibility for administering a state Medicaid plan or a child health plan under SSA title XXI the identity of any provider or supplier under Medicare or CHIP who is terminated.

(Sec. 6402) Requires CMS to include in the integrated data repository claims and payment data from Medicare, Medicaid, CHIP, and health-related programs administered by the Departments of Veterans Affairs (VA) and DOD, the Social Security Administration, and IHS.

Directs the Secretary to enter into data-sharing agreements with the Commissioner of Social Security, the VA and DOD Secretaries, and the IHS Director to help identity fraud, waste, and abuse.

Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

Directs the Secretary to issue a regulation requiring all Medicare, Medicaid, and CHIP providers to include their National Provider Identifier on enrollment applications.

Authorizes the Secretary to withhold the federal matching payment to states for medical assistance expenditures whenever a state does not report enrollee encounter data in a timely manner to the state's Medicaid Management Information System.

Authorizes the Secretary to exclude providers and suppliers participation in any federal health care program for providing false information on any application to enroll or participate.

Subjects to civil monetary penalties excluded individuals who: (1) order or prescribe an item or service; (2) make false statements on applications or contracts to participate in a federal health care program; or (3) know of an overpayment and do not return it. Subjects the latter offense to civil monetary penalties of up to $50,000 or triple the total amount of the claim involved.

Authorizes the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question.

Requires the Secretary take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond. Authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Appropriates an additional $10 million, adjusted for inflation, to the Health Care Fraud and Abuse Control each of FY2011-FY2020. Applies inflation adjustments as well to Medicare Integrity Program funding.

Requires the Medicaid Integrity Program and Program contractors to provide the Secretary and the HHS Office of Inspector General with performance statistics, including the number and amount of

overpayments recovered, the number of fraud referrals, and the return on investment for such activities.

(Sec. 6403) Requires the Secretary to furnish the National Practitioner Data Bank (NPDB) with all information reported to the national health care fraud and abuse data collection program on certain final adverse actions taken against health care providers, suppliers, and practitioners.

Requires the Secretary to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in it is transferred to the NPDB.

(Sec. 6404) Reduces from three years to one year after the date of service the maximum period for submission of Medicare claims.

(Sec. 6405, as modified by Sec. 10604) Requires DME or home health services to be ordered by an enrolled Medicare eligible professional or physician. Authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

(Sec. 6406) Authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services.

Authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

(Sec. 6407, as modified by Sec. 10605) Requires a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant to have a face-to-face encounter with an individual before issuing a certification for home health services or DME.

Authorizes the Secretary to apply the same face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse. Applies the same requirement, as well, to physicians making certifications for home health services under Medicaid.

(Sec. 6408) Revises civil monetary penalties for making false statements or delaying inspections.

Applies specified enhanced sanctions and civil monetary penalties to MA or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent; (2) transfer an individual from one plan to another for the purpose of earning a commission; (3) fail to comply with marketing requirements and CMS guidance; or (4) employ or contract with an individual or entity that commits a violation.

(Sec. 6409) Requires the Secretary to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.

Authorizes the Secretary to reduce the amount due and owing for all violations of such law.

(Sec. 6410) Requires the Secretary to: (1) expand the number of areas to be included in round two of the competitive bidding program from 79 to 100 of the largest metropolitan statistical areas; and (2) use competitively bid prices in all areas by 2016.

(Sec. 6411) Requires states to establish contracts with one or more Recovery Audit Contractors (RACs), which shall identify underpayments and overpayments and recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

Requires the Secretary to expand the RAC program to Medicare parts C (Medicare+Choice) and D (Prescription Drug Program).

Subtitle F: Additional Medicaid Program Integrity Provisions - (Sec. 6501) Amends SSA title XIX (Medicaid) to require states to terminate individuals or entities (providers) from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.

(Sec. 6502) Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

(Sec. 6503) Requires state Medicaid plans to require any billing agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary.

(Sec. 6504) Requires states to submit data elements from the state mechanized claims processing and information retrieval system (under the Medicaid Statistical Information System) that the Secretary determines necessary for program integrity, program oversight, and administration.

Requires a Medicaid managed care entity contract to provide for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients (as under current law) at a frequency and level of detail to be specified by the Secretary.

(Sec. 6505) Requires a state Medicaid plan to prohibit the state from making any payments for items or services under a Medicaid state plan or a waiver to any financial institution or entity located outside of the United States.

(Sec. 6506) Extends the period for states to recover overpayments from 60 days to one year after discovery of the overpayment. Declares that, when overpayments due to fraud are pending, state repayments of the federal portion of such overpayments shall not be due until 30 days after the date of the final administrative or judicial judgment on the matter.

(Sec. 6507) Requires state mechanized Medicaid claims processing and information retrieval systems to incorporate methodologies compatible with Medicare's National Correct Coding Initiative.

Subtitle G: Additional Program Integrity Provisions - (Sec. 6601) Amends the Employee Retirement Income Security Act of 1974 (ERISA) to prohibit employees and agents of multiple employer welfare arrangements (MEWAs), subject to criminal penalties, from making false

statements in marketing materials regarding an employee welfare benefit plan's financial solvency, benefits, or regulatory status.

(Sec. 6603) Amends the Public Health Service Act to direct the Secretary to request NAIC to develop a model uniform report form for a private health insurance issuer seeking to refer suspected fraud and abuse to state insurance departments or other responsible state agencies for investigation.

(Sec. 6604) Amends ERISA to direct the Secretary of Labor to adopt regulatory standards and/or issue orders to subject MEWAs to state law relating to fraud and abuse.

(Sec. 6605) Authorizes the Secretary of Labor to: (1) issue cease-and-desist orders to shut down temporarily the operations of MEWAs conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed; and (2) seize a plan's assets if it appears that the plan is in a financially hazardous condition.

(Sec. 6606) Directs the Secretary of Labor to require MEWAs which are not group health plans to register with the Department of Labor before operating in a state.

(Sec. 6607) Authorizes the Secretary of Labor to promulgate a regulation providing an evidentiary privilege that allows confidential communication among specified federal and state officials relating to investigation of fraud and abuse.

Subtitle H: Elder Justice Act - Elder Justice Act of 2009 - (Sec. 6702) Amends SSA title XX (Block Grants to States for Social Services) with respect to elder abuse, neglect, and exploitation and their prevention. Requires the HHS Secretary to award grants and carry out activities that provide: (1) greater protection to those individuals seeking care in facilities that provide long-term care services and supports; and (2) greater incentives for individuals to train and seek employment at such facilities.

Requires facility owners, operators, and certain employees to report suspected crimes committed at a facility.

Requires facility owners or operators also to: (1) submit to the Secretary and to the state written notification of an impending closure of a facility within 60 days before the closure; and (2) include a plan for transfer and adequate relocation of all residents.

Establishes an Elder Justice Coordinating Council.

Subtitle I: Sense of the Senate Regarding Medical Malpractice - (Sec. 6801) Expresses the sense of the Senate that: (1) health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test alternative models to the existing civil litigation system; and (3) Congress should consider state demonstration projects to evaluate such alternatives.

Title VII: Improving Access to Innovative Medical Therapies - Subtitle A: Biologics Price Competition and Innovation - Biologics Price Competition and Innovation Act of 2009 - (Sec. 7002) Amends the Public Health Service Act to allow a person to submit an application for licensure of a biological product based on its similarity to a licensed biological product (the reference product).

Requires the Secretary to license the biological product if it is biosimilar to or interchangeable with the reference product.

Prohibits the Secretary from determining that a second or subsequent biological product is interchangeable with a reference product for any condition of use for specified periods based on the marketing of, and the presence or status of litigation involving, the first biosimilar biological product deemed interchangeable with the same reference product.

Prohibits the Secretary from making approval of an application under this Act effective until 12 years after the date on which the reference product was first licensed.

Subtitle B: More Affordable Medicine for Children and Underserved Communities - (Sec. 7101) Expands the 340B drug discount program (a program limiting the cost of covered outpatient drugs to certain federal grantees) to allow participation as a covered entity by certain: (1) children's hospitals; (2) freestanding cancer hospitals; (3) critical access hospitals; (4) rural referral centers; and (5) sole community hospitals. Expands the program to include drugs used in connection with an inpatient or outpatient service by enrolled hospitals (currently, only outpatient drugs are covered under the program).

Requires the Secretary to establish reasonable exceptions to the prohibition on enrolled hospitals obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, including for drugs unavailable through the program and to facilitate generic substitution when a generic covered drug is available at a lower price. Allows such hospitals to purchase covered drugs for inpatients through any such arrangement.

Requires a hospital enrolled in the 340B drug discount program to issue a credit to a state Medicaid program for inpatient covered drugs provided to Medicaid recipients.

(Sec. 7102) Requires the Secretary to: (1) provide for improvements in compliance by manufacturers and covered entities with the requirements of the 340B drug discount program; and (2) establish and implement an administrative process for resolving claims by covered entities and manufacturers of violations of such requirements.

Requires manufacturers to offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price.

(Sec. 7103) Requires the Comptroller General to report to Congress on whether those individuals served by the covered entities under the 340B drug discount program are receiving optimal health care services.

Title VIII: Class Act - Community Living Assistance Services and Supports Act or the CLASS Act - (Sec. 8002, as modified by Sec. 10801) Establishes a national, voluntary insurance program for purchasing community living assistance services and supports (CLASS program) under which: (1) all employees are automatically enrolled, but are allowed to waive enrollment; (2) payroll deductions pay monthly premiums; and (3) benefits under a CLASS Independence Benefit Plan provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community.

Title IX: Revenue Provisions - Subtitle A: Revenue Offset Provisions - (Sec. 9001, as modified by section 10901) Amends the Internal Revenue Code to impose an excise tax of 40% of the excess benefit from certain high cost employer-sponsored health coverage. Deems any amount which exceeds payment of $8,500 for an employee self-only coverage plan and $23,000 for employees with other than self-only coverage (family plans) as an excess benefit. Increases such amounts for certain retirees and employees who are engaged in high-risk professions (e.g., law enforcement officers, emergency medical first responders, or longshore workers). Imposes a penalty on employers and coverage providers for failure to calculate the proper amount of an excess benefit.

(Sec. 9002) Requires employers to include in the W-2 form of each employee the aggregate cost of applicable employer-sponsored group health coverage that is excludable from the employee's gross income (excluding the value of contributions to flexible spending arrangements).

(Sec. 9003) Restricts payments from health savings accounts, medical savings accounts, and health flexible spending arrangements for medications to prescription drugs or insulin.

(Sec. 9004) Increases to 20% the penalty for distributions from a health savings account or Archer medical savings account not used for qualified medical expenses.

(Sec. 9005, as modified by section 10902) Limits annual salary reduction contributions by an employee to a health flexible spending arrangement under a cafeteria plan to $2,500. Allows an annual inflation adjustment to such amount after 2011.

(Sec. 9006) Applies to corporations reporting requirements for payments of $600 or more to persons engaged in a trade or business.

(Sec. 9007, as modified by section 10903) Requires tax-exempt charitable hospitals to: (1) conduct a community health needs assessment every two years; (2) adopt a written financial assistance policy for patients who require financial assistance for hospital care; and (3) refrain from taking extraordinary collection actions against a patient until the hospital has made reasonable efforts to determine whether the patient is eligible for financial assistance. Imposes a penalty tax on hospitals who fail to comply with the requirements of this Act.

Requires the Secretary of the Treasury to report to Congress on information with respect to private tax-exempt, taxable, and government-owned hospitals regarding levels of charity care provided, bad debt expenses, unreimbursed costs, and costs for community benefit activities.

(Sec. 9008) Imposes an annual fee on the branded prescription drug sales exceeding $5 million of manufacturers and importers of such drugs beginning in 2010. Requires the HHS, VA, and DOD Secretaries to report to the Secretary of the Treasury on the total branded prescription drug sales within government programs within their departments.

(Sec. 9009, as modified by section 10904) Imposes an annual fee on the gross sales receipts exceeding $5 million of manufacturers and importers of certain medical devices beginning in 2011.

(Sec. 9010, as modified by section 10905) Imposes on any entity that provides health insurance for any United States health risk an annual fee beginning in 2011. Defines "United States health risk" as the health risk of an individual who is a U.S. citizen or resident or is located in the United States with respect to the period the individual is so located. Exempts entities whose net premiums written are

not more than $25 million. Requires all entities subject to such fee to report to the Secretary of the Treasury on their net written premiums and imposes a penalty for failure to report.

(Sec. 9011) Requires the VA Secretary to study and report to Congress by December 31, 2012, on the effect of fees assessed by this Act on the cost of medical care provided to veterans and on veterans' access to medical devices and branded prescription drugs.

(Sec. 9012) Eliminates the tax deduction for expenses for determining the subsidy for employers who maintain prescription drug plans for Medicare Part D eligible retirees.

(Sec. 9013) Increases the adjusted gross income threshold for claiming the itemized deduction for medical expenses from 7.5% to 10% beginning after 2012. Retains the 7.5% threshold through 2016 for individual taxpayers who have attained age 65 before the close of an applicable taxable year.

(Sec. 9014) Imposes a limitation after December 31, 2012, of $500,000 on the deductibility of remuneration paid to officers, directors, employees, and service providers of health insurance issuers who derive at least 25% of their gross premiums from providing health insurance coverage that meets the minimum essential coverage requirements established by this Act.

(Sec. 9015, as modified by section 10906) Increases after December 31, 2012, the hospital insurance tax rate by .9% for individual taxpayers earning over $200,000 ($250,000 for married couples filing joint tax returns).

(Sec. 9016) Requires Blue Cross or Blue Shield organizations or other nonprofit organizations that provide health insurance to reimburse at least 85% of the cost of clinical services provided to their enrollees to be eligible for special tax benefits currently provided to such organizations.

Subtitle B: Other Provisions - (Sec. 9021) Excludes from gross income the value of certain health benefits provided to members of Indian tribes, including: (1) health services or benefits provided or purchased by IHS; (2) medical care provided by an Indian tribe or tribal organization to a member of an Indian tribe; (3) accident or health plan coverage provided by an Indian tribe or tribal organization for medical care to a member of an Indian tribe and dependents; and (4) any other medical care provided by an Indian tribe that supplements, replaces, or substitutes for federal programs.

(Sec. 9022) Establishes a new employee benefit cafeteria plan to be known as a Simple Cafeteria Plan, defined as a plan that: (1) is established and maintained by an employer with an average of 100 or fewer employees during a two-year period; (2) requires employers to make contributions or match employee contributions to the plan; and (3) requires participating employees to have at least 1,000 hours of service for the preceding plan year; and (4) allows such employees to elect any benefit available under the plan.

(Sec. 9023) Allows a 50% tax credit for investment in any qualifying therapeutic discovery project, defined as a project that is designed to: (1) treat or prevent diseases by conducting pre-clinical activities, clinical trials, and clinical studies, or carrying out research projects to approve new drugs or other biologic products; (2) diagnose diseases or conditions to determine molecular factors related to diseases or conditions; or (3) develop a product, process, or technology to further the delivery or administration of therapeutics. Directs the Secretary of the Treasury to award grants for 50% of the investment in 2009 or 2010 in such a project, in lieu of the tax credit.

Title X: Strengthening Quality, Affordable Health Care for All Americans - Subtitle A: Provisions Relating to Title I - (Sec. 10101) Revises provisions of or related to Subtitles A, B, and C of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10104) Revises provisions of or related to Subtitle D of Title I of this Act (as reflected in the summary of those provisions). Makes changes to the False Claims Act related to the public disclosure bar on filing civil claims.

(Sec. 10105) Revises provisions of or related to Subtitles E, F, and G of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10108) Requires an offering employer to provide free choice vouchers to each qualified employee. Defines "offering employer" to mean any employer who offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan and who pays any portion of the costs of such plan. Defines "qualified employee" as an employee whose required contribution for such coverage and household income fall within a specified range. Requires: (1) a Health Insurance Exchange to credit the amount of any free choice voucher to the monthly premium of any qualified health plan in which the employee is enrolled; and (2) the offering employer to pay any amounts so credited to the Exchange. Excludes the amount of any free choice voucher from the gross income of the employee. Permits a deduction by employers for such costs.

(Sec. 10109) Amends the SSA to require the HHS Secretary to seek input to determine if there could be greater uniformity in financial and administrative health care activities and items.

Requires the Secretary to: (1) task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input regarding and recommend revisions to the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases; and (2) make appropriate revisions to such crosswalk.

Subtitle B: Provisions Relating to Title II - Part I: Medicaid and CHIP - (Sec. 10201) Revises provisions of Subtitles A through L of Title II of this Act (as reflected in the summary of those provisions).

Amends SSA title XIX (Medicaid) to set the FMAP for the state of Nebraska, with respect to all or any portion of a fiscal year that begins on or after January 1, 2017, at 100% (thus requiring the federal government to pay 100% of the cost of covering newly-eligible individuals in Nebraska).

Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any specified health care quality guideline or other standards would result in the establishment of a new cause of action or claim.

(Sec. 10202) Creates a State Balancing Incentive Payments Program to increase the FMAP for states which offer home and community-based services as a long-term care alternative to nursing homes.

(Sec. 10203) Amends SSA title XXI (CHIP) to make appropriations for CHIP through FY2015 and revise other CHIP-related requirements.

Part II: Support for Pregnant and Parenting Teens and Women - (Sec. 10212) Requires the Secretary to establish a Pregnancy Assistance Fund for grants to states to assist pregnant and parenting teens and women.

(Sec. 10214) Authorizes appropriations for FY2010-FY2019.

Part III: Indian Health Care Improvement - (Sec. 10221) Enacts into law the Indian Health Care Improvement Reauthorization and Extension Act of 2009 (S. 1790) as reported by the Senate Committee on Indian Affairs in December 2009 and with the following changes.

Amends the Indian Health Care Improvement Act, as amended by the Indian Health Care Improvement Reauthorization and Extension Act of 2009, to make an exception to the requirement that a national Community Health Aide Program exclude dental health aide therapist services. Declares that the exclusion of dental health aide therapist services from services covered under the national program shall not apply where an Indian tribe or tribal organization, located in a state (other than Alaska) in which state law authorizes the use of dental health aide therapist services or midlevel dental health provider services, elects to supply such services in accordance with state law.

Subtitle C: Provisions Relating to Title III - (Sec. 10301) Revises provisions of Subtitles A through G of Title III of this Act (as reflected in the summary of those provisions).

(Sec. 10323) Amends SSA title XVIII (Medicare) to deem eligible for Medicare coverage certain individuals exposed to environmental health hazards.

Directs the Secretary to establish a pilot program for care of certain individuals residing in emergency declaration areas.

Amends SSA title XX (Block Grants to States for Social Services) to direct the Secretary to establish a program for early detection of certain medical conditions related to environmental health hazards. Makes appropriations for FY2012-FY2019.

(Sec. 10324) Establishes floors: (1) on the area wage index for hospitals in frontier states; (2) on the area wage adjustment factor for hospital outpatient department services in frontier states; and (3) for the practice expense index for services furnished in frontier states.

(Sec. 10325) Revises the SNF prospective payment system to delay specified changes until FY2011.

(Sec. 10326) Directs the Secretary to conduct separate pilot programs, for specified kinds of hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.

(Sec. 10327) Authorizes an additional incentive payment under the physician quality reporting system in 2011 through 2014 to eligible professionals who report quality measures to CMS via a qualified Maintenance of Certification program. Eliminates the MedicareAdvantage Regional Plan Stabilization Fund.

(Sec. 10328) Requires Medicare part D prescription drug plans to include a comprehensive review of medications as part of their medication therapy management programs. Requires automatic quarterly enrollment of qualified beneficiaries, with an allowance for them to opt out.

(Sec. 10329) Requires the Secretary to develop a methodology to measure health plan value.

(Sec. 10330) Directs the Secretary to develop a plan to modernize CMS computer and data systems.

(Sec. 10331) Requires the Secretary to: (1) develop a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative; and (2) implement a plan to make information on physician performance public through Physician Compare, particularly quality and patient experience measures.

Authorizes the Secretary to provide financial incentives to Medicare beneficiaries furnished services by high quality physicians.

(Sec. 10332) Directs the Secretary to make available to qualified entities standardized extracts of Medicare claims data for the evaluation of the performance of service providers and suppliers.

(Sec. 10333) Amends the Public Health Service Act to authorize the Secretary to award grants to eligible entities to support community-based collaborative care networks for low-income populations.

(Sec. 10334) Transfers the Office of Minority Health to the Office of the Secretary. Authorizes appropriations for FY2011-FY2016.

Establishes individual offices of minority health within HHS.

Redesignates the National Center on Minority Health and Health Disparities in NIH as the National Institute on Minority Health and Health Disparities.

(Sec. 10336) Directs the Comptroller General to study and report to Congress on the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs furnished to them for the treatment of end stage renal disease in the related bundled prospective payment system.

Subtitle D: Provisions Relating to Title IV - (Sec. 10401) Revises provisions of or related to Subtitles A, B, C, D, and E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10407) Catalyst to Better Diabetes Care Act of 2009 - Requires the Secretary to prepare biennially a national diabetes report card and, to the extent possible, one for each state.

Requires the Secretary, acting through the Director of CDC, to: (1) promote the education and training of physicians on the importance of birth and death certificate data and on how to properly complete these documents; (2) encourage state adoption of the latest standard revisions of birth and death certificates; and (3) work with states to reengineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data. Allows the Secretary to promote improvements to the collection of diabetes mortality data.

Directs the Secretary to conduct a study of the impact of diabetes on the practice of medicine in the United States and the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(Sec. 10408) Requires the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs.

(Sec. 10409) Cures Acceleration Network Act of 2009 - Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to implement the Cures Acceleration

Network under which grants and contracts will be awarded to accelerate the development of high need cures. Defines "high need cure" as a drug, biological product, or device: (1) that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Establishes a Cures Acceleration Network Review Board.

(Sec. 10410) Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009 or the ENHANCED Act of 2009 - Requires the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to: (1) award grants to establish national centers of excellence for depression; and (2) designate one such center as a coordinating center. Requires the coordinating center to establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders using data collected from the national centers.

(Sec. 10411) Congenital Heart Futures Act - Authorizes the Secretary, acting through the Director of CDC, to: (1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into the National Congenital Heart Disease Surveillance System; or (2) award a grant to an eligible entity to undertake such activities.

Authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate research and related Institute activities on congenital heart disease.

(Sec. 10412) Reauthorizes appropriations for grants for public access defibrillation programs. Requires an information clearinghouse to increase public access to defibrillation in schools established under such program to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death.

(Sec. 10413) Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009 or the EARLY Act - Requires the Secretary, acting through the Director of CDC, to conduct: (1) a national education campaign to increase awareness of young women's knowledge regarding breast health and breast cancer; (2) an education campaign among physicians and other health care professionals to increase awareness of breast health of young women; and (3) prevention research on breast cancer in younger women.

Requires the Secretary, acting through the Director of NIH, to conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

Directs the Secretary to award grants for the provision of health information to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

Subtitle E: Provisions Relating to Title V - (Sec. 10501) Revises provisions of or related to Title V of this Act (as reflected in the summary of those provisions).

Requires the Secretary, acting through the Director of CDC, to establish a national diabetes prevention program targeted at adults at high risk for diabetes.

Directs the Secretary to develop a Medicare prospective payment system for payment for services furnished by federally qualified health centers.

Requires the Secretary, acting through the Administrator of the HRSA, to establish a grant program to assist accredited schools of allopathic or osteopathic medicine in: (1) recruiting students most likely to practice medicine in underserved rural communities; (2) providing rural-focused training and experience; and (3) increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

Directs the Secretary, acting through the Administrator of HRSA, to award grants or enter into contracts with eligible entities to provide training to graduate medical residents in preventive medicine specialties.

Reauthorizes appropriations for public health workforce activities.

Revises provisions related to fulfillment of service obligations under the National Health Service Corps related to half-time clinical practice and teaching.

(Sec. 10502) Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services and that meets certain requirements, including that it is critical for the provision of greater access to health care within the state.

(Sec. 10503) Establishes a Community Health Center Fund to provide for expanded and sustained national investment in community health centers. Authorizes appropriations to such Fund.

(Sec. 10504) Requires the Secretary, acting through the Administrator of HRSA, to establish a demonstration project to provide access to comprehensive health care services to the uninsured at reduced fees.

Subtitle F: Provisions Relating to Title VI - (Sec. 10601) Revises provisions of Subtitles A through E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10606) Directs the U.S. Sentencing Commission to amend the Federal Sentencing Guidelines to provide two-level, three-level, and four-level increases in the offense level for any defendant convicted of a federal health care offense relating to a government health care program of a loss between $1 million and $7 million, between $7 million and $20 million, and at least $20 million, respectively.

Provides that a person need not have actual knowledge of the prohibition against health care fraud nor specific intent to violate it in order to commit health care fraud.

Expands the scope of violations constituting a federal health care offense.

Amends the Civil Rights of Institutionalized Persons Act to authorize the Attorney General to require access to an institution by subpoena to investigate conditions depriving residents of specified constitutional or federal rights.

(Sec. 10607) Authorizes the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

(Sec. 10608) Amends the Public Health Service Act to extend medical malpractice coverage to free clinics by deeming their officers, employees, board members, and contractors to be employees of the Public Health Service.

(Sec. 10609) Amends the Federal Food, Drug, and Cosmetic Act to set forth circumstances under which a generic drug may be approved with a label different from the listed drug.

Subtitle G: Provisions Relating to Title VIII - (Sec. 10801) Revises provisions of or related to Title VIII of this Act (as reflected in the summary of those provisions).

Subtitle H: Provisions Relating to Title IX: (Sec. 10901) Revises provisions of or related to Title IX of this Act (as reflected in the summary of those provisions).

(Sec. 10907) Amends the Internal Revenue Code to impose a 10% excise tax on any amount paid for indoor tanning services on or after July 1, 2010. Exempts phototherapy services performed by a licensed medical professional from the definition of "indoor tanning services."

(Sec. 10908) Excludes from gross income any payments under the National Health Service Corps Loan Repayment Program and any other state loan repayment or forgiveness programs intended to increase the availability of health care services in underserved or health professional shortage areas.

(Sec. 10909) Increases from $10,000 to $13,170 the dollar limitation on: (1) the tax credit for adoption expenses; and (2) the tax exclusion for employer-provided adoption assistance. Allows an inflation adjustment to such limitation after 2010. Makes such credit refundable. Extends through 2011 the general terminating date of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to such credit and exclusion.

Key Elements of the Affordable Care Act

Arguably for brokers, the ACA has 3 'most important' features:

1. Redefining health insurance to include certain essential benefits and exclude certain restrictions like pre-existing condition coverage considerations, annual or lifetime maximum payouts and policy rescission;
2. Establishing individual and employer coverage mandates and exchanges and subsidies in the individual market; and
3. Expanding Medicaid

We present below the original texts of **Title 1** that addresses the first 2 features above and **Title 2** that addresses the third. This will allow readers to grasp the essence and intent of the lawmakers without any potential interpretive biases from me.

Title 1

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 2

Medicaid expansion

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 3

Improving the Quality and Efficiency of Healthcare

Subtitle A: Transforming the Health Care Delivery System - Part I: Linking Payment to Quality Outcomes under the Medicare Program - (Sec. 3001) Amends SSA title XVIII (Medicare) to direct the Secretary to establish a hospital value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet specified performance standards for a certain performance period.

Directs the Secretary to establish value-based purchasing demonstration programs for: (1) inpatient critical access hospital services; and (2) hospitals excluded from the program because of insufficient numbers of measures and cases.

(Sec. 3002) Extends through 2013 the authority for incentive payments under the physician quality reporting system. Prescribes an incentive (penalty) for providers who do not report quality measures satisfactorily, beginning in 2015.

Requires the Secretary to integrate reporting on quality measures with reporting requirements for the meaningful use of electronic health records.

(Sec. 3003) Requires specified new types of reports and data analysis under the physician feedback program.

(Sec. 3004) Requires long-term care hospitals, inpatient rehabilitation hospitals, and hospices, starting in rate year 2014, to submit data on specified quality measures. Requires reduction of the annual update of entities which do not comply.

(Sec. 3005) Directs the Secretary, starting FY2014, to establish quality reporting programs for inpatient cancer hospitals exempt from the prospective payment system.

(Sec. 3006, as modified by Sec. 10301) Directs the Secretary to develop a plan to implement value-based purchasing programs for Medicare payments for skilled nursing facilities (SNFs), home health agencies, and ambulatory surgical centers.

(Sec. 3007) Directs the Secretary to establish a value-based payment modifier, under the physician fee schedule, based upon the quality of care furnished compared to cost.

(Sec. 3008) Subjects hospitals to a penalty adjustment to hospital payments for high rates of hospital acquired conditions.

Part II: National Strategy to Improve Health Care Quality - (Sec. 3011, as modified by Sec. 10302) Amends the Public Health Service Act to direct the Secretary, through a transparent collaborative process, to establish a National Strategy for Quality Improvement in health care services, patient health outcomes, and population health, taking into consideration certain limitations on the use of comparative effectiveness data.

(Sec. 3012) Directs the President to convene an Interagency Working Group on Health Care Quality.

(Sec. 3013, as modified by Sec. 10303) Directs the Secretary, at least triennially, to identify gaps where no quality measures exist as well as existing quality measures that need improvement, updating, or expansion, consistent with the national strategy for use in federal health programs.

Directs the Secretary to award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding such quality measures.

Requires the Secretary to develop and update periodically provider-level outcome measures for hospitals and physicians, as well as other appropriate providers.

(Sec. 3014, as modified by Sec. 10304) Requires the convening of multi-stakeholder groups to provide input into the selection of quality and efficiency measures.

(Sec. 3015, as modified by Sec. 10305) Directs the Secretary to: (1) establish an overall strategic framework to carry out the public reporting of performance information; and (2) collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery. Authorizes the Secretary to award grants for such purpose.

Directs the Secretary to make available to the public, through standardized Internet websites, performance information summarizing data on quality measures.

Part III: Encouraging Development of New Patient Care Models - (Sec. 3021, as modified by Sec. 10306) Creates within CMS a Center for Medicare and Medicaid Innovation to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals. Makes appropriations for FY2010-FY2019.

(Sec. 3022, as modified by Sec. 10307) Directs the Secretary to establish a shared savings program that: (1) promotes accountability for a patient population; (2) coordinates items and services under Medicare parts A and B; and (3) encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery.

(Sec. 3023, as modified by Sec. 10308) Directs the Secretary to establish a pilot program for integrated care (involving payment bundling) during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.

(Sec. 3024) Directs the Secretary to conduct a demonstration program to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to applicable beneficiaries.

(Sec. 3025, as modified by Sec. 10309) Requires the Secretary to establish a hospital readmissions reduction program involving certain payment adjustments, effective for discharges on or after October 1, 2012, for certain potentially preventable Medicare inpatient hospital readmissions.

Directs the Secretary to make available a program for hospitals with a high severity adjusted readmission rate to improve their readmission rates through the use of patient safety organizations.

(Sec. 3026) Directs the Secretary to establish a Community-Based Care Transitions Program which provides funding to eligible entities that furnish improved care transitions services to high-risk Medicare beneficiaries.

(Sec. 3027) Amends the Deficit Reduction Act of 2005 to extend certain Gainsharing Demonstration Projects through FY2011.

Subtitle B: Improving Medicare for Patients and Providers - Part 1: Ensuring Beneficiary Access to Physician Care and Other Services - (Sec. 3101, deleted by section 10310) (Sec. 3102) Extends through calendar 2010 the floor on geographic indexing adjustments to the work portion of the physician fee schedule. Revises requirements for calculation of the practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011. Directs the Secretary to analyze current methods of establishing practice expense geographic adjustments and make appropriate further adjustments (a new methodology) to such adjustments for 2010 and subsequent years.

(Sec. 3103) Extends the process allowing exceptions to limitations on medically necessary therapy caps through December 31, 2010.

(Sec. 3104) Amends the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 to extend until January 1, 2010, an exception to a payment rule that permits laboratories to receive direct Medicare reimbursement when providing the technical component of certain physician pathology services that had been outsourced by certain (rural) hospitals.

(Sec. 3105, as modified by Sec. 10311) Amends SSA title XVIII (Medicare) to extend the bonus and increased payments for ground ambulance services until January 1, 2011.

Amends the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to extend the payment of certain urban air ambulance services until January 1, 2011.

(Sec. 3106, as modified by Sec. 10312) Amends the Medicare, Medicaid, and SCHIP Extension Act of 2007, as modified by the American Recovery and Reinvestment Act, to extend for two years: (1) certain payment rules for long-term care hospital services; and (2) a certain moratorium on the establishment of certain hospitals and facilities.

(Sec. 3107) Amends MIPPA to extend the physician fee schedule mental health add-on payment provision through December 31, 2010.

(Sec. 3108) Allows a physician assistant who does not have an employment relationship with a SNF, but who is working in collaboration with a physician, to certify the need for post-hospital extended care services for Medicare payment purposes.

(Sec. 3109) Amends title XVIII, as modified by MIPPA, to exempt certain pharmacies from accreditation requirements until the Secretary develops pharmacy-specific standards.

(Sec. 3110) Creates a special part B enrollment period for military retirees, their spouses (including widows/ widowers), and dependent children, who are otherwise eligible for TRICARE (the health care plan under the Department of Defense [DOD]) and entitled to Medicare part A (Hospital Insurance) based on disability or end stage renal disease, but who have declined Medicare part B (Supplementary Medical Insurance).

(Sec. 3111) Sets payments for dual-energy x-ray absorptiometry services in 2010 and 2011 at 70% of the 2006 reimbursement rates. Directs the Secretary to arrange with the Institute of Medicine of the National Academies to study and report to the Secretary and Congress on the ramifications of Medicare reimbursement reductions for such services on beneficiary access to bone mass measurement benefits.

(Sec. 3112) Eliminates funding in the Medicare Improvement Fund FY2014.

(Sec. 3113) Directs the Secretary to conduct a demonstration project under Medicare part B of separate payments for complex diagnostic laboratory tests provided to individuals.

(Sec. 3114) Increases from 65% to 100% of the fee schedule amount provided for the same service performed by a physician the fee schedule for certified-midwife services provided on or after January 1, 2011.

Part II: Rural Protections - (Sec. 3121) Extends through 2010 hold harmless provisions under the prospective payment system for hospital outpatient department services.

Removes the 100-bed limitation for sole community hospitals so all such hospitals receive an 85% increase in the payment difference in 2010.

(Sec. 3122) Amends the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as modified by other federal law, to extend from July 1, 2010, until July 1, 2011, the reasonable cost reimbursement for clinical diagnostic laboratory service for qualifying rural hospitals with under 50 beds.

(Sec. 3123, as modified by Sec. 10313) Extends the Rural Community Hospital Demonstration Program for five additional years. Expands the maximum number of participating hospitals to 30, and to 20 the number of demonstration states with low population densities.

(Sec. 3124) Extends the Medicare-dependent Hospital Program through FY2012.

(Sec. 3125, as modified by Sec. 10314) Modifies the Medicare inpatient hospital payment adjustment for low-volume hospitals for FY2011-FY2012.

(Sec. 3126) Revises requirements for the Demonstration Project on Community Health Integration Models in Certain Rural Counties to allow additional counties as well as physicians to participate.

(Sec. 3127) Directs MEDPAC to study and report to Congress on the adequacy of payments for items and services furnished by service providers and suppliers in rural areas under the Medicare program.

(Sec. 3128) Allows a critical access hospital to continue to be eligible to receive 101% of reasonable costs for providing: (1) outpatient care regardless of the eligible billing method such hospital uses; and (2) qualifying ambulance services.

(Sec. 3129) Extends through FY2012 FLEX grants under the Medicare Rural Hospital Flexibility Program. Allows the use of grant funding to assist small rural hospitals to participate in delivery system reforms.

Part III: Improving Payment Accuracy - (Sec. 3131, as modified by Sec. 10315) Requires the Secretary, starting in 2014, to rebase home health payments by an appropriate percentage, among

other things, to reflect the number, mix, and level of intensity of home health services in an episode, and the average cost of providing care.

Directs the Secretary to study and report to Congress on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. Authorizes a Medicare demonstration project based on the study results.

(Sec. 3132) Requires the Secretary, by January 1, 2011, to begin collecting additional data and information needed to revise payments for hospice care.

Directs the Secretary, not earlier than October 1, 2013, to implement, by regulation, budget neutral revisions to the methodology for determining hospice payments for routine home care and other services, which may include per diem payments reflecting changes in resource intensity in providing such care and services during the course of an entire episode of hospice care.

Requires the Secretary to impose new requirements on hospice providers participating in Medicare, including requirements for: (1) a hospice physician or nurse practitioner to have a face-to-face encounter with the individual regarding eligibility and recertification; and (2) a medical review of any stays exceeding 180 days, where the number of such cases exceeds a specified percentage of them for all hospice programs.

(Sec. 3133, as modified by Sec. 10316) Specifies reductions to Medicare DSH payments for FY2015 and ensuing fiscal years, especially to subsection (d) hospitals, to reflect lower uncompensated care costs relative to increases in the number of insured. (Generally, a subsection [d] hospital is an acute care hospital, particularly one that receives payments under Medicare's inpatient prospective payment system when providing covered inpatient services to eligible beneficiaries.)

(Sec. 3134) Directs the Secretary periodically to identify physician services as being potentially misvalued and make appropriate adjustments to the relative values of such services under the Medicare physician fee schedule.

(Sec. 3135) Increases the presumed utilization rate for calculating the payment for advanced imaging equipment other than low-tech imaging such as ultrasound, x-rays and EKGs.

Increases the technical component payment "discount" for sequential imaging services on contiguous body parts during the same visit.

(Sec. 3136) Restricts the lump-sum payment option for new or replacement chairs to the complex, rehabilitative power-driven wheelchairs only. Eliminates the lump-sum payment option for all other power-driven wheelchairs. Makes the rental payment for power-driven wheelchairs 15% of the purchase price for each of the first three months (instead of 10%), and 6% of the purchase price for each of the remaining 10 months of the rental period (instead of 7.5%).

(Sec. 3137, as modified by Sec. 10317) Amends the Tax Relief and Health Care Act of 2006, as modified by other federal law, to extend "Section 508" hospital reclassifications until September 30, 2010, with a special rule for FY2010. ("Section 508" refers to Section 508 of the Medicare Modernization Act of 2003, which allows the temporary reclassification of a hospital with a low Medicare area wage index, for reimbursement purposes, to a nearby location with a higher Medicare

area wage index, so that the "Section 508 hospital" will receive the higher Medicare reimbursement rate.)

Directs the Secretary to report to Congress a plan to reform the hospital wage index system.

(Sec. 3138) Requires the Secretary to determine if the outpatient costs incurred by inpatient prospective payment system-exempt cancer hospitals, including those for drugs and biologicals, with respect to Medicare ambulatory payment classification groups, exceed those costs incurred by other hospitals reimbursed under the outpatient prospective payment system (OPPS). Requires the Secretary, if this is so, to provide for an appropriate OPPS adjustment to reflect such higher costs for services furnished on or after January 1, 2011.

(Sec. 3139) Allows a biosimilar biological product to be reimbursed at 6% of the average sales price of the brand biological product.

(Sec. 3140) Directs the Secretary to establish a Medicare Hospice Concurrent Care demonstration program under which Medicare beneficiaries are furnished, during the same period, hospice care and any other Medicare items or services from Medicare funds otherwise paid to such hospice programs.

(Sec. 3141) Requires application of the budget neutrality requirement associated with the effect of the imputed rural floor on the area wage index under the Balanced Budget Act of 1997 through a uniform national, instead of state-by-state, adjustment to the area hospital wage index floor.

(Sec. 3142) Directs the Secretary to study and report to Congress on the need for an additional payment for urban Medicare-dependent hospitals for inpatient hospital services under Medicare.

(Sec. 3143) Declares that nothing in this Act shall result in the reduction of guaranteed home health benefits under the Medicare program.

Subtitle C: Provisions Relating to Part C - (Sec. 3201, as modified by Sec. 10318) Bases the MedicareAdvantage (MA) benchmark on the average of the bids from MA plans in each market.

Revises the formula for calculating the annual Medicare+Choice capitation rate to reduce the national MA per capita Medicare+Choice growth percentage used to increase benchmarks in 2011.

Increases the monthly MA plan rebates from 75% to 100% of the average per capita savings.

Requires that bid information which MA plans are required to submit to the Secretary be certified by a member of the American Academy of Actuaries and meet actuarial guidelines and rules established by the Secretary.

Directs the Secretary, acting through the CMS Chief Actuary, to establish actuarial guidelines for the submission of bid information and bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

Directs the Secretary to: (1) establish new MA payment areas for urban areas based on the Core Based Statistical Area; and (2) make monthly care coordination and management performance bonus payments, quality performance bonus payments, and quality bonuses for new and low enrollment MA plans, to MA plans that meet certain criteria.

Directs the Secretary to provide transitional rebates for the provision of extra benefits to enrollees.

(Sec. 3202) Prohibits MA plans from charging beneficiaries cost sharing for chemotherapy administration services, renal dialysis services, or skilled nursing care that is greater than what is charged under the traditional fee-for-service program.

Requires MA plans to apply the full amount of rebates, bonuses, and supplemental premiums according to the following order: (1) reduction of cost sharing, (2) coverage of preventive care and wellness benefits, and (3) other benefits not covered under the original Medicare fee-for-service program.

(Sec. 3203) Requires the Secretary to analyze the differences in coding patterns between MA and the original Medicare fee-for-service programs. Authorizes the Secretary to incorporate the results of the analysis into risk scores for 2014 and subsequent years.

(Sec. 3204) Allows beneficiaries to disenroll from an MA plan and return to the traditional Medicare fee-for-service program from January 1 to March 15 of each year.

Revises requirements for annual beneficiary election periods.

(Sec. 3205) Amends SSA title XVIII (Medicare), as modified by MIPPA, to extend special needs plan (SNP) authority through December 31, 2013.

Authorizes the Secretary to establish a frailty payment adjustment under PACE payment rules for fully-integrated, dual-eligible SNPs.

Extends authority through calendar 2012 for SNPs that do not have contracts with state Medicaid programs to continue to operate, but not to expand their service areas.

Directs the Secretary to require an MA organization offering a specialized MA plan for special needs individuals to be approved by the National Committee for Quality Assurance.

Requires the Secretary to use a risk score reflecting the known underlying risk profile and chronic health status of similar individuals, instead of the default risk score, for new enrollees in MA plans that are not specialized MA SNPs.

(Sec. 3206) Extends through calendar 2012 the length of time reasonable cost plans may continue operating regardless of any other MA plans serving the area.

(Sec. 3208) Creates a new type of MA plan called an MA Senior Housing Facility Plan, which would be allowed to limit its service area to a senior housing facility (continuing care retirement community) within a geographic area.

(Sec. 3209) Declares that the Secretary is not required to accept any or every bid submitted by an MA plan or Medicare part D prescription drug plan that proposes to increase significantly any beneficiary cost sharing or decrease benefits offered.

(Sec. 3210) Directs the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new standards for certain Medigap plans.

Subtitle D: Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans - (Sec. 3301) Amends Medicare part D (Voluntary Prescription Drug Benefit Program) to establish

conditions for the availability of coverage for part D drugs. Requires the manufacturer to participate in the Medicare coverage gap discount program. Directs the Secretary to establish such a program.

(Sec. 3302) Excludes the MA rebate amounts and quality bonus payments from calculation of the regional low-income subsidy benchmark premium for MA monthly prescription drug beneficiaries.

(Sec. 3303) Directs the Secretary to permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is *de minimis*. Provides that, if such premium is waived, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

Authorizes the Secretary to auto-enroll subsidy eligible individuals in plans that waive *de minimis* premiums.

(Sec. 3304) Sets forth a special rule for widows and widowers regarding eligibility for low-income assistance. Allows the surviving spouse of an eligible couple to delay redetermination of eligibility for one year after the death of a spouse.

(Sec. 3305) Directs the Secretary, in the case of a subsidy eligible individual enrolled in one prescription drug plan but subsequently reassigned by the Secretary to a new prescription drug plan, to provide the individual with: (1) information on formulary differences between the individual's former plan and the new plan with respect to the individual's drug regimens; and (2) a description of the individual's right to request a coverage determination, exception, or reconsideration, bring an appeal, or resolve a grievance.

(Sec. 3306) Amends MIPPA to provide additional funding for FY2010-FY2012 for outreach and education activities related to specified Medicare low-income assistance programs.

(Sec. 3307) Authorizes the Secretary to identify classes of clinical concern through rulemaking, including anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. Requires prescription drug plan sponsors to include all drugs in these classes in their formularies.

(Sec. 3308) Requires part D enrollees who exceed certain income thresholds to pay higher premiums. Revises the current authority of the IRS to disclose income information to the Social Security Administration for purposes of adjusting the part B subsidy.

(Sec. 3309) Eliminates cost sharing for certain dual eligible individuals receiving care under a home and community-based waiver program who would otherwise require institutional care.

(Sec. 3310) Directs the Secretary to require sponsors of prescription drug plans to utilize specific, uniform techniques for dispensing covered part D drugs to enrollees who reside in an long-term care facility in order to reduce waste associated with 30-day refills.

(Sec. 3311) Directs the Secretary to develop and maintain an easy to use complaint system to collect and maintain information on MA-PD plan and prescription drug complaints received by the Secretary until the complaint is resolved.

(Sec. 3312) Requires a prescription drug plan sponsor to: (1) use a single, uniform exceptions and appeals process for determination of a plan enrollee's prescription drug coverage; and (2) provide instant access to this process through a toll-free telephone number and an Internet website.

(Sec. 3313) Requires the HHS Inspector General to study and report to Congress on the inclusion in formularies of: (1) drugs commonly used by dual eligibles; and (2) prescription drug prices under Medicare part D and Medicaid.

(Sec. 3314) Allows the costs incurred by AIDS drug assistance programs and by IHS in providing prescription drugs to count toward the annual out-of-pocket threshold.

(Sec. 3315) Increases by $500 the 2010 standard initial coverage limit (thus decreasing the time that a part D enrollee would be in the coverage gap).

Subtitle E: Ensuring Medicare Sustainability - (Sec. 3401, as modified by Sec. 10319 and Sec. 10322) Revises certain market basket updates and incorporates a full productivity adjustment into any updates that do not already incorporate such adjustments, including inpatient hospitals, home health providers, nursing homes, hospice providers, inpatient psychiatric facilities, long-term care hospitals, inpatient rehabilitation facilities, and Part B providers.

Establishes a quality measure reporting program for psychiatric hospitals beginning in FY2014.

(Sec. 3402) Revises requirements for reduction of the Medicare part B premium subsidy based on income. Maintains the current 2010 income thresholds for the period of 2011 through 2019.

(Sec. 3403, as modified by Sec. 10320) Establishes an Independent Payment Advisory Board to develop and submit detailed proposals to reduce the per capita rate of growth in Medicare spending to the President for Congress to consider. Establishes a consumer advisory council to advise the Board on the impact of payment policies under this title on consumers.

Subtitle F: Health Care Quality Improvements - (Sec. 3501) Amends the Public Health Service Act to direct the Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to conduct or support activities for best practices in the delivery of health care services and support research on the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Authorizes appropriations for FY2010-FY2014.

Requires the AHRQ Director, through the AHRQ Center for Quality Improvement and Patient Safety, to award grants or contracts to eligible entities to provide technical support or to implement models and practices identified in the research conducted by the Center.

(Sec. 3502, as modified by Sec. 10321) Directs the Secretary to establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

(Sec. 3503) Directs the Secretary, acting through the Patient Safety Research Center, to establish a program to provide grants or contracts to eligible entities to implement medication management services provided by licensed pharmacists, as a collaborative multidisciplinary, inter-professional

approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such disease.

(Sec. 3504) Directs the Secretary, acting through the Assistant Secretary for Preparedness and Response, to award at least four multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

Requires the Secretary to support federal programs administered by the National Institutes of Health (NIH), the AHRQ, the Health Resources and Services Administration (HRSA), the CMS, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine.

Directs the Secretary to support federal programs administered by the such agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine.

Authorizes appropriations for FY2010-FY2014.

(Sec. 3505) Requires the Secretary to establish three programs to award grants to qualified public, nonprofit IHS, Indian tribal, and urban Indian trauma centers to: (1) assist in defraying substantial uncompensated care costs; (2) further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer; and (3) provide emergency relief to ensure the continued and future availability of trauma services. Authorizes appropriations for FY2010-FY2015.

Directs the Secretary to provide funding to states to enable them to award grants to eligible entities for trauma services. Authorizes appropriations for FY2010-FY2015.

(Sec. 3506) Directs the Secretary to: (1) establish a program to award grants or contracts to develop, update, and produce patient decision aids to assist health care providers and patients; (2) establish a program to provide for the phased-in development, implementation, and evaluation of shared decision making using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options; and (3) award grants for establishment and support of Shared Decisionmaking Resource Centers. Authorizes appropriations for FY2010 and subsequent fiscal years.

(Sec. 3507) Requires the Secretary, acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format to the promotional labeling or print advertising of such drugs would improve heath care decisionmaking by clinicians and patients and consumers.

(Sec. 3508) Authorizes the Secretary to award grants to eligible entities or consortia to carry out demonstration projects to develop and implement academic curricula that integrate quality improvement and patient safety in the clinical education of health professionals.

(Sec. 3509) Establishes an Office on Women's Health within the Office of the Secretary, the Office of the Director of the Centers for Disease Control and Prevention (CDC), the Office of the AHRQ Director, the Office of the Administrator of HRSA, and the Office of the Commissioner of Food and Drugs.

Authorizes appropriations for FY2010-FY2014 for all such Offices on Women's Health.

(Sec. 3510) Extends from three years to four years the duration of a patient navigator grant.

Prohibits the Secretary from awarding such a grant unless the recipient entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies tailored for the main focus or intervention of the navigator involved.

Authorizes appropriations for FY2010-FY2015.

(Sec. 3511) Authorizes appropriations to carry out this title, except where otherwise provided in the title.

(Sec. 3512, as added by Sec. 10201) Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any guideline or other standards under specified provisions of this Act would result in the establishment of a new cause of action or claim.

Subtitle G: Protecting and Improving Guaranteed Medicare Benefits - (Sec. 3601) Provides that nothing in this Act shall result in a reduction of guaranteed benefits under the Medicare program.

States that savings generated for the Medicare program under this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.

(Sec. 3602) Declares that nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in MA plans.

Title IV

Prevention of Chronic Disease and Improving Public Health

Subtitle A: Modernizing Disease Prevention and Public Health Systems - (Sec. 4001, as modified by Sec. 10401) Requires the President to: (1) establish the National Prevention, Health Promotion and Public Health Council; (2) establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health; and (3) appoint the Surgeon General as Chairperson of the Council in order to develop a national prevention, health promotion, and public health strategy.

Requires the Secretary and the Comptroller General to conduct periodic reviews and evaluations of every federal disease prevention and health promotion initiative, program, and agency.

(Sec. 4002, as modified by Sec. 10401) Establishes a Prevention and Public Health Fund to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs. Authorizes appropriations and appropriates money to such Fund.

(Sec. 4003) Requires (currently, allows) the Director of AHRQ to convene the Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community.

Requires the Director of CDC to convene an independent Community Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations for individuals and organizations delivering populations-based services and other policy makers

(Sec. 4004, as modified by Sec. 10401) Requires the Secretary to provide for the planning and implementation of a national public-private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span.

Requires the Secretary, acting through the Director of CDC, to: (1) establish and implement a national science-based media campaign on health promotion and disease prevention; and (2) enter into a contract for the development and operation of a federal website personalized prevention plan tool.

Subtitle B: Increasing Access to Clinical Preventive Services - (Sec. 4101, as modified by Sec. 10402) Requires the Secretary to establish a program to award grants to eligible entities to support the operation of school-based health centers.

(Sec. 4102) Requires the Secretary, acting through the Director of CDC, to carry out oral health activities, including: (1) establishing a national public education campaign that is focused on oral health care prevention and education; (2) awarding demonstration grants for research-based dental caries disease management activities; (3) awarding grants for the development of school-based dental sealant programs; and (4) entering into cooperative agreements with state, territorial, and Indian tribes or tribal organizations for oral health data collection and interpretation, a delivery system for oral health, and science-based programs to improve oral health.

Requires the Secretary to: (1) update and improve the Pregnancy Risk Assessment Monitoring System as it relates to oral health care; (2) develop oral health care components for inclusion in the National Health and Nutrition Examination Survey; and (3) ensure that the Medical Expenditures Panel Survey by AHRQ includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(Sec. 4103, as modified by Sec. 10402) Amends SSA title XVIII (Medicare) to provide coverage of personalized prevention plan services, including a health risk assessment, for individuals. Prohibits cost-sharing for such services.

(Sec. 4104, as modified by Sec. 10406) Eliminates cost-sharing for certain preventive services recommended by the United States Preventive Services Task Force.

(Sec. 4105) Authorizes the Secretary to modify Medicare coverage of any preventive service consistent with the recommendations of such Task Force.

(Sec. 4106) Amends SSA title XIX (Medicaid) to provide Medicaid coverage of preventive services and approved vaccines. Increases the FMAP for such services and vaccines.

(Sec. 4107) Provides for Medicaid coverage of counseling and pharmacotherapy for cessation of tobacco use by pregnant women.

(Sec. 4108) Requires the Secretary to award grants to states to carry out initiatives to provide incentives to Medicaid beneficiaries who participate in programs to lower health risk and demonstrate changes in health risk and outcomes.

Subtitle C: Creating Healthier Communities - (Sec. 4201, as modified by Sec. 10403) Requires the Secretary, acting through the Director of CDC, to award grants to state and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence base of effective prevention programming.

(Sec. 4202) Requires the Secretary, acting through the Director of CDC, to award grants to state or local health departments and Indian tribes to carry out pilot programs to provide public health community interventions, screenings, and clinical referrals for individuals who are between 55 and 64 years of age.

Requires the Secretary to: (1) conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries; and (2) evaluate community prevention and wellness programs that have demonstrated potential to help Medicare beneficiaries reduce their risk of disease, disability, and injury by making healthy lifestyle choices.

(Sec. 4203) Amends the Rehabilitation Act of 1973 to require the Architectural and Transportation Barriers Compliance Board to promulgate standards setting forth the minimum technical criteria for medical diagnostic equipment used in medical settings to ensure that such equipment is accessible to, and usable by, individuals with accessibility needs.

(Sec. 4204) Authorizes the Secretary to negotiate and enter into contracts with vaccine manufacturers for the purchase and delivery of vaccines for adults. Allows a state to purchase additional quantities of adult vaccines from manufacturers at the applicable price negotiated by the Secretary. Requires the Secretary, acting through the Director of CDC, to establish a demonstration program to award grants to states to improve the provision of recommended immunizations for children and adults through the use of evidence-based, population-based interventions for high-risk populations.

Reauthorizes appropriations for preventive health service programs to immunize children and adults against vaccine-preventable diseases without charge.

Requires the Comptroller General to study the ability of Medicare beneficiaries who are 65 years or older to access routinely recommended vaccines covered under the prescription drug program since its establishment.

(Sec. 4205) Amends the Federal Food, Drug, and Cosmetic Act to require the labeling of a food item offered for sale in a retail food establishment that is part of a chain with 20 or more locations under the same name to disclose on the menu and menu board: (1) the number of calories contained in the standard menu item; (2) the suggested daily caloric intake; and (3) the availability on the premises and upon request of specified additional nutrient information. Requires self-service facilities to place adjacent to each food offered a sign that lists calories per displayed food item or per serving. Requires vending machine operators who operate 20 or more vending machines to provide a sign disclosing the number of calories contained in each article of food.

(Sec. 4206) Requires the Secretary to establish a pilot program to test the impact of providing at-risk populations who utilize community health centers an individualized wellness plan designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

(Sec. 4207) Amends the Fair Labor Standards Act of 1938 to require employers to provide a reasonable break time and a suitable place, other than a bathroom, for an employee to express breast milk for her nursing child. Excludes an employer with fewer than 50 employees if such requirements would impose an undue hardship.

Subtitle D: Support for Prevention and Public Health Innovation - (Sec. 4301) Requires the Secretary, acting through the Director of CDC, to provide funding for research in the area of public health services and systems.

(Sec. 4302) Requires the Secretary to ensure that any federally conduced or supported health care or public health program, activity, or survey collects and reports specified demographic data regarding health disparities.

Requires the Secretary, acting through the National Coordinator for Health Information Technology, to develop: (1) national standards for the management of data collected; and (2) interoperability and security systems for data management.

(Sec. 4303, as modified by Sec. 10404) Requires the Director of CDC to: (1) provide employers with technical assistance, consultation, tools, and other resources in evaluating employer-based wellness programs; and (2) build evaluation capacity among workplace staff by training employers on how to evaluate such wellness programs and ensuring that evaluation resources, technical assistance, and consultation are available.

Requires the Director of CDC to conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(Sec. 4304) Requires the Secretary, acting through the Director of CDC, to establish an Epidemiology and Laboratory Capacity Grant Program to award grants to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance.

(Sec. 4305) Requires the Secretary to: (1) enter into an agreement with the Institute of Medicine to convene a Conference on Pain, the purposes of which shall include to increase the recognition of pain as a significant public health problem in the United States; and (2) establish the Interagency Pain Research Coordinating Committee.

(Sec. 4306) Appropriates funds to carry out childhood obesity demonstration projects.

Subtitle E: Miscellaneous Provisions - (Sec. 4402) Requires the Secretary to evaluate programs to determine whether existing federal health and wellness initiatives are effective in achieving their stated goals.

Title 5

Healthcare Workforce

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 6

Transparency and Program Integrity

Subtitle A: Physician Ownership and Other Transparency - (Sec. 6001, as modified by Sec. 10601) Amends SSA title XVIII (Medicare) to prohibit physician-owned hospitals that do not have a provider agreement by August 1, 2010, to participate in Medicare. Allows their participation in Medicare under a rural provider and hospital exception to the ownership or investment prohibition if they meet certain requirements addressing conflict of interest, bona fide investments, patient safety issues, and expansion limitations.

(Sec. 6002) Amends SSA title XI to require drug, device, biological and medical supply manufacturers to report to the Secretary transfers of value made to a physician, physician medical practice, a physician group practice, and/or teaching hospital, as well as information on any physician ownership or investment interest in the manufacturer. Provides penalties for noncompliance. Preempts duplicative state or local laws.

(Sec. 6003) Amends SSA title XVIII (Medicare), with respect to the Medicare in-office ancillary exception to the prohibition against physician self-referrals, to require a referring physician to inform the patient in writing that the patient may obtain a specified imaging service from a person other than the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual directly supervised by the physician or by another physician in the group practice. Requires the referring physician also to provide the patient with a written list of suppliers who furnish such services in the area in which the patient resides.

(Sec. 6004) Amends SSA title XI to require prescription drug manufacturers and authorized distributors of record to report to the Secretary specified information pertaining to drug samples.

(Sec. 6005) Amends SSA title XI to require a pharmacy benefit manager (PBM) or a health benefits plan that manages prescription drug coverage under a contract with a Medicare or Exchange health plan to report to the Secretary information regarding the generic dispensing rate, the rebates, discounts, or price concessions negotiated by the PBM, and the payment difference between health plans and PBMs and the PBMs and pharmacies.

Subtitle B: Nursing Home Transparency and Improvement - Part I: Improving Transparency of Information - (Sec. 6101) Amends SSA title XI to require SNFs under Medicare and nursing facilities (NFs) under Medicaid to make available, upon request by the Secretary, the HHS Inspector General, the states, or a state long-term care ombudsman, information on ownership of the SNF or NF, including a description of the facility's governing body and organizational structure, as well as information regarding additional disclosable parties.

(Sec. 6102) Requires SNFs and NFs to operate a compliance and ethics program effective in preventing and detecting criminal, civil, and administrative violations.

Directs the Secretary to establish and implement a quality assurance and performance improvement program for SNFs and NFs, including multi-unit chains of facilities.

(Sec. 6103) Amends SSA title XVIII (Medicare) to require the Secretary to publish on the Nursing Home Compare Medicare website: (1) standardized staffing data; (2) links to state websites regarding

state survey and certification programs; (3) the model standardized complaint form; (4) a summary of substantiated complaints; and (5) the number of adjudicated instances of criminal violations by a facility or its employees.

(Sec. 6104) Requires SNFs to report separately expenditures on wages and benefits for direct care staff, breaking out registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(Sec. 6105) Requires the Secretary to develop a standardized complaint form for use by residents (or a person acting on a resident's behalf) in filing complaints with a state survey and certification agency and a state long-term care ombudsman program. Requires states to to establish complaint resolution processes.

(Sec. 6106) Amends SSA title XI to require the Secretary to develop a program for facilities to report direct care staffing information on payroll and other verifiable and auditable data in a uniform format based.

(Sec. 6107) Requires the Comptroller General to study and report to Congress on the Five-Star Quality Rating System for nursing homes of CMS.

Part II: Targeting Enforcement - (Sec. 6111) Amends SSA title XVIII (Medicare) to authorize the Secretary to reduce civil monetary penalties by 50% for certain SNFs and NFs that self-report and promptly correct deficiencies within 10 calendar days of imposition of the penalty. Directs the Secretary to issue regulations providing for an informal dispute resolution process after imposition of a penalty, as well as an escrow account for money penalties pending resolution of any appeals.

(Sec. 6112) Directs the Secretary to establish a demonstration project for developing, testing, and implementing a national independent monitor program to oversee interstate and large intrastate chains of SNFs and NFs.

(Sec. 6113) Requires the administrator of a SNF or a NF that is preparing to close to notify in writing residents, legal representatives of residents or other responsible parties, the Secretary, and the state long-term care ombudsman program in advance of the closure by at least 60 days. Requires the notice to include a plan for the transfer and adequate relocation of residents to another facility or alternative setting. Requires the state to ensure a successful relocation of residents.

(Sec. 6114) Requires the Secretary to conduct two SNF- and NF-based demonstration projects to develop best practice models in two areas: (1) one for facilities involved in the "culture change" movement; and (2) one for the use of information technology to improve resident care.

Part III: Improving Staff Training - (Sec. 6121) Requires SNFs and NFs to include dementia management and abuse prevention training as part of pre-employment initial training and, if appropriate, as part of ongoing in-service training for permanent and contract or agency staff.

Subtitle C: Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term Care Facilities and Providers - (Sec. 6201) Requires the Secretary to establish a nationwide program for national and state background checks on prospective direct patient access employees of long-term care facilities and providers.

Subtitle D: Patient-Centered Outcomes Research - (Sec. 6301, as modified by Sec. 10602) Amends SSA title XI to establish the Patient-Centered Outcomes Research Institute to identify priorities for, and establish, update, and carry out, a national comparative outcomes research project agenda. Provides for a peer review process for primary research.

Prohibits the Institute from allowing the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved by the Institute under a data use agreement.

Amends the Public Health Service Act to direct the Office of Communication and Knowledge Transfer at AHRQ to disseminate broadly the research findings published by the Institute and other government-funded research relevant to comparative clinical effective research.

Prohibits the Secretary from using evidence and findings from Institute research to make a determination regarding Medicare coverage unless such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

Amends the Internal Revenue Code to establish in the Treasury the Patient-Centered Outcomes Research Trust Fund. Directs the Secretary to make transfers to that Trust Fund from the Medicare Trust Funds.

Imposes annual fees of $2 times the number of insured lives on each specified health insurance policy and on self-insured health plans.

(Sec. 6302) Terminates the Federal Coordinating Council for Comparative Effectiveness Research upon enactment of this Act.

Subtitle E: Medicare, Medicaid, and CHIP Program Integrity Provisions - (Sec. 6401, as modified by Sec. 10603) Amends SSA title XVIII (Medicare) to require the Secretary to: (1) establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and CHIP; and (2) determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier.

Requires providers and suppliers applying for enrollment or revalidation of enrollment in Medicare, Medicaid, or CHIP to disclose current or previous affiliations with any provider or supplier that: (1) has uncollected debt; (2) has had its payments suspended; (3) has been excluded from participating in a federal health care program; or (4) has had billing privileges revoked. Authorizes the Secretary to deny enrollment in a program if these affiliations pose an undue risk to it.

Requires providers and suppliers to establish a compliance program containing specified core elements.

Directs the CMS Administrator to establish a process for making available to each state agency with responsibility for administering a state Medicaid plan or a child health plan under SSA title XXI the identity of any provider or supplier under Medicare or CHIP who is terminated.

(Sec. 6402) Requires CMS to include in the integrated data repository claims and payment data from Medicare, Medicaid, CHIP, and health-related programs administered by the Departments of Veterans Affairs (VA) and DOD, the Social Security Administration, and IHS.

Directs the Secretary to enter into data-sharing agreements with the Commissioner of Social Security, the VA and DOD Secretaries, and the IHS Director to help identity fraud, waste, and abuse.

Requires that overpayments be reported and returned within 60 days from the date the overpayment was identified or by the date a corresponding cost report was due, whichever is later.

Directs the Secretary to issue a regulation requiring all Medicare, Medicaid, and CHIP providers to include their National Provider Identifier on enrollment applications.

Authorizes the Secretary to withhold the federal matching payment to states for medical assistance expenditures whenever a state does not report enrollee encounter data in a timely manner to the state's Medicaid Management Information System.

Authorizes the Secretary to exclude providers and suppliers participation in any federal health care program for providing false information on any application to enroll or participate.

Subjects to civil monetary penalties excluded individuals who: (1) order or prescribe an item or service; (2) make false statements on applications or contracts to participate in a federal health care program; or (3) know of an overpayment and do not return it. Subjects the latter offense to civil monetary penalties of up to $50,000 or triple the total amount of the claim involved.

Authorizes the Secretary to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question.

Requires the Secretary take into account the volume of billing for a durable medical equipment (DME) supplier or home health agency when determining the size of the supplier's and agency's surety bond. Authorizes the Secretary to require other providers and suppliers to post a surety bond if the Secretary considers them to be at risk.

Authorizes the Secretary to suspend payments to a provider or supplier pending a fraud investigation.

Appropriates an additional $10 million, adjusted for inflation, to the Health Care Fraud and Abuse Control each of FY2011-FY2020. Applies inflation adjustments as well to Medicare Integrity Program funding.

Requires the Medicaid Integrity Program and Program contractors to provide the Secretary and the HHS Office of Inspector General with performance statistics, including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment for such activities.

(Sec. 6403) Requires the Secretary to furnish the National Practitioner Data Bank (NPDB) with all information reported to the national health care fraud and abuse data collection program on certain final adverse actions taken against health care providers, suppliers, and practitioners.

Requires the Secretary to establish a process to terminate the Healthcare Integrity and Protection Databank (HIPDB) and ensure that the information formerly collected in it is transferred to the NPDB.

(Sec. 6404) Reduces from three years to one year after the date of service the maximum period for submission of Medicare claims.

(Sec. 6405, as modified by Sec. 10604) Requires DME or home health services to be ordered by an enrolled Medicare eligible professional or physician. Authorizes the Secretary to extend these requirements to other Medicare items and services to reduce fraud, waste, and abuse.

(Sec. 6406) Authorizes the Secretary to disenroll, for up to one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services.

Authorizes the Secretary to exclude from participation in any federal health care program any individual or entity ordering, referring for furnishing, or certifying the need for an item or service that fails to provide adequate documentation to verify payment.

(Sec. 6407, as modified by Sec. 10605) Requires a physician, nurse practitioner, clinical nurse specialist, certified nurse-midwife, or physician assistant to have a face-to-face encounter with an individual before issuing a certification for home health services or DME.

Authorizes the Secretary to apply the same face-to-face encounter requirement to other items and services based upon a finding that doing so would reduce the risk of fraud, waste, and abuse. Applies the same requirement, as well, to physicians making certifications for home health services under Medicaid.

(Sec. 6408) Revises civil monetary penalties for making false statements or delaying inspections.

Applies specified enhanced sanctions and civil monetary penalties to MA or Part D plans that: (1) enroll individuals in an MA or Part D plan without their consent; (2) transfer an individual from one plan to another for the purpose of earning a commission; (3) fail to comply with marketing requirements and CMS guidance; or (4) employ or contract with an individual or entity that commits a violation.

(Sec. 6409) Requires the Secretary to establish a self-referral disclosure protocol to enable health care providers and suppliers to disclose actual or potential violations of the physician self-referral law.

Authorizes the Secretary to reduce the amount due and owing for all violations of such law.

(Sec. 6410) Requires the Secretary to: (1) expand the number of areas to be included in round two of the competitive bidding program from 79 to 100 of the largest metropolitan statistical areas; and (2) use competitively bid prices in all areas by 2016.

(Sec. 6411) Requires states to establish contracts with one or more Recovery Audit Contractors (RACs), which shall identify underpayments and overpayments and recoup overpayments made for services provided under state Medicaid plans as well as state plan waivers.

Requires the Secretary to expand the RAC program to Medicare parts C (Medicare+Choice) and D (Prescription Drug Program).

Subtitle F: Additional Medicaid Program Integrity Provisions - (Sec. 6501) Amends SSA title XIX (Medicaid) to require states to terminate individuals or entities (providers) from their Medicaid programs if they were terminated from Medicare or another state's Medicaid program.

(Sec. 6502) Requires Medicaid agencies to exclude individuals or entities from participating in Medicaid for a specified period of time if the entity or individual owns, controls, or manages an entity that: (1) has failed to repay overpayments during a specified period; (2) is suspended, excluded, or terminated from participation in any Medicaid program; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from Medicaid participation.

(Sec. 6503) Requires state Medicaid plans to require any billing agents, clearinghouses, or other alternate payees that submit claims on behalf of health care providers to register with the state and the Secretary.

(Sec. 6504) Requires states to submit data elements from the state mechanized claims processing and information retrieval system (under the Medicaid Statistical Information System) that the Secretary determines necessary for program integrity, program oversight, and administration.

Requires a Medicaid managed care entity contract to provide for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients (as under current law) at a frequency and level of detail to be specified by the Secretary.

(Sec. 6505) Requires a state Medicaid plan to prohibit the state from making any payments for items or services under a Medicaid state plan or a waiver to any financial institution or entity located outside of the United States.

(Sec. 6506) Extends the period for states to recover overpayments from 60 days to one year after discovery of the overpayment. Declares that, when overpayments due to fraud are pending, state repayments of the federal portion of such overpayments shall not be due until 30 days after the date of the final administrative or judicial judgment on the matter.

(Sec. 6507) Requires state mechanized Medicaid claims processing and information retrieval systems to incorporate methodologies compatible with Medicare's National Correct Coding Initiative.

Subtitle G: Additional Program Integrity Provisions - (Sec. 6601) Amends the Employee Retirement Income Security Act of 1974 (ERISA) to prohibit employees and agents of multiple employer welfare arrangements (MEWAs), subject to criminal penalties, from making false statements in marketing materials regarding an employee welfare benefit plan's financial solvency, benefits, or regulatory status.

(Sec. 6603) Amends the Public Health Service Act to direct the Secretary to request NAIC to develop a model uniform report form for a private health insurance issuer seeking to refer suspected fraud and abuse to state insurance departments or other responsible state agencies for investigation.

(Sec. 6604) Amends ERISA to direct the Secretary of Labor to adopt regulatory standards and/or issue orders to subject MEWAs to state law relating to fraud and abuse.

(Sec. 6605) Authorizes the Secretary of Labor to: (1) issue cease-and-desist orders to shut down temporarily the operations of MEWAs conducting fraudulent activities or posing a serious threat to the public, until hearings can be completed; and (2) seize a plan's assets if it appears that the plan is in a financially hazardous condition.

(Sec. 6606) Directs the Secretary of Labor to require MEWAs which are not group health plans to register with the Department of Labor before operating in a state.

(Sec. 6607) Authorizes the Secretary of Labor to promulgate a regulation providing an evidentiary privilege that allows confidential communication among specified federal and state officials relating to investigation of fraud and abuse.

Subtitle H: Elder Justice Act - Elder Justice Act of 2009 - (Sec. 6702) Amends SSA title XX (Block Grants to States for Social Services) with respect to elder abuse, neglect, and exploitation and their prevention. Requires the HHS Secretary to award grants and carry out activities that provide: (1) greater protection to those individuals seeking care in facilities that provide long-term care services and supports; and (2) greater incentives for individuals to train and seek employment at such facilities.

Requires facility owners, operators, and certain employees to report suspected crimes committed at a facility.

Requires facility owners or operators also to: (1) submit to the Secretary and to the state written notification of an impending closure of a facility within 60 days before the closure; and (2) include a plan for transfer and adequate relocation of all residents.

Establishes an Elder Justice Coordinating Council.

Subtitle I: Sense of the Senate Regarding Medical Malpractice - (Sec. 6801) Expresses the sense of the Senate that: (1) health reform presents an opportunity to address issues related to medical malpractice and medical liability insurance; (2) states should be encouraged to develop and test alternative models to the existing civil litigation system; and (3) Congress should consider state demonstration projects to evaluate such alternatives.

Title 8

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 10

Strengthening Quality, Affordable Health Care for All Americans

Subtitle A: Provisions Relating to Title I - (Sec. 10101) Revises provisions of or related to Subtitles A, B, and C of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10104) Revises provisions of or related to Subtitle D of Title I of this Act (as reflected in the summary of those provisions). Makes changes to the False Claims Act related to the public disclosure bar on filing civil claims.

(Sec. 10105) Revises provisions of or related to Subtitles E, F, and G of Title I of this Act (as reflected in the summary of those provisions).

(Sec. 10108) Requires an offering employer to provide free choice vouchers to each qualified employee. Defines "offering employer" to mean any employer who offers minimum essential coverage to its employees consisting of coverage through an eligible employer-sponsored plan and who pays any portion of the costs of such plan. Defines "qualified employee" as an employee whose required contribution for such coverage and household income fall within a specified range. Requires: (1) a Health Insurance Exchange to credit the amount of any free choice voucher to the monthly premium of any qualified health plan in which the employee is enrolled; and (2) the offering employer to pay any amounts so credited to the Exchange. Excludes the amount of any free choice voucher from the gross income of the employee. Permits a deduction by employers for such costs.

(Sec. 10109) Amends the SSA to require the HHS Secretary to seek input to determine if there could be greater uniformity in financial and administrative health care activities and items.

Requires the Secretary to: (1) task the ICD-9-CM Coordination and Maintenance Committee to convene a meeting to receive input regarding and recommend revisions to the crosswalk between the Ninth and Tenth Revisions of the International Classification of Diseases; and (2) make appropriate revisions to such crosswalk.

Subtitle B: Provisions Relating to Title II - Part I: Medicaid and CHIP - (Sec. 10201) Revises provisions of Subtitles A through L of Title II of this Act (as reflected in the summary of those provisions).

Amends SSA title XIX (Medicaid) to set the FMAP for the state of Nebraska, with respect to all or any portion of a fiscal year that begins on or after January 1, 2017, at 100% (thus requiring the federal government to pay 100% of the cost of covering newly-eligible individuals in Nebraska).

Directs the Comptroller General to study and report to Congress on whether the development, recognition, or implementation of any specified health care quality guideline or other standards would result in the establishment of a new cause of action or claim.

(Sec. 10202) Creates a State Balancing Incentive Payments Program to increase the FMAP for states which offer home and community-based services as a long-term care alternative to nursing homes.

(Sec. 10203) Amends SSA title XXI (CHIP) to make appropriations for CHIP through FY2015 and revise other CHIP-related requirements.

Part II: Support for Pregnant and Parenting Teens and Women - (Sec. 10212) Requires the Secretary to establish a Pregnancy Assistance Fund for grants to states to assist pregnant and parenting teens and women.

(Sec. 10214) Authorizes appropriations for FY2010-FY2019.

Part III: Indian Health Care Improvement - (Sec. 10221) Enacts into law the Indian Health Care Improvement Reauthorization and Extension Act of 2009 (S. 1790) as reported by the Senate Committee on Indian Affairs in December 2009 and with the following changes.

Amends the Indian Health Care Improvement Act, as amended by the Indian Health Care Improvement Reauthorization and Extension Act of 2009, to make an exception to the requirement that a national Community Health Aide Program exclude dental health aide therapist services. Declares that the exclusion of dental health aide therapist services from services covered under the national program shall not apply where an Indian tribe or tribal organization, located in a state (other than Alaska) in which state law authorizes the use of dental health aide therapist services or midlevel dental health provider services, elects to supply such services in accordance with state law.

Subtitle C: Provisions Relating to Title III - (Sec. 10301) Revises provisions of Subtitles A through G of Title III of this Act (as reflected in the summary of those provisions).

(Sec. 10323) Amends SSA title XVIII (Medicare) to deem eligible for Medicare coverage certain individuals exposed to environmental health hazards.

Directs the Secretary to establish a pilot program for care of certain individuals residing in emergency declaration areas.

Amends SSA title XX (Block Grants to States for Social Services) to direct the Secretary to establish a program for early detection of certain medical conditions related to environmental health hazards. Makes appropriations for FY2012-FY2019.

(Sec. 10324) Establishes floors: (1) on the area wage index for hospitals in frontier states; (2) on the area wage adjustment factor for hospital outpatient department services in frontier states; and (3) for the practice expense index for services furnished in frontier states.

(Sec. 10325) Revises the SNF prospective payment system to delay specified changes until FY2011.

(Sec. 10326) Directs the Secretary to conduct separate pilot programs, for specified kinds of hospitals and hospice programs, to test the implementation of a value-based purchasing program for payments to the provider.

(Sec. 10327) Authorizes an additional incentive payment under the physician quality reporting system in 2011 through 2014 to eligible professionals who report quality measures to CMS via a qualified Maintenance of Certification program. Eliminates the MedicareAdvantage Regional Plan Stabilization Fund.

(Sec. 10328) Requires Medicare part D prescription drug plans to include a comprehensive review of medications as part of their medication therapy management programs. Requires automatic quarterly enrollment of qualified beneficiaries, with an allowance for them to opt out.

(Sec. 10329) Requires the Secretary to develop a methodology to measure health plan value.

(Sec. 10330) Directs the Secretary to develop a plan to modernize CMS computer and data systems.

(Sec. 10331) Requires the Secretary to: (1) develop a Physician Compare website with information on physicians enrolled in the Medicare program and other eligible professionals who participate in the Physician Quality Reporting Initiative; and (2) implement a plan to make information on physician performance public through Physician Compare, particularly quality and patient experience measures.

Authorizes the Secretary to provide financial incentives to Medicare beneficiaries furnished services by high quality physicians.

(Sec. 10332) Directs the Secretary to make available to qualified entities standardized extracts of Medicare claims data for the evaluation of the performance of service providers and suppliers.

(Sec. 10333) Amends the Public Health Service Act to authorize the Secretary to award grants to eligible entities to support community-based collaborative care networks for low-income populations.

(Sec. 10334) Transfers the Office of Minority Health to the Office of the Secretary. Authorizes appropriations for FY2011-FY2016.

Establishes individual offices of minority health within HHS.

Redesignates the National Center on Minority Health and Health Disparities in NIH as the National Institute on Minority Health and Health Disparities.

(Sec. 10336) Directs the Comptroller General to study and report to Congress on the impact on Medicare beneficiary access to high-quality dialysis services of including specified oral drugs furnished to them for the treatment of end stage renal disease in the related bundled prospective payment system.

Subtitle D: Provisions Relating to Title IV - (Sec. 10401) Revises provisions of or related to Subtitles A, B, C, D, and E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10407) Catalyst to Better Diabetes Care Act of 2009 - Requires the Secretary to prepare biennially a national diabetes report card and, to the extent possible, one for each state.

Requires the Secretary, acting through the Director of CDC, to: (1) promote the education and training of physicians on the importance of birth and death certificate data and on how to properly complete these documents; (2) encourage state adoption of the latest standard revisions of birth and death certificates; and (3) work with states to reengineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data. Allows the Secretary to promote improvements to the collection of diabetes mortality data.

Directs the Secretary to conduct a study of the impact of diabetes on the practice of medicine in the United States and the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(Sec. 10408) Requires the Secretary to award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs.

(Sec. 10409) Cures Acceleration Network Act of 2009 - Amends the Public Health Service Act to require the Secretary, acting through the Director of NIH, to implement the Cures Acceleration Network under which grants and contracts will be awarded to accelerate the development of high need cures. Defines "high need cure" as a drug, biological product, or device: (1) that is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and (2) for which the incentives of the commercial market are unlikely to result in its adequate or timely development. Establishes a Cures Acceleration Network Review Board.

(Sec. 10410) Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009 or the ENHANCED Act of 2009 - Requires the Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration, to: (1) award grants to establish national centers of excellence for depression; and (2) designate one such center as a coordinating center. Requires the coordinating center to establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders using data collected from the national centers.

(Sec. 10411) Congenital Heart Futures Act - Authorizes the Secretary, acting through the Director of CDC, to: (1) enhance and expand infrastructure to track the epidemiology of congenital heart disease and to organize such information into the National Congenital Heart Disease Surveillance System; or (2) award a grant to an eligible entity to undertake such activities.

Authorizes the Director of the National Heart, Lung, and Blood Institute to expand, intensify, and coordinate research and related Institute activities on congenital heart disease.

(Sec. 10412) Reauthorizes appropriations for grants for public access defibrillation programs. Requires an information clearinghouse to increase public access to defibrillation in schools established under such program to be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death.

(Sec. 10413) Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009 or the EARLY Act - Requires the Secretary, acting through the Director of CDC, to conduct: (1) a national education campaign to increase awareness of young women's knowledge regarding breast health and breast cancer; (2) an education campaign among physicians and other health care professionals to increase awareness of breast health of young women; and (3) prevention research on breast cancer in younger women.

Requires the Secretary, acting through the Director of NIH, to conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

Directs the Secretary to award grants for the provision of health information to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

Subtitle E: Provisions Relating to Title V - (Sec. 10501) Revises provisions of or related to Title V of this Act (as reflected in the summary of those provisions).

Requires the Secretary, acting through the Director of CDC, to establish a national diabetes prevention program targeted at adults at high risk for diabetes.

Directs the Secretary to develop a Medicare prospective payment system for payment for services furnished by federally qualified health centers.

Requires the Secretary, acting through the Administrator of the HRSA, to establish a grant program to assist accredited schools of allopathic or osteopathic medicine in: (1) recruiting students most likely to practice medicine in underserved rural communities; (2) providing rural-focused training and experience; and (3) increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

Directs the Secretary, acting through the Administrator of HRSA, to award grants or enter into contracts with eligible entities to provide training to graduate medical residents in preventive medicine specialties.

Reauthorizes appropriations for public health workforce activities.

Revises provisions related to fulfillment of service obligations under the National Health Service Corps related to half-time clinical practice and teaching.

(Sec. 10502) Authorizes appropriations to HHS for debt service on, or direct construction or renovation of, a health care facility that provides research, inpatient tertiary care, or outpatient clinical services and that meets certain requirements, including that it is critical for the provision of greater access to health care within the state.

(Sec. 10503) Establishes a Community Health Center Fund to provide for expanded and sustained national investment in community health centers. Authorizes appropriations to such Fund.

(Sec. 10504) Requires the Secretary, acting through the Administrator of HRSA, to establish a demonstration project to provide access to comprehensive health care services to the uninsured at reduced fees.

Subtitle F: Provisions Relating to Title VI - (Sec. 10601) Revises provisions of Subtitles A through E of Title IV of this Act (as reflected in the summary of those provisions).

(Sec. 10606) Directs the U.S. Sentencing Commission to amend the Federal Sentencing Guidelines to provide two-level, three-level, and four-level increases in the offense level for any defendant convicted of a federal health care offense relating to a government health care program of a loss between $1 million and $7 million, between $7 million and $20 million, and at least $20 million, respectively.

Provides that a person need not have actual knowledge of the prohibition against health care fraud nor specific intent to violate it in order to commit health care fraud.

Expands the scope of violations constituting a federal health care offense.

Amends the Civil Rights of Institutionalized Persons Act to authorize the Attorney General to require access to an institution by subpoena to investigate conditions depriving residents of specified constitutional or federal rights.

(Sec. 10607) Authorizes the Secretary to award demonstration grants to states for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations.

(Sec. 10608) Amends the Public Health Service Act to extend medical malpractice coverage to free clinics by deeming their officers, employees, board members, and contractors to be employees of the Public Health Service.

(Sec. 10609) Amends the Federal Food, Drug, and Cosmetic Act to set forth circumstances under which a generic drug may be approved with a label different from the listed drug.

Subtitle G: Provisions Relating to Title VIII - (Sec. 10801) Revises provisions of or related to Title VIII of this Act (as reflected in the summary of those provisions).

Subtitle H: Provisions Relating to Title IX: (Sec. 10901) Revises provisions of or related to Title IX of this Act (as reflected in the summary of those provisions).

(Sec. 10907) Amends the Internal Revenue Code to impose a 10% excise tax on any amount paid for indoor tanning services on or after July 1, 2010. Exempts phototherapy services performed by a licensed medical professional from the definition of "indoor tanning services."

(Sec. 10908) Excludes from gross income any payments under the National Health Service Corps Loan Repayment Program and any other state loan repayment or forgiveness programs intended to increase the availability of health care services in underserved or health professional shortage areas.

(Sec. 10909) Increases from $10,000 to $13,170 the dollar limitation on: (1) the tax credit for adoption expenses; and (2) the tax exclusion for employer-provided adoption assistance. Allows an inflation adjustment to such limitation after 2010. Makes such credit refundable. Extends through 2011 the general terminating date of the Economic Growth and Tax Relief Reconciliation Act of 2001 with respect to such credit and exclusion.

Chapter 4
The Trump Proposals of 2018

This chapter consists of three discrete sections. The first and longest part was originally published in 2017 as 'Reforming America's Healthcare System Through Choice and Competition' by the US Department of Health and Human Services and endorsed by then HHS Secretary Alex Azar II, Treasury Secretary Steven Mnuchin and Labor Secretary Alexander Acosta. I present the entire report here so readers can get both the factual discussion and nuances without any potential biases from me. All footnotes appear at the end. 'Reforming America's Healthcare System' is available online at https://www.hhs.gov/about/news/2018/12/03/reforming-americas-healthcare-system-through-choice-and-competition.html.

I encourage readers to consider this as a statement of the Republican approach to solving our healthcare financing problems. Read it less as a specific policy proposal and more as an overall approach..

The Trump supported two additions to these market based reform proposals: Individual Coverage Health Reimbursement Accounts (ICHRAs) and Association Health Plans. I present discussions of both at the end of this chapter.

The ICHRA discussion comes from the 2019 Department of Health and Human Services FAQs on ICHRAs. It is available online at https://www.hhs.gov/about/news/2019/06/13/hhs-labor-treasury-expand-access-quality-affordable-health-coverage.html.

The Association Benefit Plan discussion comes from the 2020 CBO Paper: INCREASING SMALL-FIRM HEALTH INSURANCE COVERAGE THROUGH ASSOCIATION HEALTH PLANS AND HEALTHMARTS, January 2000. https://www.cbo.gov/publication/12066. Numbers in the text and tables of this paper may not add up to totals because of rounding. All dollar values are expressed as 1999 dollars.

The United States healthcare system increasingly imposes a bewildering array of complexity and inefficiency throughout the commercial insurance markets. In addition, our nation's healthcare system is encumbered with mandates and regulations that raise costs, decrease competition, and sometimes do little on net to improve the nation's health. These inefficiencies, mandates and regulations contribute to higher costs and higher health insurance premiums. Health insurance premiums, particularly for individual coverage (the markets most affected by the Affordable Care Act, or ACA) have soared—more than doubling in the individual market between 2013 and 2017[2]— while out-of-pocket spending has also skyrocketed.[3] Even though the ACA was supposed to hold down healthcare costs, premiums in the individual market rose after 2013 when the ACA's insurance rules took effect. The average monthly premiums for all plans rose: For the benchmark plan—the second-lowest cost silver plan—premiums increased by 88 percent between 2014 and 2018 in states with the federally run healthcare exchange (Healthcare.gov).[4] Spending by employers for employer-sponsored health benefits is also rising. The average premium for family coverage has increased 20 percent since 2013 and 55 percent since 2008.[5] While private spending is increasing, so, too, is government spending. Spending on government

health programs now accounts for nearly half of all U.S. healthcare expenditures, increasing the burden on taxpayers.[6] Part of this increase in government spending is driven by an aging population, as the baby boomer generation shifts from private coverage to Medicare. Given the magnitude of this spending, it should not be surprising that there are growing concerns about whether the spending is producing benefits that justify the cost.

In addition to increased spending, the federal regulation of healthcare has risen sharply. Unfortunately, government bureaucracies are often slow to change and adapt to health-care innovations and new payment models. Given government's large role in the healthcare sector, this likely contributes to lower productivity in the sector. For example, the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) found that multifactor productivity—the output from joined units of capital and labor—in hospitals had a 0.1 to 0.6 percent 10-year moving average productivity growth rate from 1990 to 2013, compared to 1 percent in private nonfarm businesses.[7] Slower-than-average productivity growth suggests that there is a misallocation of resources and widespread inefficiency in the healthcare system, particularly in public programs.[8] Since the government share of healthcare spending is so large, government rules impose inefficiencies on private firms dependent on public funding, even if they also serve privately funded patients. Simply put, government has played a large role in limiting the value Americans obtain for their healthcare spending. The United States is spending a large and increasing share of its national income on healthcare, and much of this spending does not lead to citizens living longer, healthier lives.

One of the most important mechanisms available to enhance the value Americans receive for their healthcare spending is increased competition. Market competition should encourage healthcare providers to charge lower prices and provide higher-quality services. Although the traditional view among economists is that government should step in to correct so-called market failures, this report finds many cases where government regulation and rules prevent healthcare markets from working efficiently. This report examines many sectors of the U.S. healthcare market to assess the degree to which competition for healthcare services exists and the role government regulation plays in affecting competition for healthcare services. In doing so, the report identifies numerous government policies that inhibit choice and competition in healthcare markets, dampen productivity gains among providers, lead to increased consolidation and market concentration, and prevent the introduction of more efficient or innovative ways of delivering and paying for care.

A highly-effective and well-functioning healthcare market is important for two reasons. First, the state of health and well-being Americans enjoy contributes in economic and non-economic ways to the quality of American life. Second, the significant resources Americans spend on healthcare crowd out resources that would otherwise be available for other individual and national priorities. The United States spends nearly one-fifth of its national income on healthcare,[9] and much of this spending provides little, if any, positive value. For example, the 2018 Economic Report to the President, prepared by the Council of Economic Advisers, reviewed several studies that showed a poor relationship between government coverage expansions and health improvements.

When it comes to healthcare, Americans should expect more value for the dollars they spend. This report details many opportunities to increase the value provided throughout our healthcare system through the actions that create greater choice and competition.

The Fundamental Bases of Commercial Health Insurance Reforms

Commercial health insurance reforms are based on the concept of enhanced user / patient decision making responsibilities. Economists generally accept that free-market competition produces the most efficient production and distribution of goods and services. When consumers have choices, the incentives and information needed to optimize value, firms have the incentive to improve quality and lower costs through innovation. Competitive market forces and the incentive to innovate typically raise quality and drive down prices, including quality-adjusted prices, for goods and services over time (features observed in many well-functioning sectors of the economy but which are generally absent in the highly regulated healthcare market).[10] However, when government policies and regulations suppress competition, producers may use their market power to raise prices, produce lower-quality goods and services, or become complacent in innovating. In other words, without competitive pressure, the incentive to lower prices, improve quality, and innovate diminishes. As the government share of healthcare spending has increased over time, the healthcare market has become increasingly vulnerable to rules and regulations that impede market forces.

The importance of market competition is apparent in the relevant data. Hospitals without local competitors typically charge higher prices, which could add thousands of dollars to a hospital bill.[11] Since healthcare expenses largely drive insurance premiums, these costs are mostly passed on to consumers or taxpayers. The lack of insurer competition also leads to higher prices: Researchers have estimated that adding a single insurer offering to health exchange plans in 2014 reduced premiums by 4.5 percent on average.[12] A recent paper in Health Affairs estimated that exchange plan premiums were 50 percent higher, on average, in rating areas with only one insurer compared to those with more than two insurers.[13] The lack of competition produces similar affects within the employer market for health insurance. A paper in the American Economic Review estimated that premiums in average markets were approximately 7 percentage points higher by 2007 due to increases in local concentration of health insurers from 1998 through 2006.[14] One example is that, according to one study, the merger between Aetna and Prudential in 1999 led to a 7 percent increase in premiums for large employers.[15] Similarly, according to another study, the merger of Sierra and United Health in 2008 led to an almost 14 percent increase in small group premiums.[16]

Perhaps more importantly, there is evidence that the lack of competition in provider markets leads to reduced quality of care.[17] For example, a 2000 study of more than 500,000 Medicare beneficiaries found that those who experienced a heart attack had a statistically significant (1.5 percentage point) higher chance of dying within one year of treatment if they received care in a hospital with fewer potential competitors.[18] To drive that point

home, Americans have 790,000 heart attacks each year.[19] Assuming that half the country lives in relatively noncompetitive hospital markets, we would expect from these findings that 5,925 premature deaths to be associated with a lack of competition. Of course, this calculation is just for heart attacks, just one of numerous diseases or conditions that kill Americans prematurely each year. Other findings demonstrate the relationship between competitive healthcare markets and improved outcomes, increased quality, and lower prices. For example, the inflation- adjusted price of LASIK eye surgery declined by 25 percent between 1999 and 2011, even as quality markedly improved.[20] Notably, third-party payers (including the government) generally do not cover the procedure and so ophthalmologists have had to compete directly for consumer dollars.[21] Similarly, though the price of healthcare grew at double the rate of inflation between 1992 and 2012, the price of cosmetic surgery—for which consumers pay almost exclusively out of pocket—grew at less than half the rate of inflation.[22] These examples also highlight that when consumers are spending their own dollars and shopping accordingly, providers have greater incentives to improve quality and cut costs.

Unfortunately, a lack of consumer choice permeates most health insurance markets as well. Most Americans receive insurance selected by their employer or receive coverage through government programs, characterized by exceptionally heavy regulation and bureaucratic controls. Because of the ACA, insurance companies were not allowed to offer certain low-cost plans and withdrew from some markets. Although some people who were previously uninsured are covered, many with subsidies, Americans without employer or publicly-supported coverage often face limited choices in the individual market.[23] Starting in 2014, new individual market plans had to satisfy ACA requirements. In 2017, people in one-third of U.S. counties could purchase health insurance only through the ACA exchanges from a single insurer.[24] As additional insurers have withdrawn from government-designed and regulated markets, people in more than half of U. S. counties (representing 29 percent of exchange enrollees) have options from only a single insurer in 2018.[25] Notably, government policies promote many factors that prevent the free-market from operating. Specifically, government has encouraged excessive third-party payment, created counterproductive barriers to entry, incentivized opaque pricing practices, skewed innovation activity, and placed restrictions on the reimbursement policies of government programs. Overall, these practices have resulted in less choice, less competition, and sub-optimally functioning markets that deliver higher prices and lower quality.

Some healthcare expenditures are for emergency services that are not conducive to consumer shopping. That said, the common claim that the healthcare sector as a whole cannot function under free-market principles is untrue. The vast majority of healthcare services are routine or elective services that can be organized by markets to enhance patient welfare. One study found that emergency department spending is roughly six percent of total United States health spending.[26] Another study classified 43 percent of healthcare spending as “shoppable,” with another 11 percent of spending on prescription drugs, an item that is generally shoppable.[27] Distinguishing between shoppable and non-shoppable healthcare services is important, and encouraging normal market economic forces to

govern the shoppable transactions constituting the majority of the sector is prudent. As this report explains, government policy and regulation often does precisely the opposite, actively discouraging the application of normal market forces to the shoppable category of healthcare services, and, in effect, treating the whole sector as if it were similar to emergency services.

Another common argument contends that the gap in expertise between the sellers of healthcare services (i.e., healthcare providers) and buyers (i.e., patients) makes the idea of informed consumer choices implausible. While true to some extent, the same could be said about other markets that operate successfully under free-market principles, as anyone who has taken a car to an auto-mechanic or employed a financial adviser can attest. Indeed, the implication that healthcare providers will take advantage of patients by selling them services they do not understand or need suspects the worst of professions (such as medicine and nursing) that adopt strict ethical standards. Even if there were agreement that this risk is justified, there are other ways to solve this problem without abandoning free-market principles. For instance, in many markets where there is a gap in expertise between buyers and sellers, the less knowledgeable party will employ an unbiased consultant to help them make good decisions. In addition, third-party entities, like consumer watchdog groups, can produce reviews of actors within the healthcare system. The lack of transparent, reliable price and quality information currently inhibits such reviews.

Another reason given by some against market-based healthcare is that there are inherent economies of scale within healthcare that lead to natural monopolies and limit the extent to which markets can properly function. For example, there might be high fixed costs in building and equipping a healthcare facility. Once the facility is built, the marginal cost of extra services declines. This is why, the argument goes, it may make economic sense to have only a single hospital or nursing home in lightly-populated rural areas, and why certain healthcare mergers can increase economic efficiency by lowering production costs.[28] These natural economies of scale contribute to the creation of entities with significant pricing power. One can make a similar argument with regard to disease burdens, wherein smaller communities are only likely to have a need for so many specialists of a certain type given a population size and disease incidence rate. This leads to an economic incentive for specialists to form a practice together and take advantage of their pricing power. Furthermore, it is possible that a relatively small market cannot support the entrance of a competitor that would drive down prices since demand for the relevant type of specialist is roughly fixed among the population, meaning that the addition of another provider would merely drive prices to a point where neither entity were profitable and one ultimately would exit.

While these claims have some merit, most people live in areas with markets large enough to sustain multiple hospitals, nursing homes, or other providers. More importantly, economies of scale are inherent in many markets, yet the markets function well for consumers. Overall, there is little reason to think that these issues are so intrinsic to healthcare markets that they undermine a market-based approach. Indeed, with vigorous law enforcement to prevent unlawful consolidation and anti-competitive behavior, there is good reason to think that healthcare markets will function like most other competitive

markets.

As this report will discuss, the government has actually adopted many policies that promote consolidation in the healthcare sector, favoring established incumbents at the expense of smaller providers and start-ups. Additionally, the ability to create regional monopolies in healthcare markets is largely dependent on geographic factors, which recent innovations such as telehealth could substantially disrupt. Rather than adopt policies that allow disruptive technology like telehealth to compete, the government has often intervened to create an uneven playing field that limits choice and competition to the benefit of established incumbents and at the expense of consumers. While there are economies of scale in healthcare markets, they are hardly unique and do not prevent the market as a whole from functioning well. What is unique is the extent to which the government has adopted policies that exacerbate these issues.

The Third Party Payment Environment of Commercial Health Insurance Policies

Why do healthcare markets not function like other economic markets with price transparency, clear quality metrics, shopping, and declining real, quality-adjusted prices through time? The answer is primarily because government policies have combined to produce an excessive reliance on third-party payment mechanisms and numerous barriers to entry.

Third-party payment mechanisms insulate the ultimate consumer from the direct payment for healthcare goods and services. Instead of paying for healthcare services directly, consumers rely on an intermediary to do so on their behalf. Some degree of third-party payment in healthcare is understandable and necessary since there are low-probability, hard-to-predict, and costly health events that would otherwise subject an individual or family to a large financial loss. While insurance, along with saving and financing, is an efficient mechanism to reduce the impact of unlikely and high-cost events, insurance that covers routine, predictable, or shoppable services has significant drawbacks. First, an insurance system is often administratively complex to implement and accordingly can have high administrative costs. Second, consumers are incented to extract as much value out of an insurance policy as possible (since the premium is in effect a fixed fee), which in turn creates a coverage-induced demand for low-value products and services, and generates greater administrative costs as insurers validate claims. For these reasons, firms offer, and insurance consumers in most other markets select, policies that provide protection against improbable but high-cost events. Because routine, predictable, or shoppable services are not covered by a third party in other insurance markets, consumers have significant incentive to maximize the value they receive from these uncovered, routine services.

Auto insurance is a good example. Auto insurance typically covers a car crash and related healthcare expenses, but it does not cover gasoline or routine maintenance. Imagine if auto insurance did provide coverage for gasoline and routine maintenance. First, consumers would shop for their gas less carefully (since the insurance pool would bear the marginal cost of premium gasoline versus standard gasoline), and they would consume more maintenance. Second, in response to rising utilization and corresponding premium increases, auto insurance companies might establish preferred networks of gasoline and

maintenance providers to better incentivize consumer behavior and control cost. In the long term, complex bureaucratic management schemes might emerge to tackle resource allocation with large national networks coming to dominate the market. While one could keep going with this thought experiment, the example highlights that as insurance covers more of an individual's routine expenses, consumers experience diminished incentives to obtain value.

Federal policy has a long history of subsidizing highly-comprehensive health insurance.[29] In the 1940s and 1950s, the exclusion of employer-provided health insurance premiums from income and payroll taxes created incentives for employers to offer comprehensive insurance coverage to compete for workers. Notably, this incentivized employers to compensate employees with health insurance rather than wage increases or other benefits that lacked a comparably generous tax exemption. The creation of Medicare and Medicaid in 1965 led to additional government subsidization of comprehensive coverage. Most recently, the ACA mandated that individuals have comprehensive coverage or pay a tax penalty. (This penalty has been reduced to $0 as of 2019 because of the Tax Cuts and Jobs Act of 2017.) Similarly, employers with 50 or more full-time workers who do not offer comprehensive coverage pay a tax penalty if at least one of their employees receives a premium tax credit for an exchange plan. The ACA also created additional federal subsidies for comprehensive coverage through Medicaid expansion and premium tax credits and cost-sharing reduction payments for exchange plans.

Because of open-ended tax subsidies for employer-provided health insurance, health insurance in the United States generally covers routine, predictable and shoppable services in addition to low-probability events. Federal laws, including the ACA, and state laws governing health insurance policies also require coverage for specific health benefits, often with low or no copayments. The Medicaid program, with nominal or zero copays and deductibles, exemplifies this problem. As a result, consumers typically do not have an incentive to shop for value, eliminating one mechanism that could help constrain provider prices. This set of policy choices has created a market for healthcare goods and services that is inherently inflationary.

As healthcare costs increase, insurers should feel market pressure to aggressively manage these costs on behalf of their customers. In competitive insurance markets, insurers feel the pressure of market forces to lower healthcare costs and premiums. However, some have claimed that insurers benefit from rising provider costs.[30] One recent article discussed that insurers may lack adequate incentives to bring down provider charges, partly because higher provider prices translate into higher insurer profits.[31] This may be particularly problematic in markets without vigorous competition among payers. Regardless of the motivation, one might ascribe to insurer actions, healthcare costs have consistently increased faster than wages and the overall economy.

Third-party payment also creates notable separation between producers and consumers, and leaves bureaucracies with the role of allocating resources. Bureaucracies are extremely susceptible to pressure from special interest groups, which lobby lawmakers to require coverage for the products they produce or services they provide. While a boon to special interests, mandated benefits cause a greater amount of healthcare services to be financed

through third-party arrangements, raising premiums and taxes. The increased premiums, in turn, may incentivize some people to obtain more treatment and services so as to maximize the value received for the premium paid. This behavior drives up utilization and increases low-value spending. Moreover, excessive third-party payment results in providers serving the interest of payers—government bureaucracies and insurance companies—rather than consumers.

In conclusion, in most other markets, consumers pay the full price of what they purchase and are therefore likely to carefully consider the value of products relative to alternatives. Active shopping by consumers motivates competition on price and quality among producers. Third-party payment for routine, predictable and shoppable expenses reduces consumers' incentives to obtain maximum value and has contributed to opaque and byzantine prices and bureaucratic complexities. As a result, consumers have less ability and less incentive to carefully shop for healthcare, compare prices and quality, and select the most efficient providers. This, in turn, means that providers have a diminished incentive to innovate and increase their efficiency.

Under normal market conditions, high prices and/or high profit margins attract new producers and sellers. This increased supply leads to lower prices and higher quality over time. Without the possibility of new entrants and real competition, however, existing producers can use market power to keep prices high and quality low. While barriers to entry can be the result of normal market forces, such as economies of scale, they may also be the result of government restrictions. Government-erected barriers to entry can lead to a highly-concentrated and inefficient market. Moreover, firms protected from competitive forces can be expected to devote resources to maintaining these rents (e.g., by erecting or maintaining entry barriers) rather than to improving efficiency and innovating.[32] Some government-erected barriers, such as patents, are enacted to support a careful balance that promotes innovation and consumer options. However, many government-erected barriers harm consumers by blocking or restricting market entry.[33]

These harmful barriers, such as state laws requiring potential new entrants to gain governmental permission (and, occasionally, permission from established incumbents) to enter markets, or preventing healthcare professionals from practicing to their full ability, are of primary interest in this report.

Over the past few decades, there has been a substantial increase in mergers and acquisitions throughout the healthcare sector, particularly among healthcare providers. More recently, industry consolidation (fewer and larger firms in the market) and industry concentration (the extent to which a small number of firms control most of the transactions) has occurred, in part, due to the increased complexity and administrative burden resulting from the ACA[34] and other government requirements. As will be discussed in Section 2 of this report, significant evidence shows that reduced competition in healthcare markets contributes to higher prices and reduced quality.

Perhaps the best evidence for why the healthcare system needs reform and that the ACA moved the system in the wrong direction was outlined in the President's 2018 Economic

Report.[35] This report (at pages 283-285) details the literature showing that our previous focus on expanding health insurance coverage has had mixed and surprisingly small effects on health outcomes. Probably the best investigation– the oft-cited Oregon Medicaid study– found that low-income, uninsured individuals randomly selected to enroll in Medicaid did not experience statistically significant improvement in any of the physical measures of health observed—cholesterol, blood pressure, and blood sugar–although there were some benefits for mental health.[36]

A subsequent Oregon Medicaid expansion study estimated that Medicaid enrollees only valued each dollar of program spending at between 20 to 40 cents, and that 60 percent of expansion costs were transfers to providers who would have otherwise provided uncompensated care to these patients.[37] A separate study of how many enrollees dropped out when charged higher premiums for Medicaid-like coverage in Massachusetts found that most enrollees valued coverage at less than half the cost. The availability of uncompensated care was the central reason that enrollees place low value on the coverage – substantially less than the cost of providing that coverage.[38]

Notably, despite the ACA expanding coverage options to the uninsured, largely through Medicaid, American life expectancy dropped three-tenths of a year from 2014 to 2017—in part due to rising opioid abuse—something that has not happened since the 1960s.[39] The Economic Report of the President outlined several explanations for why insurance, particularly expansions of public programs like the ACA's Medicaid expansion, have limited health benefits and in many locations contribute to access problems. Some Medicaid recipients have difficulty finding providers to provide care.[40] Moreover, as Atul Gawande, former adviser to President Bill Clinton, has discussed, some medical care can actually decrease health because there are separate health risks associated with the receipt of medical care, including over-testing and resulting issues like stress, radiation exposure and over-treatment (e.g. medically unnecessary surgeries), that need to be counted.[41]

This report discusses government-induced barriers to competition and choice and makes recommendations that would reduce or eliminate these barriers. These reforms are critical to unleashing competitive forces to improve consumer choices and spur provider and payer innovation to deliver high-value products and services to consumers. Without enacting a bold set of reforms that increase choice and competition in healthcare, government-created inefficiencies will continue to dominate the U.S. healthcare system, particularly publicly-financed care, frustrating Americans as the rising cost of healthcare squeezes family and government budgets. Reform will involve taking on entrenched special interests that maintain their advantage over consumers by lobbying government to restrain competitive forces.

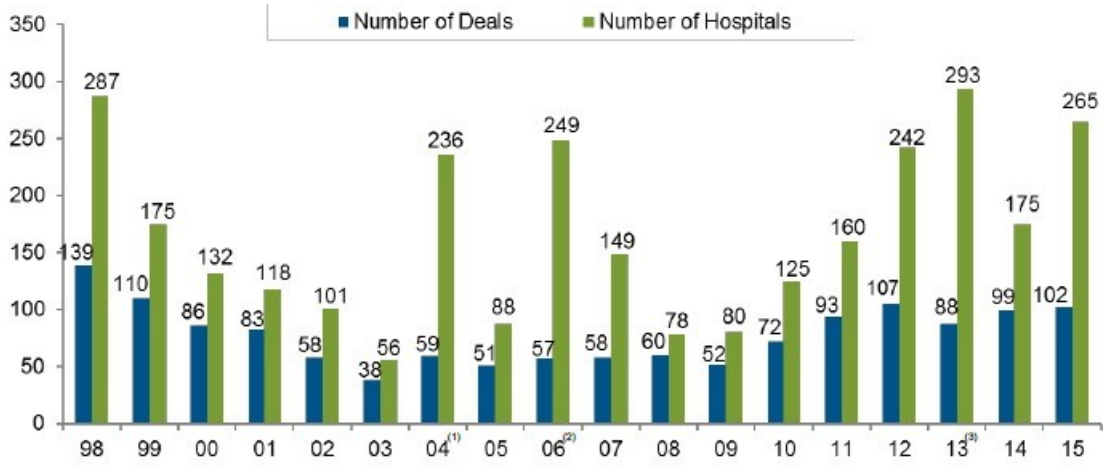
In particular, this report aims to address these issues as crystalized in the following problem statement: Many government laws, regulations, guidance, requirements and policies, at both the federal and state level, have reduced incentives for price- and non-price competition, increased barriers to entry, promoted and allowed excessive consolidation, and resulted in healthcare markets that lack the benefits of vigorous competition. Increasing competition and innovation in the healthcare sector will reduce costs and increase quality of care—improving the lives of Americans.

The remaining three sections of this report are devoted to analyzing these important issues with a focus on changing government regulations to improve health-market outcomes through enhancing choice and competition. Section 2 provides detailed analysis of trends in consolidation and concentration in certain healthcare markets. Section 3 provides analysis of several specific areas of federal and state policies associated with increased consolidation or reduced competition. Section 4 presents recent and emerging policy alternatives that can address these issues by facilitating more efficient allocation of healthcare dollars. The final section offers specific policy recommendations based on these analyses.

Trends in Merger Activity

According to a recent analysis of metropolitan areas that are considered single markets, roughly 77 percent of Americans in these urban markets live in highly concentrated hospital markets.[45] Over the past several decades, many hospitals have consolidated into multi-hospital systems.[46] According to data compiled by Irving Levin Associates, depicted by the American Hospital Association in Figure 1, the number of announced hospital transactions (including mergers and acquisitions) per year fell from 139 in 1998 to 38 in 2003, before starting to increase in 2010 and reaching 102 in 2015.[47] In 2010 alone, the number of mergers jumped 40 percent to 59, with more than 60 deals in each subsequent year. The number of hospitals involved in those deals has shown more variation from year to year, although data from recent years show a rise in mergers and acquisition.

Figure 1: Announced Hospital Mergers and Acquisitions, 1998-2015



Source: Irving Levin Associates, Inc. (2016). *The Health Care Services Acquisition Report*, Twenty-Second Edition.
(1) In 2004, the privatization of Select Medical Corp., an operator of long-term and acute-care hospitals, and divestiture of hospitals by Tenet Healthcare Corporation helped to increase the number of hospitals affected.
(2) In 2006, the privatization of Hospital Corporation of America, Inc. affected 176 acute-care hospitals. The acquisition was the largest health care transaction ever announced.
(3) In 2013, consolidation of several investor-owned systems resulted in a large number of hospitals involved in acquisition activity.
Chart 2.10 in 2009 and earlier years' Chartbooks.

An acquisition that combines healthcare providers that were competing in some aspect of

their business may substantially lessen competition and thereby violate Section 7 of the Clayton Act.[48] Because preservation of healthcare competition is vital to preserving consumer choice, price containment, and quality, federal antitrust authorities, specifically the Federal Trade Commission (FTC) and the Department of Justice, have for many years maintained vigorous enforcement programs to scrutinize healthcare mergers for their potential effects on competition. Antitrust enforcers seek to identify and challenge mergers likely to have anti-competitive effects.

Empirical evidence on the impact of mergers on competition in healthcare markets—based on studies by FTC staff and independent scholars—shows that healthcare consumers benefit from competitive markets and the associated lower prices and higher quality services.[49] Economic studies also consistently demonstrate that reducing hospital competition leads to higher prices for hospital care.[50] These effects are not limited to for-profit hospitals: mergers between not-for-profit hospitals can also result in substantial anti-competitive price increases.[51] Economic evidence also shows that hospital competition tends to be highly localized.[52]

The Impact of Lost Competition

FTC merger retrospective studies, supplemented by a large and growing body of literature, strongly suggest that healthcare providers with significant market power can (and often do) negotiate higher-than-competitive payment rates.[53] The price differences ultimately paid by consumers in concentrated markets can be significant.[54] For example, price increases as high as 40 percent have resulted when competition was lost after one hospital system acquired a competing hospital.[55]

Federal antitrust agencies prevailed in some early challenges to anti-competitive hospital mergers[56] and obtained a number of consent decrees that allowed problematic hospital mergers to proceed only if certain hospitals were divested.[57] However, in the 1990s, several courts rejected the agencies' attempts to block hospital mergers (on the grounds that the government had not established geographic or products markets) that they claimed would harm competition.[58] This string of losses led the FTC to launch a Hospital Merger Retrospective Project to determine whether consummated hospital mergers led to higher prices. The FTC selected four consummated hospital mergers for intensive study and published retrospective studies in early 2011.[59] The study of one consummated merger in particular—the Evanston/Highland Park (Illinois) merger—led to an FTC administrative challenge determining that the acquisition had violated the antitrust laws.[60]

The Hospital Merger Retrospective Project led to important insights about the nature of hospital competition and the competitive effects of hospital mergers that have continued to guide FTC case selection and enforcement decisions today.[61] For instance, in 2011, the FTC challenged ProMedica Health System's acquisition of its rival, St. Luke's Hospital.[62] The proposed merger would have given ProMedica, already the largest hospital system in the Toledo, Ohio, area, over half the market for general acute care hospital services and

over 80 percent of the market for inpatient obstetrics services. Hospital documents indicated that St. Luke's management saw the acquisition leading to higher prices by increasing its "negotiating clout" over insurers. The FTC's order required ProMedica to undo its merger and re-establish St. Luke's as an independent competitor. The FTC has since successfully challenged other hospital mergers as well.[63]

The FTC has also challenged mergers between competing physician practices. For example, the FTC and the State of Idaho successfully challenged the acquisition by St. Luke's Health System of Saltzer Medical Group in Nampa, Idaho.[64] St. Luke's, the state's dominant health system, had numerous employed primary care physicians from prior acquisitions, including eight primary care physicians in Nampa, before acquiring from Saltzer 16 additional primary care physicians also practicing in Nampa. Although their prior acquisitions gave St. Luke's greater bargaining power, payers had been able to resist at least some of St. Luke's demands because of the presence of an alternative provider, Saltzer. The FTC alleged, and the court agreed, that the St. Luke's acquisition of Saltzer eliminated that remaining competitive option and would have led to higher prices for physician services.[65]

In sum, consolidation in well-defined antitrust markets can harm competition and consumers. Retrospective studies of healthcare mergers provide credible examples of harmful consolidation. These studies lend support for vigorous antitrust enforcement to prevent the accumulation of market power in healthcare markets. They can also help to guide case selection by the antitrust agencies and illustrate the mechanism by which excessive consolidation can stifle competition and harm healthcare consumers. However, as will be discussed in Section 3, certain state policies, such as certificate-of-need laws and certificates of public advantage, may suppress entry or prevent antitrust scrutiny of mergers that lead to increased concentration in local healthcare markets.[66]

Consolidation in Specific Healthcare Markets

While the evidence above demonstrates that some specific transactions have had anti-competitive consequences, it does not speak to general trends in the ownership structure of healthcare service providers. This section discusses research tracking various measures of concentration that differ from those used in antitrust analysis, generally calculating concentration in geographic areas that are broader than geographic markets consistent with antitrust standards, as well as explaining possible limitations with measures.[67]

Consequently, while these studies provide information about trends in changes of ownership of various types of healthcare providers, they do not reliably distinguish between concentration that may lessen competition and concentration that may be competitively benign.

Measures of Concentration

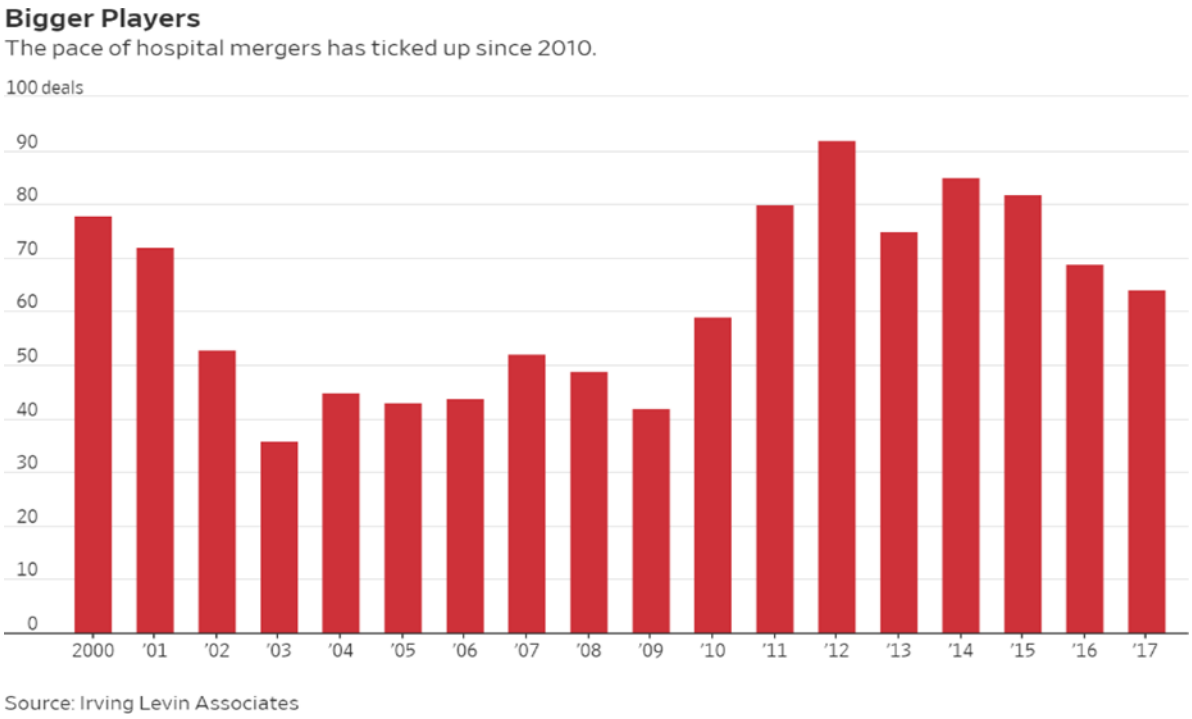
Industrial organization economists and antitrust practitioners have developed several

market concentration indices. Two of the more common are the "four firm concentration ratio" (CR_4) and the Herfindahl-Hirschman Index (HHI). The CR_4 is the sum of the market shares of the four largest firms (as measured by market share), and the HHI is the sum of the squared share of each firm in the market, multiplied by 10,000. For example, a market with five firms each having a share of 20 percent would have a CR_4 of 80 percent and an HHI of 2,000. A merger between any two of those five firms will yield a CR_4 of 100 percent and an HHI of 2,800. The 2010 Department of Justice-Federal Trade Commission Horizontal Merger Guidelines[68] explain the HHI as a measure of market concentration for use in merger analysis. These guidelines generally classify markets with an HHI below 1,500 as unconcentrated and markets with an HHI exceeding 2,500 as highly concentrated. However, these thresholds apply only to well-defined antitrust markets, i.e., markets carefully defined to reflect the scope of both geographic and product/service competition that is relevant in antitrust analysis. HHIs calculated for broader geographic units, such as counties or metropolitan statistical areas (MSAs), may sometimes be informative, but considerable care is required in interpreting the results. HHIs calculated for larger geographic regions can both overstate and understate changes in the level of concentration in a relevant geographic market as it would be defined for purposes of antitrust analysis.[69]

Inpatient Hospital Industry

Much of the research into concentration in the healthcare sector has been focused on hospitals, largely due to data availability and the outsized role of hospitals in the healthcare system. Recent analysis suggests a noticeable shift during 2010-2016 in site of practice for primary care physicians into hospital systems, as well an increase in the number of hospital consolidations since 2009.[70] One recent study by Gaynor et al.[71] measured concentration in the hospital industry by calculating the HHI for each MSA in the United States. The study calculated concentration measures at the MSA level using each hospital system's share of admissions.[72] It found that the mean HHI across MSAs in the inpatient hospital industry increased from 2,370 in 1987 to 3,261 in 2006—an increase of more than 900 points.[73] It also found that most of this increase had occurred by the year 2000. The report found that the mean hospital HHI increased by an average of about 100 points per year over the period 1990-2000 but was largely flat over the period 2000-2006. It also found that the percentage of MSAs with an HHI that exceeded 2,500 increased from 65 percent in 1990 to 77 percent in 2006.

Fig 2: The Pace of Hospital Mergers



More recent work by Fulton measured hospital concentration over the period 2010-2016.[75] Like Gaynor et al., Fulton calculated the HHI for inpatient hospitals within each MSA in the United States. He found that the mean HHI across MSAs increased from about 5,500 to about 5,786, an increase of 5.2 percent. This finding implies an average increase in the mean HHI of about 48 points per year. Fulton also reported that the percentage of MSAs with an HHI that exceeded 2,500 increased from about 87 percent in 2010 to 90 percent in 2016. The mean HHI of 5,500 in 2010 found by Fulton is substantially higher than the mean HHI of 3,261 in 2006 found earlier by Gaynor.[76]

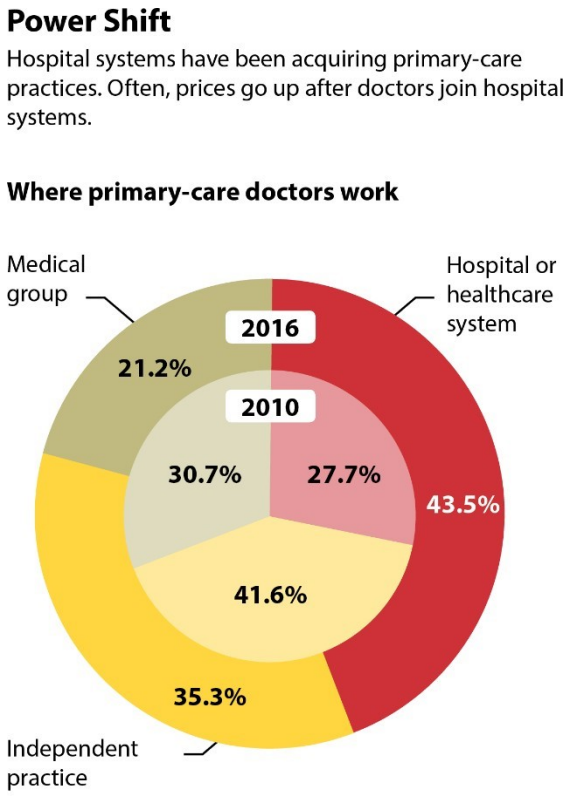
Physician Services

More recently, researchers have been able to obtain data to study consolidation involving physician practices. Fulton calculated HHIs at the MSA level for primary care physicians and specialist physicians.[77] He found a high degree of concentration at the MSA level for specialist physician services, but the increase over the period 2010-2016 was modest. The mean HHI across MSAs ranged from about 3,000 to about 3,400 over the period. The mean HHI increased by about 5 percent over the period 2010-2016. This implies an average increase in the mean HHI of about 26 points per year. The percentage of MSAs with an HHI that exceeded 2,500 for specialist physicians increased from about 60 percent in 2010 to about 62 percent in 2016. Fulton also found that the levels of concentration for primary care physician services were much lower, but the increase over the period 2010-2016 was more substantial. The mean HHI for primary care services across MSAs ranged from about

1,700 to about 2,300 over the period 2010-2016, but increased by about 29 percent over this period. This implies an average increase in the mean HHI of about 87 points per year. The percentage of MSAs with an HHI greater than 2,500 for primary care physicians increased from about 21 percent in 2010 to about 35 percent in 2016.

Other research, while not examining trends in physician consolidation, also found higher concentration levels for specialist physicians than for primary care physicians. Kleiner examined shares by physician practice within specialty-specific geographic areas using 2009 patient-level Medicare data.[79] The study found median two firm concentration ratios (CR_2) across all areas of 33 percent for primary care services, but 58 percent for cardiology, 72 percent for oncology, 49 percent for orthopedics, and 57 percent for radiology. Similarly, it found a median HHI of 761 for primary care services, but 2,370 for cardiology, 3,606 for oncology, 1,751 for orthopedics, and 2,190 for radiology. These differences in concentration metrics between specialist physicians and primary care physicians may be due to higher barriers to entry faced by specialists.

Figure 3: Hospital Systems are Increasingly Acquiring Primary Care Practices[78]



Some of the consolidation in physician services might be due to the acquisition of physician practices by local hospitals, as opposed to mergers between physician practices. For example, in a market consisting of two hospitals and ten physician practices, an acquisition of the ten practices by the two local hospitals would yield a significant increase in concentration in the market for physician services. Hospitals have increasingly been acquiring physician practices. One study reported that the share of physician practices in the United States owned by hospitals doubled over the period 2002-2008.[80] Another study examined the effect of the acquisition of physician practices by hospitals on prices and expenditures over the period 2007-2013.[81] It reported that hospitals acquired 10 percent of the physician practices in their sample during their sample period. In its 2013 Report to the Congress, the Medicare Payment Advisory Commission

(MedPAC), an independent, non-partisan, Congressional support agency, similarly reported that while the number of physicians and dentists employed by hospitals was relatively constant from 1998 to 2003, it increased by 55 percent from 2003 to 2011.[82] Another survey by the Medical Group Management Association found a 75 percent increase in the employment of doctors by hospitals between 2000 and 2012.[83] The overall effects of a hospital becoming the owner of a physician practice raise significant anti-competitive concerns, although in some cases they can produce pro-competitive effects.[84]

Need for Continued Vigilance

While the studies cited above do not definitively confirm that increased concentration has led to increased market power or increased payments, they do demonstrate a steady stream of transactions affecting the ownership of hospitals and physician services. Given the strong evidence of consumer harm from some transactions that have been shown to diminish competition, these concentration trends highlight the need for continued vigilance by the antitrust authorities to identify and prevent anti-competitive activity. Furthermore, in instances where markets have become concentrated due to a lawful accumulation of market power, elimination of regulatory barriers to entry can help to keep that in check, as will be discussed in the next section.

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

Government Healthcare Policies and Their Effects

Healthcare Workforce and Labor Markets

In competitive markets, suppliers of goods or services respond to market signals that suggest growing demand for the goods or services by increasing prices, which provides incentives to increase the supply of goods and services. Government policies that reduce the available supply of qualified healthcare service providers or the range of services they may safely offer can increase the prices paid for healthcare services, reduce access to care, and suppress the benefits of competition and innovation in healthcare delivery. Such regulations can also unnecessarily limit the types or locations of providers authorized to practice or the range of services they can provide.

Government rules restrict competition if they keep healthcare providers from practicing to the "top of their license"— i.e., to the full extent of their abilities, given their education, training, skills, and experience, consistent with the relevant standards of care. Such rules, including restrictions on the appropriate use of telehealth technologies, unnecessarily limit

the types or locations of providers authorized to practice, or the range of services they can provide, in contrast to regulations tailored to address specific and non-speculative health and safety concerns.

With respect to physicians in particular, certain policies relating to graduate medical education (GME), as well as significant restrictions on the ability of foreign-trained doctors to practice in the United States may also unnecessarily limit the supply of physicians available to provide care to Americans. Reduced competition among qualified physicians inevitably leads to higher prices for physician services and generally reduces the quality of care. Consistent with overarching patient health and safety concerns, the discussion below examines potential benefits of more flexible approaches to GME and the treatment of foreign-trained doctors that could increase physician supply and promote additional competition and consumer choice.

Scope of Practice

State licensing and scope-of-practice (SOP) restrictions are common components of state licensure statutes and regulatory codes for healthcare professions.[85] Licensure regulates entry into an occupation since a worker must obtain the permission of a government agency or government-authorized regulatory board before providing certain services.[86] For numerous healthcare occupations, a state licensing authority stipulates minimum education, training requirements, and certification, among other criteria, for those who seek to acquire or maintain a license to practice a given profession or provide certain services.[87] SOP regulations "describe the metes-and-bounds of licensure—what a given professional license permits a person to do and, often, prohibits others from doing."[88]

SOP laws and regulations, like other health and safety regulations, may be justified when there are substantial risks of consumer harm.[89] These regulations may be especially important with respect to certain healthcare professions, where consumers might be at risk of serious harm if they were treated by unqualified individuals, and where patients might find it difficult (if not impossible) to assess quality of care at the time of delivery.[90] Still, even well-intentioned regulations may impose unnecessary restrictions on provider supply and, therefore, competition. Oftentimes, too, SOP restrictions limit provider entry and ability to practice in ways that do not address demonstrable or substantial risks to consumer health and safety.[91] When this happens, these undue restrictions are likely to reduce healthcare competition and harm consumers—including patients, and taxpayers more generally.[92]

When state regulators impose excessive entry barriers and undue restrictions on SOP for particular types of providers, they often are not responding to legitimate consumer protection concerns. There is a risk that healthcare professionals with overlapping skill sets will seek these restrictions; they view SOP restrictions as an easy, state-sanctioned opportunity to insulate themselves from competition.[93] The risk of anti-competitive harm may be even greater when the regulatory board that imposes SOP restrictions on one occupation is controlled by members of another, overlapping occupation that provides complementary or substitute services,[94] and the board members are themselves active

market participants with a financial stake in the outcome.[95]

For example, advanced practice registered nurses (APRNs),[96] physician assistants (PAs),[97] pharmacists,[98] optometrists, [99] and other highly trained professionals can safely and effectively provide some of the same healthcare services as physicians, in addition to providing complementary services. Similarly, dental therapists and dental hygienists can safely and effectively provide some services offered by dentists, as well as complementary services.[100]

SOP statutes and rules often unnecessarily limit the services these "allied health professionals"[101] can offer. A 2011 Institute of Medicine (IOM) report surveyed "[e]vidence suggest[ing] that access to quality care can be greatly expanded by increasing the use of . . . APRNs in primary, chronic, and transitional care,"[102] and expressed concern that SOP restrictions "have undermined the nursing profession's ability to provide and improve both general and advanced care."[103] In fact, research suggests that allowing allied health professionals to practice to the full extent of their abilities is not a zero sum game for other medical professionals, and may actually improve overall health system capacity.[104] The previously mentioned IOM report found that APRNs' scope of practice varies widely "for reasons that are related not to their ability, education or training, or safety concerns, but to **the political decisions of the state** in which they work."[105]

State decisions about scope of practice and reimbursement can also affect the development and utilization of allied health professionals, particularly in public programs. Private insurance has the flexibility to incentivize patients to find lower-cost, higher-quality provider alternatives when feasible. Public programs, more restricted by state regulations, can be less responsive to such changes in the healthcare workforce, even after scope of practice regulations accommodate them. Currently, for example, states vary widely in the degree to which they permit their Medicaid programs to reimburse allied health professionals directly for services. Services provided under the direct supervision of a physician are reimbursed as if the physician provided those services. State Medicaid programs can also pay for PA, nurse practitioner, and certified nurse midwife (CNM) services provided outside of a physician's office, but only if state scope-of-practice laws do not require onsite supervision by physicians. Some states allow allied health professionals to bill Medicaid directly, while other states require them to bill under the physician's number. For patients to realize the benefits of changes to state SOP restrictions, state Medicaid programs would need to reimburse allied health professionals independently for their services.

As noted by FTC staff, "when APRN access to the primary care market is restricted, healthcare consumers—patients and other payers—are denied some of the competitive benefits that APRNs, as additional primary care service providers, can offer."[106] Slightly more than half the states require supervision and "collaborative practice" requirements, which can operate as de facto supervision requirements. These are a particular source of concern to the extent that they raise the cost of APRN-provided services.[107] In addition, rigid "collaborative practice agreement" requirements can impede collaborative care rather

than foster it because they limit the ability of healthcare professionals to adapt to varied healthcare demands, thereby constraining provider innovation in team-based care.[108] Economic analysis indicates that expanding APRN SOP, consistent with APRN education, training, and experience, would have clear consumer benefits, particularly in rural and poorer areas:

> In underserved areas and for underserved populations, the benefits of expanding supply are clear: Consumers will have access to services that were otherwise unavailable. Even in well-served areas, the supply expansion will tend to lower prices for any given level of demand, thus lowering healthcare costs.[109]

Similar concerns about the competitive impact of supervision and "collaborative practice" requirements can apply to other healthcare occupations. Even when some form of collaboration or supervision might be desirable, particular requirements might be unnecessary, over-rigid, and costly barriers to the efficient delivery of healthcare services.[110]

Extremely rigid collaborative practice agreements and other burdensome forms of physician and dentist supervision are generally not justified by legitimate health and safety concerns. Thus, many states have granted full practice authority to APRNs, but there is significant room for improvement in other states and for other professions.[111] Emerging healthcare occupations, such as dental therapy, can increase access and drive down costs for consumers, while still ensuring safe care. States should be particularly wary of undue statutory and regulatory impediments to the development of such new occupations.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.
- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Workforce Mobility

State-based licensing requirements, by their nature, inhibit provider mobility.[112] These requirements add time and expense when healthcare providers seek to move or work across

state lines. Markets cannot be as responsive to economic change when workers cannot easily move to meet the demand for their services.[113]

State-based licensing also often inhibits delivery of healthcare services across state lines by making it more difficult for qualified healthcare professionals licensed in one state to work in another state, even though most healthcare providers complete nationally certified education and training programs and sit for national qualifying exams.[114] Appropriate standards of care do not differ from state to state. Yet, even when a profession's underlying standards are national in scope, and when state licensing requirements are similar throughout the United States, the process of obtaining a license in another state is often slow, burdensome, and costly.[115] There is little economic justification for the redundant licensing processes that many states impose on licensed, out-of-state applicants. Even when there may be plausible consumer-protection concerns, the harm to consumers likely outweighs any benefits.[116]

The effects of state-based licensing are especially apparent in fields where providers routinely communicate electronically and provide services in multiple states. For this reason, state-based licensing requirements can inhibit the efficient development and use of telehealth (discussed below), as well as in-person services.[117]

Interstate compacts and model laws can mitigate the effects of state-based licensing requirements by enhancing license portability. Professional associations and associations of licensing boards typically draft model laws, which may be passed with minor variations between jurisdictions. Almost all states and other United States jurisdictions have adopted model laws with license portability provisions in other professions such as accountancy and pharmacy.[118] By contrast, interstate compacts, which are binding contracts between two or more states authorized by the United States Constitution, must be identical and have been used only recently to improve licensure portability.[119] The first interstate licensure compact, on nurse licensure, was initially implemented in 1999 and has been adopted by 30 states.[120] Other licensure compacts in the health professions are in the early stages of implementation.[121] Federal grants to state professional licensing boards have encouraged the development and implementation of various licensure compacts in several professions.[122]

Model laws and interstate compacts typically use one of two approaches to enhance licensure portability. One is reciprocity as practitioners licensed by one state are able to practice in other states without obtaining another license. Second, some states require a license in each state of practice but expedite the process.[123] By making it easier to practice in multiple states, interstate compacts and model laws can enhance access to healthcare services and improve provider mobility.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve

license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.

- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Telehealth

Telehealth, the use of telecommunications to provide healthcare services, has been hailed as a significant innovation in healthcare delivery.[124] It encompasses a broad variety of services and technologies, and is particularly effective when it replicates in-person care, speeds input from knowledgeable practitioners, provides information more frequently than would be possible with in-person visits, or involves conditions that can be evaluated from digital images. Examples of healthcare services that may be provided by telehealth include mental health services,[125] dermatology,[126] ophthalmology,[127] specialist-to-provider consultations in neurology and pathology,[128] and direct-to-consumer services for minor conditions.[129]

Telehealth often increases the virtual supply of providers and extends their reach to new locations, promoting beneficial competition. By doing so, telehealth can enhance price and non-price competition, reduce transportation expenditures, and improve access to quality care.[130] Indeed, telehealth has great potential to improve access in underserved locations, reduce costs, and generate improved short- and long-term health outcomes.[131]

Nonetheless, a variety of regulatory barriers have kept telehealth from reaching its full potential to increase competition and access. State laws and regulations typically require that providers be licensed in the state where the patient is located, thus restricting the provision of telehealth services across state lines.[132] State licensing requirements and variations in scope of practice are barriers for even well-established and natural telehealth services, such as mental and behavioral healthcare.[133] Public and private reimbursement laws and policies are also frequently cited as major impediments to the development and use of telehealth services.[134] For example, Medicare fee-for-service pays for telehealth services only when patients are located at certain types of healthcare facilities ("originating sites")[135] in rural areas with a shortage of health professionals.[136] Another barrier is that states may require practitioners to have first provided services in person before caring for a patient by telehealth.[137]

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of

state licensure standards and approaches to telehealth.

- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.
- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Foreign-Trained Doctors

The United States has the highest physician salaries in the world, with per-capita physician spending significantly higher than in other countries and making up about a fifth of overall healthcare spending.[138] Increasing the supply of goods or services in any market is generally the best approach to lowering prices, and physician services are no exception. Expanding domestic education and training opportunities—including the opening of new medical schools is a priority—efforts should be made to reduce the burdens on highly skilled, fully trained, foreign medical doctors looking to practice in the United States. Currently, any physician trained outside the United States or Canada must obtain an Educational Commission for Foreign Medical Graduates (ECFMG) certification, complete a United States residency program, and apply for a state license.[139] [140] This process is expensive (exams can cost up to $15,000). In the interim, easing the licensing pathway for highly qualified, foreign-trained doctors is one step that could be taken in the short-run to expand the supply of medical practitioners and thus constrain the price of physician services and lower overall healthcare costs for American consumers.

While increasing the supply of high-skilled, domestically trained United States medical professionals might help to constrain salaries for specialty physicians, facilitating the entry of additional foreign-trained doctors would be particularly helpful in alleviating the country's shortage of primary care physicians (PCPs). On average, PCPs earn 46 percent less than medical specialists. Because American medical school students graduate with an average of $180,000 of debt, many of them pursue higher paid specialties rather than the much needed primary-care fields.[141] While forecasts are often inaccurate, it is projected that by 2025, the United States will face a shortage of between 14,900 and 35,600 PCPs.[142] Foreign-trained doctors have already helped meet this growing need—over 40 percent of current American PCPs were trained abroad; however, if it were easier for foreign-trained

doctors to enter the United States marketplace, this percentage would likely rise.[143]

Highly skilled, foreign-trained doctors could also be encouraged to practice in underserved regions of the country, where Americans often are unwilling to practice. For example, under the Conrad 30 Waiver Program, foreign-trained doctors can receive sponsorship to work in the United States if they commit to spend at least three years in an underserved region.[144] Over the past decade, this program has attracted more than 10,000 foreign-trained doctors to practice in areas faced with physician shortages.[145]

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted "residency waivers," allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign-trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Federal Funding of Medical Education

Spending on physician services comprises approximately 20 percent of all healthcare expenditures in the United States, and prices for physician services tend to be substantially higher in the U.S. than in other wealthy countries.[146] As mentioned above, one option to reduce prices is to increase the supply of physicians. Physician supply in the United States, measured as physicians per 1,000 population, is well below the OECD median and is lower than 8 of 10 other OECD countries.[147] Unlike many other professions, in which market forces determine supply, the number of persons trained to be physicians is limited by organizations that are themselves often run by physicians, which creates natural conflict-of-interest concerns and raises questions concerning cartel-style rent seeking. Some barriers to entry in the physician sector (such as extensive educational, training and testing requirements, including state licensing and specialty board certification), may be justified to ensure professional competence. Nonetheless, this does not warrant non-market-based limits placed on the number of persons seeking to enter the medical field. Medical schools admit only a fraction of applicants, with many qualified individuals unable to enter due to the sharply limited spaces available.

Not only is the supply of potential physician practitioners limited, federal policy currently subsidizes medical training for an artificially low number of persons. The Department of Education administers loan programs that are available to medical school students, including private loans guaranteed by the federal government and direct loans from the federal government through the students' schools. The Health Resources and Services Administration (HRSA), part of HHS, administers National Health Service Corps (NHSC)

scholarships and loan repayment programs for health professionals who commit to practice in underserved areas and to train in primary care. An even larger amount of federal support is directed toward Graduate Medical Education (GME)—residency and fellowship programs that provide further training for medical school graduates. As of 2015, federal taxpayers paid $287 million to support the NHSC, $10.3 billion for Medicare GME, and $2.4 billion for Medicaid GME, and $265 million for the Children's Hospital Graduate Medical Education Payment Program.[148] Medical education is costly, but its estimated rate of financial return is high and clearly sufficient to entice many qualified individuals to seek admission to medical school. Current subsidies of medical education are generally regressive by reducing the cost to the very persons who can expect high financial returns to their valuable education and training.

The Structure of Medical Education

Medical education in the United States generally consists of four years of college education, followed by four years of medical school (undergraduate medical education), followed by graduate medical education (GME) consisting of three to six years of residency training in a medical specialty that is sometimes followed by a year or more of additional fellowship training. Medical school graduates must complete at least a year of residency training (often called an internship), depending on the state, to be licensed.

Medical students attend either allopathic medical schools (granting M.D. degrees) or osteopathic schools of medicine (granting D.O. degrees). The Liaison Committee on Medical Education (LCME), jointly sponsored by the Association of American Medical Colleges (AAMC) and the American Medical Association (AMA), is the United States Department of Education's recognized body for accrediting allopathic medical schools.[149] The American Osteopathic Association's (AOA) Commission on Osteopathic College Accreditation accredits osteopathic schools. In 2017-2018 there were 118,885 United States medical students including 46,315 men and 43,571 women at allopathic schools[150] and 15,904 men and 13,076 women at osteopathic schools.[151] Residents and fellows train at programs accredited by the Accreditation Council for Graduate Medical Education (ACGME) or programs jointly accredited by the ACGME and the AOA. The Department of Veterans Affairs, through affiliation agreements with medical schools and teaching hospitals, is the largest single provider of medical training in the United States, providing the site of training for medical students, residents and a small number of fellows.[152]

To receive postgraduate training medical students must participate in a "match" process that determines where they receive residency training. This process is administered by the National Resident Matching Program that is sponsored in part by the AAMC. Applicants and training programs both submit rank-ordered preference lists, and then an algorithm matches applicants to programs to produce stable matchings as favorable as possible to applicants.[153] In 2004—in response to a lawsuit alleging that operating the match and accrediting residency programs was anti-competitive and violated the anti-trust statutes by limiting the number of residency positions and driving down resident choices and salaries—Congress granted the matching program an anti-trust exemption.[154]

Graduate Medical Education (GME) Funding

Funding for GME subsidizes training for medical school graduates in hospitals and other teaching institutions in what are commonly known as residency and fellowship training programs. In 2015, federal agencies and state Medicaid programs provided $16.3 billion to support GME. Five federal agencies (see Table 1) spent $14.5 billion with the bulk of federal funding coming through Medicare (71 percent), Medicaid (16 percent), and the VA (10 percent); 45 state Medicaid agencies spent an additional $1.8 billion on GME.[155]

Table 1. Federal Spending on Graduate Medical Education (GME) Training, 2015

Program	Total GME spending (dollars in millions)	Percent of total spending (percent)
HHS programs		
Medicare	10,335	71
Medicaid (federal share)	2,351	16
Children's Hospital GME Payment Program	249	2
Teaching Health Center GME Program	76	1
VA program	1,499	10
Total	**14,509**	**100**

Source: GAO analysis of departments of Health and Human Services (HHS) and Veterans Affairs (VA) data and GAO web-based survey administered to state Medicaid agencies. GAO-18- 240.

About 30 percent of Medicare GME spending is for direct graduate medical education (DGME) to pay the salaries of residents and supervising physicians. Another 70 percent goes for indirect medical education (IME) to provide funding to hospitals that run training programs.[156] DGME payments are based on a per-resident amount and the number of full-time-equivalent (FTE) residents. IME Medicare payments are an add-on to the predetermined amount paid under the inpatient prospective payment system for each discharge with an adjustment for the number of FTE residents per hospital bed to represent the incremental care costs of providing GME training. DGME payments are also adjusted for the share of hospitals' patients covered by Medicare. The Balanced Budget Amendment of 1997 capped the number of FTE residents that programs may count for DGME and IME payment at the number of FTE residents working at the end of 1996.[157]

While GME programs undoubtedly generate indirect costs, they also produce benefits for teaching institutions. Residents are an inexpensive source of labor. They work longer, more irregular hours than more experienced health professionals. They also increase attending physicians' productivity by enabling them to increase the amount of patient services they

can perform and for which they can bill.[158]

The Medicare Payment Advisory Commission (MedPAC), an independent agency that advises Congress about Medicare, estimates that indirect graduate medical education payments are at least twice as high as actual costs, exceeding actual costs by $3.5 billion each year.[159] Similarly, an HHS-sponsored study found that Medicare is overpaying for IME costs.[160] Some residency programs generate profits for hospitals. Hospitals value residency programs enough that they self-finance 12,000 residency positions.[161]

The current number of first year residency positions (30,232) exceeds the number of American medical school graduates (18,818 allopathic graduates and 4,617 osteopathic graduates) applying for them. The balance of positions are largely filled with foreign-born or U.S. citizen graduates of foreign medical schools, or in some cases, they go unfilled.[162]

Physician Supply in the United States

There is likely an inadequate supply of physicians in the United States. Moreover, there is an uneven distribution in physician supply (both geographically and across specialties), GME training slots, and in government support for GME.[163] Yet there is inadequate information to assess overall physician needs, and for different specialties in different geographic areas.[164] GME slots are currently determined by the industry accrediting bodies and the hospitals or medical schools themselves. Similarly, medical school positions are accredited by physician industry groups.

These findings suggest several areas for policy research and potential change. First, as requested in the FY 2019 President's Budget, the federal government should more efficiently spend taxpayer resources by streamlining federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. Under this Budget proposal, total funds available for graduate medical education in FY 2019 would equal the sum of Medicare's 2016 payments for DGME and IME, Medicaid's 2016 payments for GME, and the Children's Hospital GME Payment Program, adjusted for inflation. This amount would increase annually with inflation as measured by the consumer price index for all urban consumers (CPI-U) minus one percentage point per year. The new grant program would be funded out of the Treasury and jointly operated by the administrators of CMS and HRSA. This proposal is estimated to save $48.1 billion between 2019 and 2028. The Budget proposal also provides the HHS Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities. This flexibility will allow the federal government to more effectively target funding to those hospitals that are committed to building a strong medical workforce and to addressing medically underserved communities and health professional shortages.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President's Budget, the federal government should

streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary, including addressing healthcare professional shortages and educational priorities.

- The administration should continue the work done by the HRSA's National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
    - The administration's workforce development programs.
    - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Healthcare Provider Markets

Certificate of Need (CON) Requirements

State "certificate-of-need" ("CON") laws require healthcare providers to obtain permission from a state (or state-authorized) agency to construct new healthcare facilities, expand existing ones, or offer certain healthcare services.[165] States initially adopted CON laws to further laudable policy goals, including cost control and access to care. The evidence to date, however, suggests that CON laws are frequently costly barriers to entry for healthcare providers rather than successful tools for controlling costs or improving healthcare quality. Based on that evidence and their enforcement experience, the two federal antitrust agencies–the FTC and the Antitrust Division of the Justice Department—have long suggested that states should repeal or retrench their CON laws.[166]

Most states adopted CON programs in response to a since-repealed federal mandate, the National Health Planning and Resources Development Act of 1974,[167] which offered the states powerful incentives to adopt CON programs.[168] CON programs were supposed to control healthcare costs and mitigate incentives for an arms race in healthcare spending fostered by cost-based healthcare reimbursement systems.[169] Although both public and commercial reimbursement systems have changed significantly over time, many states have maintained substantial CON requirements. Congress repealed the 1974 Development Act in 1986, and a number of states have since repealed or revised their CON laws.[170]

Fifteen states have eliminated their CON requirements altogether.[171] Although most other states maintain CON programs,[172] some remaining CON laws address only specific types of healthcare facilities (such as hospitals or nursing homes),[173] exempt certain types of healthcare facilities,[174] or apply only to facilities of a certain size.[175] Some CON laws are subject to sunset provisions.[176]

CON proponents continue to raise cost control as a justification for CON programs; they

also argue that CON laws improve the quality of healthcare services and assure access to healthcare services by disadvantaged citizens. However, available evidence suggests that CON laws have failed to produce cost savings, higher quality healthcare, or greater access to care, whether in underserved communities or in underserved areas.

CON Laws Impose Costs, Including Loss of Beneficial Competition

Empirical evidence on competition in healthcare markets generally demonstrates that consumers benefit from lower prices when provider markets are more competitive.[177] Scrutiny of hospital mergers by the FTC and the Antitrust Division has been particularly useful in understanding concentrated provider markets, and retrospective studies of the effects of provider consolidation by agency staff and independent scholars suggest that "increases in hospital market concentration lead to increases in the price of hospital care."[178]

FTC and Antitrust Division staff have examined the competitive impact of CON laws for several decades. For example, staff from the FTC's Bureau of Economics conducted several studies of CON laws in the late 1980s, both before and after repeal of the federal law that had encouraged their adoption.[179] In addition, the agencies jointly conducted 27 days of hearings on healthcare competition matters in 2003, receiving testimony about CON laws and market entry, hospital provider concentration, and other pertinent aspects of healthcare competition;[180] they jointly released a substantial report on healthcare competition issues, including those related to CON laws, in 2004.[181] Finally, through their competition advocacy programs, the Agencies have reviewed numerous state CON laws and encouraged states to consider the competitive impact of those laws.[182]

The best empirical evidence suggests that greater competition incentivizes providers to become more efficient. Recent work shows that hospitals faced with a more competitive environment have better management practices.[183] Consistent with this is evidence suggesting that repealing or narrowing CON laws can reduce the per-patient cost of healthcare.[184] Studies have found no empirical evidence that CON laws have restricted "over-investment."[185] However, CON laws can restrict investments that would benefit consumers and lower costs in the long term and are likely to increase, rather than constrain, healthcare costs. This is because CON regimes impose the legal and regulatory costs of preparing an application, then seeing that application through an often-lengthy approval process and potential third-party challenges.[186] As a result, healthcare providers must spend resources on administrative processes rather than on constructing healthcare facilities or delivering healthcare services. In addition, those regulatory costs can be a barrier to entry, discouraging some would-be providers from entering certain healthcare markets, and discouraging some incumbent providers from expanding or innovating in ways that would make business sense but for the costs of the CON system. Even for providers willing to bear those regulatory costs, CON requirements may be hard barriers to entry if their applications are denied. Hence, CON laws can diminish the supply of healthcare facilities and services while exacerbating concentration in provider markets.

CON Laws Have Not Improved Healthcare Quality or Access

CON proponents have argued that CON laws support policy goals relating to healthcare quality and access. However, CON laws would be an indirect—and likely inefficient—way to achieve these goals. Moreover, the evidence suggests CON laws are ineffective. There is no compelling evidence suggesting that CON laws improve quality or access, inefficiently or otherwise.

Quality-based arguments on behalf of CON laws typically refer to evidence on volume/outcome relationships (i.e., the extent to which quality of care is related to how often a particular healthcare institution or provider performs a given procedure), rather than direct evidence of CON laws' impact on care quality. Even this volume/outcome evidence is mixed. Pronounced effects may be limited to certain relatively complicated procedures;[187] and even there, where certain studies have shown a volume/outcome relationship (e.g., coronary artery bypass graft surgery[188]), evidence suggests that volume effects may not offset CON laws' larger negative impact on quality.[189] Studies that directly analyze the impact of changes in CON laws on health outcomes provide a more complete picture; the weight of that research has found that repealing or narrowing CON laws is generally unlikely to lower quality of care, and may improve the quality of certain types of care.[190] Moreover, CON programs can tend to foster or sustain undue provider concentration; and additional empirical evidence suggests that, "[a]t least for some procedures, hospital concentration reduces quality."[191]

Evidence also fails to support the claim that CON programs would increase access to care for the indigent, or in medically underserved areas. The general argument has been that CON laws, by limiting competition, allow incumbent healthcare providers to earn greater profits—by charging higher prices and preserving their volume of lucrative procedures—than they would earn in a competitive environment. It is posited that those extra profits will be used to cross-subsidize care for the underserved. There are inherent weaknesses in this supposition. First, the charity-care rationale is at odds with the cost-control rationale. The notion that CON-protected incumbents would use their market power and profits to cross-subsidize charity care presumes that those providers will charge supra-competitive prices for non-charity care. Such supra-competitive pricing might harm many healthcare consumers, including low-income or under-insured patients who are ineligible for charity care. Second, because CON programs impede entry, expansion, and innovation, they can impede access to care for all patients, including low-income patients. Finally, the evidence does not show that CON laws promote charity care. Research suggests that safety-net hospitals are no stronger financially in CON states than in non-CON states.[192] There is also empirical evidence contradicting the notion that dominant providers use their market power to cross-subsidize charity care, including an empirical study of the relationship between competition and charity care that found a "complete lack of support for the 'cross-subsidization hypothesis.'"[193]

CON Laws Can Foster Competition Problems Missed By Benefit/Cost Analysis

Not only may CON laws impose costly barriers to provider entry, but by interfering with

market forces that normally determine the supply of facilities and services, they can suppress supply, misallocate resources, and shield incumbent healthcare providers from competition from new entrants.[194] In addition, incumbent firms may use CON laws to thwart or delay entry or expansion by new or existing competitors.[195] CON programs have also facilitated anti-competitive agreements among competitors. For example, in 2006, a hospital in Charleston, West Virginia, used the threat of objection during the CON process to keep a potentially competitive hospital from expanding.[196]

Finally, as illustrated by the FTC's experience in the *Phoebe Putney* case, CON laws can entrench anti-competitive mergers by limiting the government's ability to implement effective structural remedies to consummated transactions. *Phoebe Putney* involved a challenge to the merger of two hospitals in Albany, Georgia.[197] Seeking a preliminary injunction in federal court, the FTC alleged that the merger would create a monopoly of inpatient general acute care hospital services sold to commercial health plans in Albany and surrounding areas. The district court dismissed the suit, finding that the merger was protected from antitrust scrutiny by the "state action doctrine."[198] The United States Court of Appeals for the Eleventh Circuit affirmed the district court's dismissal on state action grounds, although finding that "the joint operation of [the two hospitals] would substantially lessen competition or tend to create, if not create, a monopoly."[199] The Supreme Court reversed this decision, unanimously holding that "state action immunity" did not apply.[200] However, the merging parties already had consummated the transaction while appeals were pending, and Georgia's CON regime precluded structural relief for the anticompetitive merger.[201] As the Commission explained, "[W]hile [divestiture] would have been the most appropriate and effective remedy to restore the lost competition in Albany and the surrounding six-county area from this merger to monopoly, Georgia's [CON] laws and regulations unfortunately render a divestiture in this case virtually impossible."[202]

Certificates of Public Advantage

Certificate-of-public-advantage (COPA) regulations allow healthcare providers to enter into cooperative agreements that might otherwise be subject to antitrust scrutiny and can cover a wide range of provider collaboration and merger activity.[203] COPA schemes displace competition in favor of state regulatory oversight and may, under the state action doctrine, immunize provider activity for conduct that might otherwise violate federal antitrust laws.[204] Typically, states have the authority to approve COPA proposals if they determine that the likely benefits of the cooperative agreement outweigh any disadvantages attributable to a reduction in competition.[205] In practical terms, COPAs significantly limit the ability of antitrust enforcement agencies to challenge collaborations and mergers that create or enhance provider market power, and therefore are likely to harm consumers.[206] Moreover, COPA review and oversight frequently are subject to the influence of special interests through state political processes.

As a condition for COPA approval, states often impose terms and conditions on the COPA

recipient intended to mitigate the potential for anti-competitive harms. Such regimes may include rate regulation, prohibitions on certain contracting practices, and commitments to improve quality or return cost savings to the local community. These types of regulatory conditions are often difficult to implement and monitor and may not accomplish intended goals. In addition, some states that have approved COPA schemes have later repealed or revised the COPA statutes allowing them, effectively terminating the state regulatory oversight that was supposed to constrain the exercise of market power and potentially empowering an unrestrained monopolist.[207] For these reasons, the FTC has raised concerns that COPAs may create or enhance provider market power without offering sufficient mechanisms for mitigating potential harms to competition and consumers.[208]

As discussed in Section 1, compelling empirical research suggests that market-based competition among healthcare providers yields positive results for consumers such as reduced prices and improved quality of care. Conversely, there is limited empirical research regarding the impact of COPA regulations. For this reason, FTC staff are currently assessing the potential benefits and disadvantages of COPAs and recently issued a notice requesting empirical research and public comments on these issues.[209]

The antitrust laws are intended to achieve the goals of reduced prices, improved quality, and greater innovation and access for healthcare services and not prevent procompetitive provider collaborations that would generate efficiencies and benefit consumers.[210] COPAs that immunize otherwise anti-competitive collaborations and mergers from antitrust scrutiny pose a substantial risk of consumer harm.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example by ensuring that competitors of CON applicants cannot weigh in on these applications.
- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the benefits and disadvantages of CON and COPA statutes and regimes.
- States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Nonprofit Exemption from Federal Trade Commission Jurisdiction

Currently, the FTC Act limits the FTC's jurisdiction over nonprofits. The FTC Act applies to "persons, partnerships, or corporations,"[211] and the act defines "corporation" as an entity that "is organized to carry on business for its own profit or that of its members."[212] In healthcare provider markets, where the FTC has particular expertise, the inability to regulate conduct by various nonprofit entities has prevented the agency from taking action

against potentially anti-competitive behavior of nonprofits engaged in business.[213] Economic research suggests that antitrust law and policy could yield significant efficiency gains for nonprofit firms; therefore, the promotion of competition for both nonprofit and for-profit organizations would yield significant social value.[214] The FTC has jurisdiction over nonprofit entities for purposes of the Clayton Act, most notably Section 7, which prohibits mergers or acquisitions where "the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."[215] The FTC has accordingly challenged a number of healthcare mergers involving a nonprofit entity,[216] and courts generally recognize that the nonprofit status of a healthcare provider does not mitigate the potential for anti-competitive harm arising from the merger.[217]

Nonetheless, the jurisdictional limitation contained in the FTC Act creates an arbitrary and inefficient burden on the FTC's ability to enforce the antitrust laws to prevent anti-competitive conduct by certain nonprofit entities. For example, nonprofit healthcare entities may structure an affiliation that has the economic effect of a merger but is technically an agreement between competitors—thus subject to Section one of the Sherman Act rather than a merger subject to the Clayton Act. Similarly, while investigating a merger involving nonprofit healthcare providers, FTC staff may discover an anti-competitive agreement subject to the Sherman Act. In both instances, because the FTC's ability to enforce the Sherman Act through the FTC Act is limited to for-profit corporations, the FTC would have to refer these cases to the Antitrust Division at Justice, which has direct authority to enforce the Sherman Act without the limitations related to nonprofit

entities.[218] This referral process serves no public interest objective, but prevents the federal government from making the best use of the FTC's valuable institutional knowledge and experience. Removing the nonprofit limitation from the FTC Act would streamline the competition investigation and enforcement process.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Employment Agreement Non-Compete Clauses

Non-compete clauses were first found to be anti-competitive in 1414.[219] Legal scholars suggest that the point of these clauses was "shoring up the crumbling values of the medieval economic system against enterprising master craftsmen," aka entrepreneurs. These clauses can have dramatic economic consequences: California's public policy against enforcement of non-compete clauses, for example, is credited with fostering Silicon's Valley's rapid growth and innovation, outpacing the rival high-tech district around Boston.[220]

In the healthcare industry, some hospitals and physician groups continue to use these restrictive covenants to limit providers from practicing, typically in a certain geographical area for a given period after the provider leaves employment of the contracting hospital or

physician group.[221] A survey of physicians found that roughly 45 percent of physicians in group practices were bound by non-compete agreements.[222] The AMA suggests that these contracts may disrupt competition and the continuity of care, and could constrain a patient's choice of provider. However, recent empirical analysis found evidence consistent with these agreements being used to prevent patients from being poached by departing doctors.[223]

At least one case has viewed a non-compete clause in the healthcare industry with skepticism. The Tennessee Supreme Court opined on a non-compete clause between a physician and a private medical practice that had employed him in the 2005 case Murfreesboro Medical Clinic (MMC) v. David Udom.[224] Here, the court ruled that certain provisions in non-compete clauses can be harmful to public policy and therefore unenforceable. The court indicated that the non-compete clause in question had been too broad and was not based on the extent to which MMC would compete with a provider (in this case, David Udom).

While there is not a large body of case law on non-compete clauses in the healthcare industry, cases in other industries also suggest that non-compete clauses that are unreasonable in scope and duration may not be enforceable. The enforceability of non-compete clauses, including those clauses and contractual provisions related to healthcare, is typically an issue of state law.

Legal experts have suggested that a non-compete clause may be defensible where it is reasonable in scope and duration and necessary to protect against a former employee who had access to trade secret information or closely-guarded customer relationships injuring a business by utilizing that information or those customer relationships upon leaving.[225,226] Employers that invest in substantial training for their provider employees might also seek to protect the investment that they make in their human capital. However, it is not clear that healthcare industry non-compete clauses are always proportionate to or even based on these concerns. In fact, other experts suggest that these clauses reduce bargaining power for employees because they reduce worker mobility.[227]

Various reports on non-compete clauses have also suggested that they are overly burdensome and restrictive on providers. Further scrutiny of these and other restrictive covenants is warranted, particularly where they impede patient access to care and limit the supply of providers. By suppressing competition, these clauses may inflate healthcare prices, elevating patient and federal spending on healthcare goods and services.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Health Insurance Markets

"Any-Willing-Provider" (AWP) Laws

"Any-willing-provider" (AWP) laws, like related "freedom of choice" (FOC) laws, are restrictions on certain types of selective contracting practices by health plans or pharmacy benefit plans. AWP laws require plan sponsors—or sometimes intermediaries, such as pharmacy benefit managers (PBMs)—to contract with any healthcare provider willing to meet the terms of participation in that plan's network agreements.[228] FOC laws permit plan beneficiaries (or enrollees) to choose their providers, regardless of whether a chosen provider is part of their plan's network.[229] Research suggests that AWP (and, perhaps to a lesser extent, FOC) laws can suppress pro-competitive forms of health and pharmacy benefit plan contracting.[230]

Basic economic theory suggests that a buyer can obtain a negotiating advantage by contracting selectively with a subset of providers, or at least having a credible option to do so, because providers will compete aggressively to be included. For that reason, health plans and pharmacy benefit plans often seek to employ some form of selective contracting, entering into agreements with limited networks of providers. Commonly, plans also offer tiered benefits to incent the use of lower-cost (or otherwise more efficient) providers, services, or prescription drugs by plan beneficiaries.[231] Incentives to use a preferred tier may include (a) lower copayments, (b) lower co-insurance percentages, or (c) lower deductibles.[232] In effect, such tools differentiate the out-of-pocket prices associated with different providers, services, or drugs—tier by tier—for the beneficiaries of plans that employ tiering.[233]

Selective contracting and tiered benefits are not always efficiency-enhancing or procompetitive. They can also limit consumer choice. To guard against such concerns and potential conflicts of interest,[234] some states have enacted AWP or FOC laws, but, as will be explained below, these rules raise their own set of issues.

Medicare includes a type of AWP restriction—an "any willing pharmacy" provision—while also permitting selective contracting and tiered benefits. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 173, 117 Stat. 2066, requires that Medicare part D plans "permit the participation of any pharmacy that meets the terms and conditions under the plan," but permits them to, "notwithstanding… [that requirement] reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required." That is, part D plans cannot wholly exclude participation by "willing" pharmacies but can engage in tiering—a form of selective contracting (and selective benefits).[235] In 2018, the Centers for Medicare and Medicaid Services clarified the Part D AWP rules and their expectations regarding statutorily required AWP provisions, including the ability of plans to maintain preferred networks. CMS's intent was "to ensure that Part D plan sponsors could continue to develop and maintain preferred networks while complying with the any willing pharmacy requirement, which applies to standard terms and conditions."[236]

AWP Laws are Costly Restraints on Plan Contracting

Although limited or "narrow" networks may limit patient choice and are not necessarily

efficiency-enhancing or procompetitive, empirical evidence suggests that AWP and FOC laws broadening networks can make it more difficult for health insurers, health plans, or PBMs to negotiate discounts from providers, and that these laws tend to result in higher costs. Evidence also suggests that selective contracting—which AWP laws constrain—tends to lower healthcare costs and expenditures.[237]

Empirical Evidence on AWP

Several studies have analyzed state-by-state policy variation to measure the effects of AWP laws, finding that such laws undercut negotiating strategies whereby providers compete for inclusion in a network or a preferred tier. For example, one recent study examined state-level per capita health expenditure data from 1991-2009 and associated

AWP laws with approximately 5 percent higher per-capita drug expenditures.[238] A 2009 study similarly examined variations in state AWP laws applicable to drug purchases. It found that AWP states have higher prescription drug spending than states without AWP laws. The conclusion was the same, even when using different econometric techniques to control for variations across the states, such as differences in demographics, market structure, and regulatory environment.[239] An earlier study, looking at both the imposition and relative stringency of health plan AWP laws, found that AWP laws generally undermine the ability of managed care organizations to lower healthcare spending by extracting discounts in return for inclusion in a limited network. Specifically, the study found that per capita total healthcare expenditures are higher in states with relatively strong AWP laws, observing an impact on both hospital and physician expenditures.[240]

Empirical research on these laws has focused on the impacts on costs, not prices.[241] A 2005 Maryland study, however, examined the impact of AWP/FOC types of restrictions on mail-order provision of, for example, maintenance drugs. The Maryland report estimated that greater use of mail-order maintenance drugs—enabled by liberalizing Maryland insurance law—would save Maryland consumers 2-to-6 percent on retail drug purchases overall, with 5-to-10 percent savings for third-party carriers.[242]

Empirical Evidence on Selective Contracting

Related research has examined the effect of selective contracting, more generally, in connection with healthcare provider markets. For example, a study of limited network health plans in Massachusetts found that large premium differences between broad and limited network plans were driven by real reductions in spending by those beneficiaries who switched from broad to narrow network plans; the study did not find reduced access to care or any adverse impact on beneficiary health.[243] An earlier study of Massachusetts health plans, based on different data sources, also found savings associated with selective contracting.[244] Another study concluded that Connecticut health plans' ability to negotiate discounts with hospitals increased with a plan's willingness and/or ability to channel patients to selected hospitals, consistent with the predictions of a theoretical model introduced in the same study.[245] These studies show that buyers in health insurance markets can and do use selective contracting, harnessing the benefits of competition to negotiate

lower prices.

More recently, CMS released two studies analyzing prescription drug data from March 2012 for Medicare Part D plans.[246] In both studies, CMS found substantial savings on average associated with preferred pharmacies and mail-order pharmacies. It has been noted that those CMS studies do not control for product mix, which can vary substantially across types of pharmacies.[247] Acknowledging that limitation, the findings are generally consistent with the independent research on selective contracting discussed above.[248]

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Network Adequacy Requirements

Due to increased federal regulation of insurance through the ACA, premiums and deductibles have soared, forcing insurers to narrow provider networks to temper those prices. In 2017, 9 percent of firms with at least 200 employees offered their employees a health plan with a narrow network that included fewer providers than a typical Health Maintenance Organization,[249] an increase of 2 percentage points from 2016.[250] Among ACA-compliant individual market health plans offered on exchanges in 2016, nearly one-third had fewer than 25 percent of physicians within their service area participating as in-network providers.[251]

Narrow network plans bolster competition among hospitals and physician groups vying to be included in networks to secure patient volume. Furthermore, narrow network plans offer lower premiums relative to broader network plans.[252] This feature is particularly beneficial to lower-income consumers, who tend to be extremely price sensitive,[253] suggesting they are more interested in the size of the premium relative to the breadth of the provider network.

A potential concern regarding narrow networks is that enrollees may not have adequate choice or access to providers. Networks may lack the capacity to serve all enrollees within a health plan or lack specific specialists, leading some enrollees with only the option of more expensive care from out-of-network providers.[254] These issues pertain to private insurance (group and individual markets) as well as Medicaid managed care and Medicare Advantage plans, where insurers generally contract with a limited number of providers. This discussion applies generally to issues across these markets except where noted.

Regulations, primarily through state authority, have attempted to achieve network adequacy by requiring health plans to show sufficient capacity and access, often defined by quantitative standards (e.g., physician-to-enrollee ratios, distance, and wait times). For

example, CMS requires states to develop standards for travel time and distance from enrollees' homes to providers to regulate Medicaid managed care plans. In private markets, states are primarily responsible for the enforcement of network adequacy standards. CMS's 2017 market stabilization final rule relieved burden on issuers by relying on states to regulate network adequacy for qualified health plans in the individual and small-group markets. Across states, there is substantial variation in the number and types of network adequacy measures used.

Impact on Competition and Choice

Measures used to determine network adequacy may not align with a network's ability to meet enrollees' preferences, may discourage innovative ways to meet those preferences, and may ultimately limit consumers' choices. For example, using proximity measures to regulate network adequacy may discourage insurers and providers from developing telemedicine capabilities[255] or utilizing regional or national centers of excellence outside the residency area.[256] Relying on current measures may also restrict entry into the insurance market by insurers with innovative plan designs. For example, vertically integrated health systems may be less likely to enter a market if network adequacy standards would force them to compete with other providers.[257]

Inadequate or erroneous provider directories in network plans may also discourage providers from competing on price or quality to attract patients. If consumers cannot accurately identify in-network providers, or compare networks of competing insurers, it is more difficult for them to make informed choices. In addition, without proper information, enrollees may be more likely to unknowingly receive care out of network, leading to instances of "surprise billing." Of patients aged 18-64 who receive out-of-network care, nearly 70 percent are unaware that the provider is outside their plan's network prior to receiving care.[258]

While CMS requires Medicare Advantage, Medicaid managed-care plans, and qualified health plans in the exchange to update and provide consumer-accessible provider directories, ensuring that enrollees receive accurate information in real-time may still be difficult. In a review of provider locations from online directories, CMS found errors in over half of the locations for Medicare Advantage providers, with 33 percent of errors due to the provider not working at or not accepting the plan at the listed location (CMS 2018).[259]

The provision of accurate and timely information would also bolster competition. To facilitate more competition and innovation, network adequacy standards should place greater emphasis on network outcomes while giving states flexibility to meet their specific needs. In 2015, the National Association of Insurance Commissioners opposed blanket federal network adequacy requirements in its Health Benefit Plan Network Access and Adequacy Model Act, especially as strict quantitative measure are unlikely to meet varying needs across states. Current quantitative standards could be less restrictive and used primarily as minimum thresholds to determine whether an insurer can enter a market or when a network has actually failed an enrollee.[260] These standards should take into account alternative network designs and be used alongside external review by physicians when

networks fail to provide adequate access to enrollees.[261] Insurers could be allowed to have more flexibility with provider contractors, such as "spot contracts," to fill in network gaps as needed.[262]

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.
- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

The ACA Rules Limit Choice

The Affordable Care Act introduced a number of mandates and burdensome requirements that significantly reduced choice and competition in insurance markets and caused premiums, particularly in the individual market, to soar. This occurred to a significant extent because government rules and price controls on health insurance premiums, designed to assist some people with higher anticipated health expenditures, inhibited the application of actuarially determined pricing and created an adverse selection spiral in the individual market. These requirements also produced a significant reduction in coverage options for most consumers. In addition to reducing consumer choice and competition between insurers, the higher administrative costs associated with the ACA mandates disproportionately hurt smaller employers, in part because smaller employers were unable to spread these costs as broadly as larger employers and in part because the large-group market is not bound by all of the ACA's mandates. Therefore, as a general matter, smaller employers that continued to offer coverage were forced to disproportionately raise premium contributions paid by covered workers, making them less competitive with larger employers and with other smaller employers that chose not to offer health coverage to their employees.[263]

ACA's Harmful Insurance Rules

The ACA forces insurers offering coverage in the individual and small-group markets to offer a mandated set of government-defined benefits.[264] This mandate reduces consumer choice and represents a hidden cost on the majority of consumers by forcing them to pay for more coverage – and the corresponding expense – than many customers would otherwise choose to buy voluntarily in insurance packages. Excessive mandates hinder innovation in plan design and greater access to coverage; they also limit public efforts to assure affordability without substantial government subsidies. This leaves significant swathes of consumers with coverage that includes numerous items they do not want or need and contributes to pricing others out of the market, including some of the 6.5 million people

who paid the penalty for not having minimum essential coverage under the ACA.[265] The ACA further restricts choice and competition through a prohibition on people over the age of 30 purchasing catastrophic insurance (unless they qualify for a hardship exemption).

The ACA also requires insurers to cover numerous preventive services without cost sharing under the premise that a government-imposed system-wide increase in "free" preventive care will lower overall healthcare costs.[266] Under the ACA, the U. S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices of the CDC, and HRSA are tasked with determining the required preventive services.[267] However, a New England Journal of Medicine study found that "sweeping statements about the cost-saving potential of prevention…are overreaching. Studies have concluded that preventing illness can in some cases save money but in other cases can add to healthcare costs."[268] Other research finds that 80 percent of preventive services add more to future expenditures than they save in healthcare costs.[269] These findings suggest that the ACA's coverage mandates, while certainly providing some benefit, increase premiums, as well as lead to unnecessary utilization. Atul Gawande, former adviser to President Bill Clinton and President Barack Obama, has warned about the risks of over-testing and over-treating.[270] Over-testing leads to problems like additional radiation exposure and stress from the abundance of false positive results, and over-treating leads to problems like medical errors and hospital-acquired infections.

The Medical Loss Ratio (MLR) is an ACA mandate requiring that insurers in the individual and small-group markets spend at least 80 percent of premiums on healthcare costs, allowing 20 percent for administrative costs and profit.[271] The MLR was intended to provide a minimum guaranty of value to customers, as companies that fail to meet this ratio are obligated to pay a rebate to their customers.[272] However, the MLR may create a perverse incentive that encourages insurance companies, particularly in the absence of competition, to increase premiums.[273] Some health policy experts also believe that the MLR regulations will harm the ability of some insurers, particularly smaller insurers, to compete, thus reducing consumer choices.[274]

A number of ACA rules have contributed to large increases in average premiums and have driven down choices in the individual and small-group markets. In 2013, the year before many of the ACA rules took effect, 395 insurers operated in the individual market.[275] By 2017, this number had fallen to 218, and 70 percent of counties (including 36 percent of U. S. residents) had no more than two insurers selling individual plans in the exchange.[276] In the exchanges in 2018, 29 percent of enrollees had only one issuer to choose from, up from 20 percent in 2017; 55 percent of enrollees had at most two insurers to choose from, up from 44 percent in 2017.[277] This problem is most pronounced in rural counties. As a result of high and rising premiums, relatively young and healthy people, particularly those in the middle-class who earn too much to qualify for a premium subsidy, have largely avoided the exchanges. Moreover, the ACA's special enrollment periods created an incentive for people to wait until they need healthcare to seek insurance in the exchanges, an incentive that has exacerbated adverse selection and led to spikes in premiums.[278] In an attempt to mitigate this problem, the Department of Health and Human Services issued an April 2017

rule aimed at significantly restricting peoples' ability to game the special enrollment periods.[279]

The administration has taken two major actions to provide Americans, particularly middle-class Americans without employer-sponsored insurance, with additional and more affordable health insurance choices. In June, the Labor Department released a final rule expanding the ability of employers, including sole proprietors without common law employees, to join together to form an association health plan (AHP).[280] In August, the departments of Health and Human Services, the Treasury, and Labor released a final rule expanding the ability of consumers to purchase short-term, limited-duration insurance—much more affordable products that can better serve many consumers' needs.[281] According to the Congressional Budget Office, about 6 million Americans will benefit from these actions and enroll in these plans within a few years.[282]

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.
- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

ACA Rules Restricting Physician-Owned Hospitals Reduce Competition

The ACA placed an effective moratorium on the opening and expansion of physician-owned hospitals.[283] According to the Physician Hospitals of America, 37 planned hospitals have not been constructed, and over 30,000 planned healthcare jobs have gone uncreated because of these ACA restrictions on physician-owned hospitals.[284] These restrictions, which were favored by the American Hospital Association, were included to address potential financial conflicts of interest with doctors referring patients to their own hospitals and concerns that physicians may be referring the healthiest patients to their own hospitals.[285] Those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provider higher-quality care and that patients benefit when traditional hospitals have greater competition.

Physician-owned hospitals, furthermore, have been shown to provide patients with high-quality care. According to a study published by the Journal of the American College of Surgeons, physician-owned surgical hospitals outperform other hospitals in the Medicare

value-based purchasing program.[286] More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the Centers for Medicare and Medicaid Services (CMS), compared to only 5 percent of general hospitals.[287, 288] Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital than at a general hospital.[289]

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

ACA Section 1557 (Nondiscrimination Requirements)

ACA Section 1557 has been implemented in such a way that creates a number of burdens on healthcare providers and payers. For example, current rules concerning persons with limited English proficiency require covered entities to include a notice of the right to translation services in 15 languages in nearly all "significant communications" that go to

because of these ACA restrictions on physician-owned hospitals.[284] These restrictions, which were favored by the American Hospital Association, were included to address potential financial conflicts of interest with doctors referring patients to their own hospitals and concerns that physicians may be referring the healthiest patients to their own hospitals.[285] Those concerns may have been overstated, considering that many studies suggest physician-owned hospitals provider higher-quality care and that patients benefit when traditional hospitals have greater competition.

Physician-owned hospitals, furthermore, have been shown to provide patients with high-quality care. According to a study published by the Journal of the American College of Surgeons, physician-owned surgical hospitals outperform other hospitals in the Medicare value-based purchasing program.[286] More than 40 percent of physician-owned hospitals received the top 5-star rating in a 2015 release by the Centers for Medicare and Medicaid Services (CMS), compared to only 5 percent of general hospitals.[287, 288] Further, patients are 3-to-5 times less likely to experience complications at a physician-owned specialty hospital than at a general hospital.[289]

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It is critical to structure anti-discrimination provisions so they are not barriers to entry that favor larger entities who can better absorb these types of costs and thereby limit competition. However, these and other new requirements imposed on the healthcare industry by the Section 1557 regulations were estimated to cost covered entities $637.5 million over the first two years.[292] This burden is especially hard for smaller entities to enact because unlike larger market players, they cannot take advantage of economies of scale by spreading the additional costs incurred over their larger enrollee population.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Giving Americans Control over Their Healthcare Spending

The introduction to this report highlights how third-party payment distorts healthcare markets, increases spending and premiums, and reduces consumers' incentives to seek value from their healthcare decisions. Federal law currently favors third-party control and payment through the federal exclusion of employer-sponsored insurance (ESI) premiums, including employer contributions for self-insured plans, from both income and payroll taxes, the design of the Medicare and Medicaid programs, and the ACA premium tax credits. Easing restrictions on other types of arrangements available for this tax preference could put more control in the hands of consumers and could thus promote cost-conscious consumer behavior.

The primary vehicles that put more control in the hands of consumers and reduce the bias toward third-party payment are high deductible health plans (HDHPs) paired with HSAs and Health Reimbursement Arrangements (HRAs). Research demonstrates that consumer-directed health plans, such as these, can lower healthcare spending, largely through reductions in usage of outpatient care and pharmaceuticals.[293]

Benefits of Expanding Health Savings Accounts

Under tax provisions originally enacted in 2003, persons enrolled in certain HDHPs—which are generally referred to here as HSA-qualified plans— may contribute to savings accounts to pay for healthcare expenses on a tax-preferred basis. Contributions made by an individual's employer or by an individual through payroll deduction are excluded from wages for purposes of income and payroll taxes. Contributions made directly by an individual are deductible for income-tax purposes. Individuals must be enrolled in an HSA-qualified plan and generally cannot be enrolled in any health plan other than the HSA-qualified plan to be allowed to make HSA contributions. Annual HSA contributions are limited to $3,450 for persons enrolled in single coverage under an HSA-qualified plan ($6,900 for persons enrolled in family coverage) for 2018.[294] HSA-qualified plans are required to meet the following requirements[295]:

1. Minimum deductibles ($1,350 for self-only coverage or $2,700 for family coverage in 2018).
2. An annual limit on the sum of the deductible and out-of-pocket expenses ($6,550 for self-only coverage and $13,300 for family coverage).
3. The out-of-pocket expense limits do not apply to any out-of-network benefits if the plan uses a network (that is, the out-of-pocket cap applies to the deductible and cost sharing only on in-network benefits).
4. Only preventive care benefits as defined in applicable guidance[296] may be provided before the minimum deductible is met.
5. The health plan coverage must not be not limited to vision, dental, disability, workers compensation or other specified types of limited insurance coverage.

HSA funds not used to pay health expenses over the course of the year may be saved for future use, and any funds unspent when individuals turn 65 may be withdrawn for any use without penalty.[297] Thus, HSAs promote savings for later healthcare expenses, an extremely beneficial feature since healthcare expenditures tend to grow with age.

Unfortunately, many people—likely around 60 percent—who have deductibles exceeding the required minimum deductibles for HSA-qualified plans do not have HSA-qualified plans.[298] Some of the common reasons that plans are not HSA-qualified plans are because of 1) separate drug coverage based on a tiered copayment structure with no or a low deductible, 2) coverage of generic drugs before the deductible is met, or 3) coverage of primary care visits (for free or with a copayment) before the deductible is met. Thus, certain innovative insurance products, which attempt to incentivize cost-effective health treatments and health behaviors, cannot be coupled with HSAs.

For example, an insurer looking to prudently manage the costs of diabetes by offering insulin coverage before the deductible with the goal of reducing much larger future costs that might occur from mismanagement of the disease could preclude its enrollees from contributing to an HSA. Alternatively, an insurer might offer a plan with an actuarial

value[299] similar to that of an HSA-qualified plan, but with a low deductible combined with higher copays. This plan could provide even more of an incentive for individuals to be as cost-conscious as the HSA-qualified plan requirements provide but would not be an HSA-qualified plan.

A third example of an arrangement that might not meet the current HSA requirements is a fixed-fee arrangement between providers and consumers, such as a direct primary care arrangement with a primary care physician where the patient pays a monthly fee in exchange for a set number of visits as well as basic treatments. Some or all fees under such fixed-fee arrangements might not be healthcare expenses under section 213(d) of the Internal Revenue Code (the "Code"). If so, HSA funds used for paying these fees could be subject to income taxes and a penalty.[300] Also, if the fixed-fee arrangement is determined to be insurance for tax purposes, the arrangement would likely be considered a health plan and preclude the individual from contributing to an HSA during the year because

individuals who have a health plan in addition to an HSA-qualified plan cannot contribute to an HSA.[301]

These constraints on HSA-qualified plans and the requirement that prevents an HSA contributor from having any health plan other than an HSA-qualified plan, limit the popularity of HSAs, reduce choice, and potentially increase healthcare spending as people eschew HSA-qualified plans and instead choose plans with greater third-party payment. An alternative standard for determining HSA-qualified plans would allow individuals with certain cost-conscious plan features to benefit from HSAs.

One such proposal would be to allow anyone enrolled in a health insurance plan with a 70 percent actuarial value (AV) or below to contribute to an HSA. This will incentivize employers whose current plans have an actuarial value above the threshold to switch to offer a plan or plans with a somewhat higher deductible and copayments (and a lower actuarial value) because their workers could then newly participate in an HSA. Economic theory suggests employers would fund employees' HSAs with premium savings. Expanding HSAs and the corresponding incentive to obtain greater value from healthcare spending could lead to less consumption of healthcare, particularly lower-value services and treatments, and further premium reductions.

Individuals whose current plans are at or below 70 percent AV that are not currently paired with HSAs would have an expanded tax-preference for out-of-pocket spending causing some of them to spend more although this incentive is limited since unspent HSA amounts roll over from one year to the next. However, some, but not all, of those whose current plans are above 70 percent AV and who switch to 70 percent or lower AV plans would bear higher after-tax, out-of-pocket costs for services and therefore have an increased incentive to seek value for their healthcare spending. In these situations, providers would be subject to more pressure to set transparent prices and to compete for customer business by lowering prices and improving quality. In addition, unlike with current HSA-qualified plans, insurers would have flexibility to include highly cost-effective care before the deductible is met.[302]

As noted above, an additional constraint on the availability and use of HSAs is the requirement that HSA-qualified plans can only provide certain preventive care benefits before the minimum deductible is met. Reconsideration of the scope of care that qualifies as preventive could make HSA-qualified plans more attractive and thus enhance access to HSAs. Short of creating a new statutory standard for HSA-qualified plans, the existing regulatory definition of preventive care could reasonably be interpreted more expansively for purposes of the HSA and related HSA-qualified plan rules. A broader interpretation could improve cost-effectiveness and give consumers greater options for financing their

healthcare. One reasonable approach would be to consider treatments preventive if they are highly cost-effective and treat a chronic condition that would, in a relatively high share of cases, become more severe or develop into a new condition that is considerably more expensive to treat, if the original condition were left untreated.

Another HSA reform that would reduce the bias in favor of comprehensive, employer-sponsored coverage would be allowing people with an HSA-qualified plan who also choose consumer-provider, fixed-fee arrangements, such as direct primary care arrangements, to contribute to an HSA. Doing so would provide another avenue for first-party payment of healthcare services, thereby expanding choice and making HSA-qualified plans more attractive relative to comprehensive insurance. Some of these types of arrangements are simply pre-payment, outside of traditional insurance arrangements with all the corresponding administrative costs, for certain healthcare services that are known and regular in nature. For example, a patient with diabetes might purchase a fixed-fee arrangement that supplied insulin, testing equipment, and a quarterly visit with a healthcare provider specializing in treating diabetes patients. Healthcare providers would then have an incentive to compete with respect to price and quality to attract patients with HSAs.

Another limitation of current law is that Medicare beneficiaries in HDHPs are not allowed to make tax-deductible contributions to their HSAs or Medicare Savings Accounts (MSAs) even if Medicare serves as their secondary coverage. This limitation reduces the ability of working seniors to save for future healthcare expenses and leads them to rely more upon third-party payment for healthcare services in retirement. The FY2019 President's Budget proposed to give Medicare beneficiaries greater flexibility to take control of their healthcare. The Budget proposal would allow beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs. These beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Medicare beneficiaries who have an employer-sponsored HDHP would be allowed to make contributions to their HSAs, although Medicare would not cover any expenses before the HDHP deductible is met. The Budget estimated that this proposal would reduce government revenue by about $11 billion, over 10 years.

Although the premiums for employer-sponsored coverage—both the premiums paid by the employer and employee—are generally excluded from federal income and payroll taxes, the premiums paid for non-group coverage do not receive this same tax treatment. The ACA's premium tax credits provide assistance for the purchase of individual market plans,

but this assistance declines rapidly as household income rises and does not extend to people in households with income above 400 percent of the federal poverty line. As part of its proposal to replace the ACA, the President's FY2019 Budget recommended increasing HSA contribution limits and allowing the use of tax-preferred HSA funds to pay HDHP premiums. The Treasury Department's budget estimates suggest that, as part of ACA repeal, raising the HSA contribution limits to the out-of-pocket maximums and allowing the purchase of HDHP premiums from HSAs would reduce government revenue by $28 billion over 10 years.

Another option to increase consumer control through HSA expansion would be to allow persons enrolled in Healthcare Sharing Ministries as defined in Code section 5000A(d)(2)(B)(ii) to contribute to HSAs. Healthcare Sharing Ministries are organizations in which people with shared religious or ethical beliefs help pay each other's medical costs. Contributions to HSAs by participants in Health Sharing Ministries would be permissible provided that the individuals (1) remain responsible for an amount of their own (or their family's own) healthcare expenses equal to the applicable annual deductible for an HSA-qualified plan, and (2) with respect to any particular medical expense, are not eligible for payment, sharing, or reimbursement of the expense in any manner by both the Healthcare Sharing Ministry and the HSA. In other words, the HSA-qualified plan deductible would still apply and a medical expense could not be reimbursed twice. These arrangements would encourage individuals to keep medical spending low by encouraging less costly behaviors and greater negotiation with medical providers. In expanding the flexibility of these arrangements, however, distinguishing genuine Healthcare Sharing Ministries from plans and organizations that mischaracterize themselves as such would be essential.

Benefit of Expanding Health Reimbursement Arrangements

Since HSAs are the property of the individual, increasing consumers' ability to use HSAs is likely the best way to encourage first-party payment. Expanding HRAs could also encourage more efficiency through greater consumer control over their healthcare and somewhat reduced third-party payment.

Originally described in IRS guidance in 2002,[303] HRAs allow employers to reimburse their employees' medical expenses. An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical expenses incurred by the employee or his or her family up to a maximum dollar amount for a period. Historically, HRAs have often been used by employers that did not choose to offer group insurance to their workers, as well as to supplement group coverage.

As a result of the interpretation of some ACA provisions, HRAs can currently only be

offered if employers also offer ACA-compliant group health insurance plans. In implementing the ACA, the Obama administration determined that standalone HRAs violated the ACA prohibition on annual dollar limits and the requirement that group health plans provide certain preventive care without cost sharing. Although the Obama administration issued regulations allowing HRAs to be offered as long as the employee had other group health insurance coverage, the Obama administration restricted individuals' ability to use an HRA to purchase individual market insurance of their own choosing, even if the insurance did not have annual and lifetime dollar limits and covered preventive care without cost sharing.

The following two expansions of HRAs, both proposed in a notice of proposed rule-making issue on October 23, 2018, would increase their usability and provide employers, and their employees, with a greater set of alternatives for financing health coverage. First, reversing the Obama administration restriction on HRAs for individuals with individual market insurance would encourage more employers to offer HRAs, increase consumer choice, and provide equal tax treatment for employee-selected coverage in the individual market as for traditional employer-selected group coverage.[304] In essence, allowing HRAs to be integrated with non-group coverage that does not have annual dollar limits and that covers the necessary preventive care without cost sharing would allow employers to provide a tax-advantaged, defined contribution arrangement for each employee to select the health insurance that best works for his or her circumstances. In addition to the benefit for workers, the proposed rule would better enable businesses to focus on what they do best—serve their customers—and not on navigating and managing complex health benefit designs.

This proposed rule is increasingly important as fewer employees at small and mid-sized firms are enrolled in employer coverage and most employers that do offer a plan only provide their workers a single option. For firms that employ 3-24 workers, the percentage of workers covered by employer health benefits has fallen from 44% in 2010 to 30% in 2018. For firms that employ 25-49 workers, the percentage of workers covered by employer health benefits has fallen from 59 percent in 2010 to 44 percent in 2018. 81 percent of small to midsized employers (fewer than 200 employees), and even 42 percent of larger employers (at least 200 employees), offering health benefits only provide a single coverage option for their employees. Economists have found that increasing plans available to employees is extremely valuable, providing the median consumer equivalent benefit as a 13 percent premium reduction.[305]

An additional way to expand the use of HRAs is to allow a limited "excepted benefit" HRA that, as with all excepted benefits, would not be subject to the ACA's market rules (such as the prohibition on annual dollar limits and the requirement to cover preventive care without cost sharing) or certain other requirements for group health plans under the Code and the Employee Retirement Income Security Act of 1974 (ERISA). Providing an excepted benefit HRA would reduce the bias toward comprehensive ESI and allow employees another tax-advantaged arrangement to finance limited healthcare expenses. The proposed regulation would permit employers that offer traditional group coverage to

provide an HRA of up to $1,800 per year (indexed to inflation) to reimburse an employee for certain qualified medical expenses, including standalone dental benefits and premiums for a short-term health insurance plan.

According to preliminary estimates from the Treasury Department, once fully phased in, roughly 800,000 employers are expected to provide HRAs to pay for individual health insurance coverage to over 10 million employees. Some experts, such as Harvard Business School professor Regina Herzlinger, suggest the effect could be larger since expanded HRAs will create a more efficient healthcare system as consumerism will be unleashed.[306] This phenomenon could lead to increased workforce investment and higher wages as less is spent on health insurance and could spur innovation among providers and insurers as they directly compete for consumer dollars.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA-qualified non-group premiums, allowing Medicare beneficiaries in enrolled high-deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.
- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.
- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to their employees, and to allow HRAs to be used in conjunction with non-group coverage.

The Unintended Consequences of Federal Policies

Delivery System Reform

Policymakers generally agree that the U. S. healthcare system's reliance on fee-for-service, third-party financing has contributed to a system that produces high costs with uneven quality. The increasing recognition among policymakers of this dynamic has led to recent reimbursement policies that attempt to move away from rewarding volume (fee-for-service) to rewarding value. Many delivery system reform efforts to date have sought to transfer risk to entities with better incentives for managing costs and delivering value to patients. One of the most successful examples of this has been Medicare Advantage, which has moved away from a fee-for-service model, improved incentives, and has generally

produced higher value (better care per unit of cost) for patients. The success of Medicare Advantage is based on better empowering consumers—letting them determine what constitutes value, as opposed to deferring the judgement to Washington. As HHS Secretary Azar has stated, if the government writes the equation for value, the answer is never going to be cheap or simple, and special interests will find a way to manipulate it. Relying on the free exchange of information between buyers and sellers, among competing interests, can deliver better outcomes from our healthcare system at a lower cost with patients, not the government, in charge.[307]

ACOs

Various structures have been tried in different settings by the prior administration. However, they have often relied on the government (rather than patients and the private sector) to define value, rather than allowing patient choice. One such approach has been the development of Accountable Care Organizations (ACOs), groups of doctors, hospitals and other providers that work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization, whose performance is evaluated according to quality standards established by the government. ACOs were intended to improve coordination of care between primary care providers, specialists, and hospitals by holding providers accountable for patient outcomes and total costs. When considering the future of ACOs and broader delivery system reform efforts, it is critical to understand the history of ACOs and their effect on provider competition.

The largest Medicare ACO program is the Medicare Shared Savings Program (MSSP), in which Medicare shares in the financial savings and losses generated by ACOs. In 2018, there were 561 MSSP ACOs, which enrolled 10.5 million beneficiaries.[308] Importantly, most MSSP participants are not responsible for financial risk if their spending is above established targets (i.e., one-sided financial risk). New payment models such as Medicare's Next Generation ACOs require providers to take on both shared savings and shared losses. (309). These models may offer important learning opportunities to test public-private initiatives that aim to increase value since two-sided financial risk represents better incentives to achieve value than one-sided financial risk. Over time, two-sided financial risk should be paired with some control over the inputs to match outcome accountability.

ACO Impact on Provider Competition

While changes such as ACOs and other alternative payment models (APMs) may hold the promise of improved care coordination and better aligned financial incentives, they may also encourage provider consolidation that increases market concentration, drives up prices, and decreases competition between providers. This may occur as hospitals purchase physician practices (vertical integration), or through mergers between hospitals or between physician practices (horizontal integration). Although a causal link has not yet been identified, some studies have found that vertical integration has been associated with higher prices and spending in some markets and for some providers.[311] In California, hospital-owned physician practices have higher per-patient spending than physician-owned practices.[312] Most economists believe that horizontal integration threatens consumers with

higher prices as well as reduced options.

Some experts have suggested that hospital-acquired practices increase the use of evidence-based care such as disease registries, nurse care managers, and reminders to patients that can improve quality of care and outcomes more than physician-owned practices that do not use such care management practices.[313] However, hospital-owned practices may have higher rates of emergency department visits and higher Medicare spending per patient.[314] This may be why greater physician-hospital integration has been linked to higher commercial prices for outpatient care[315] and hospital prices.[316]

The FTC and the Justice Department worked closely with CMS to develop ACO eligibility criteria so Medicare Shared Savings Program ACO applicants meet clinical integration requirements, avoiding antitrust concerns.[317] In order to facilitate compliance with antitrust rules, the FTC and DOJ developed antitrust guidance and policy for ACOs,[318] defining antitrust safety zones as well as areas of potential concern where providers have high market power based on their share of the primary service area. The antitrust authorities continue to monitor ACOs for potential antitrust violations.

Research to date indicates that ACOs tend to develop in competitive markets; and only in a minority of markets have ACOs increased physician concentration.[319] One recent study found that markets with higher ACO penetration did not experience differential changes in physician-hospital integration, practice size, or market concentration of physicians or hospitals from 2008 to 2013.[320] The study also found high ACO penetration markets had more competitive hospital and insurance markets and higher commercial HMO penetration. The authors did note that continued consolidation might be a defensive response to the potential threat from new payment models, as larger health systems may be able to resist payer pressures to enter into risk contracts.

Importantly, provider consolidation began prior to the start of delivery system reform efforts. In one study of hospital acquisition of practices between 2006 and 2013, vertical integration peaked in 2011. Hospitals mostly bought small primary care, multi-specialty, or cardiology practices; case studies of hospitals indicated the primary motivation was to increase referrals and negotiate higher payment rates with insurers.[321]

A Robert Wood Johnson Foundation project on the impact of hospital consolidation concluded that early trends in consolidation were primarily to improve bargaining power and did not necessarily involve clinical integration.[322] Some potential factors related to delivery-system reform that may be contributing to provider consolidation include large health system economies of scale and ability to handle increasing quality and cost measurement reporting. The capital and resource requirements to transform a primary care practice, even within a practice, are substantial. The financial and administrative demands of delivery system reform may incentivize small practices and solo practitioners to accept buy-outs by hospitals and health systems or leave the profession prematurely. The trend toward large systems is likely not be better for patients. A 2013 study found that larger health systems participating in payment reform have not shown better patient outcomes or lower spending,[323] whereas small practices have seen lower rates of preventable

admissions.[324] Thus, it is important that delivery system reform efforts do not harm smaller practices that lack economies of scale to satisfy new rules and requirements accompanying delivery system reform more easily.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.
- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

Positively Realigning Incentives through Payment Reform

Patients with certain clinical needs can often seek care in one of a variety of settings. Medicare fee-for-service (FFS) reimbursement is often based predominately on the setting of care and not the patient's underlying medical need. This can create incentives for providers to refer patients selectively to more highly reimbursed care settings, unjustifiably increasing concentration and spending. Two examples of service types with multiple venue options are post-acute care (PAC) and certain physician services furnished in hospital outpatient departments (HOPD).

Post-Acute Care

Medicare post-acute care (PAC) providers are primarily used for recuperation and rehabilitation. These providers include home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs). In 2016, Medicare spent approximately $60 billion on Medicare PAC services. Per statute, separate Medicare prospective payment systems (PPSs) were developed for each Medicare PAC setting. Base PPS payments for each of these settings differs considerably, even though the clinical characteristics of patients and the services delivered at any of the four PAC settings may be similar. The 2018 base PAC PPS payments (i.e., base payments prior to adjustments such as case mix) are about $15,000 per discharge for IRF, about $400 per diem for SNF (up to 100 days in a covered spell of illness), about $3,000 per 60-day episode for an HHA, and about $41,000 per discharge for a standard

LTCH stay or an inpatient hospital with comparable payment rate for patients who meet statutorily specified LTCH eligibility criteria. A unified or site-neutral PAC prospective payment system would base Medicare payment on the clinical characteristics of the patient instead of the provider setting.

Hospital Outpatient Departments

Many of the services delivered by hospital outpatient departments (HOPDs), such as evaluation and management visits, endoscopies, and imaging services, are also delivered in physician offices and ambulatory surgical centers (ASCs). Medicare FFS benefit payments are projected to be $50 billion in 2018 and $100 billion in 2027 for these services.[325] Conceptually, physician reimbursement for ambulatory services has two components: the professional component, which covers the physician time, and the technical (also called facility) component, which covers the cost of the office, equipment, and auxiliary staff's time. The professional component is paid under the Medicare Physicians Fee Schedule (PFS) regardless of the place of service. However, the technical component is typically higher in the HOPD than in a physician's office or ambulatory surgical center.

Sec. 603 of the Bipartisan Budget Act of 2015 (BBA) modified how off campus outpatient services are paid. Prior to enactment of the BBA, hospitals were able to purchase freestanding clinics and bill for outpatient services under the Outpatient Prospective Payment System (OPPS) for the services furnished at these off-campus provider based departments. Sec. 603 changed the incentives so that after January 1, 2017, services furnished by certain off-campus provider based departments would no longer be payable under the OPPS (and would generally instead be paid lower rates under the Physician Fee Schedule), effectively decreasing payments for these services and eliminating an incentive for hospitals to purchase these freestanding clinics. Clinics purchased by the hospitals prior to November 2, 2015 or which were located less than 250 yards away from a remote location of the hospital were "grandfathered," and continue to have services rendered paid under OPPS. Elimination of this incentive to consolidate will hopefully serve to maintain market competition and slow increases in Medicare and private insurance sending.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In delivering these reforms, Congress should account for differing levels of patient acuity.
- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Quality Improvement and the Measurement and Reporting of Quality

One of the earliest experiences with quality reporting was the publication of "report cards" in New York and Pennsylvania, which started reporting physician and hospital coronary artery bypass graft (CABG) surgery mortality rates in the 1990s. These efforts led to some early successes, including a 41 percent decline in risk-adjusted mortality rates[326] and 27 surgeons with low volume and high mortality rates ceasing performing CABG surgeries.[327] Potential drawbacks are that report cards may have produced some "cherry picking" by providers, so that fewer severely ill patients received CABG and health outcomes for severely ill patients worsened.[328] Several other studies have demonstrated positive results from measuring quality outcomes and publishing the results.[329]

While value is best determined by private sector interactions, the government can play a productive role in collecting and making available data that patients and insurance companies can use to make more informed decisions. In the past, the government has often failed to establish sensible metrics, creating significant reporting burdens for providers and metrics that are not informative for patients or industry and can easily be gamed when reimbursement is tied to them.

Quality Reporting History

Following the publication of the landmark reports, To Err is Human and Crossing the Quality Chasm by the Institute of Medicine in 1999 and 2001 respectively, numerous quality-reporting requirements have been imposed on providers. The premise of quality reporting is that it will motivate providers to improve the quality of healthcare they deliver and provide patients with the information they need to make informed choices about their care. Early quality public reporting initiatives centered around hospital mortality rates,[330] and required many providers to abstract data manually from patient charts.

The Deficit Reduction Act of 2005 mandated that HHS develop a plan for value-based purchasing for Medicare hospitals starting in 2009, which led to Medicare's first pay-for-reporting programs for hospitals and physicians.[331] Medicare tested the first hospital pay-for-performance program through a partnership with Premier, an alliance of hospitals, in the Hospital Quality Incentive Demonstration,[332] a six-year program that awarded top-performing hospitals with bonuses based on evidence-based quality measures for five clinical conditions. This demonstration showed improvements in quality for participants and those who publicly reported quality.[333] Refinements to Premier's methodology, rewarding both achievement and improvement as a means to address disparities,[334] have led to implementation of similar features in Medicare's current value-based purchasing programs.

Since 2003, HHS has published a national report on quality and disparities through national databases in the Agency for Healthcare Research and Quality (AHRQ). The data show

continued disparities among providers alongside overall improvements. The National Quality Forum is now looking at methodologies to display this data to providers to help improve care for disadvantaged populations (including poor, rural, and vulnerable populations) by reporting potentially preventable admissions that reflect the quality of primary care or higher rates of delayed care due to affordability.[335]

Medicare's Physician Value-Modifier (VM) program, a physician pay-for-performance program, sought to extend the goals of quality improvement in the ambulatory care setting and assess population outcomes such as preventable admissions, using Medicare claims data. In addition, the Quality Payment Program, enacted in 2015 through MACRA, has created another requirement for physicians to report on measures. Like the Value Modifier Program, the Quality Payment Program also assesses clinicians and group practices on population level outcomes including all-cause readmissions and avoidable ER visits.

Quality metrics have a greater effect on providers than on patients. Many of the patients did not consult the report cards, and of those who did, many reported that they did not affect their choice of hospitals or surgeons.[336] However, the quality metrics certainly affect providers who do not wish to be publicly identified as potentially harming patients, and this seemingly drives many providers to improve. Although measuring quality has generally produced positive results, the proliferation of measures produces a burden that discourages providers and likely takes away from patient care. Moreover, many providers have learned to game certain measures or have become sophisticated in explaining away bad results as attributable to improper risk adjustment.

The shift to value-based payment, the large number of quality measures, and the potential lack of alignment in measures required by different payers (e.g., Medicare, state Medicaid agencies, and health insurers) further increases the burden of quality reporting on providers. Each year physicians and their staff in four common practice areas (cardiology, orthopedics, primary care, and multispecialty) spend 15.1 hours per week per physician on reporting quality measures—about 785 hours per physician per year—at an estimated average annual cost of $40,069 per physician or $15.4 billion per year for these specialties.[337] This is clearly too much, especially given the problems intrinsic to many of the metrics being recorded. CMS estimated the total costs burden of MIPS in the first year to be $1.3 billion in 2017, decreasing to $694 million by 2018 due to fewer clinicians being eligible under revised volume requirements.

Half of physicians and 38 percent of nurse practitioners and physician assistants report that quality reporting requirements have a negative impact on the quality of care.[338] This stands out as another example of well-intentioned government action having unintended consequences. To address this issue, the National Quality Forum (NQF) has endorsed a set of common quality reporting measures for use by public and private payers. Under current law, NQF endorsement is required to ensure standardization and stakeholder input in measures used for quality reporting and performance-based payment.

Another recent private-public effort, Core Quality Measures Collaborative,[339] has worked to align measure specifications across payers including Medicare and Medicaid. In

addition, CMS's Meaningful Measures Initiative removed 18 hospital reporting measures and is proposing removal of 36 measures from the MIPS program that have showed no variation and are topped-out (i.e. already showing high level of performance with minimal to no variation).

Impact of Quality Reporting on Competition

A recent report by the Government Accountability Office (GAO) predicts that many small practices will be unable to transition to MIPS due to lack of financial resources.[340] The new requirements potentially disadvantage small, independent practices or solo practitioners who, unlike large health systems, are less likely to have the administrative infrastructure and staffing resources (e.g., a practice manager or other administrative staff) to report efficiently on quality and conduct regular quality improvement activities to improve performance. One potential concern is that practices that participate in these programs may harm patient care if they need to divert limited resources to reports and bureaucracy and away from actual quality improvement and patient care. The financial effects from penalties, diverted resources, and poor performance results could affect their ability to stay in business, force them to merge with larger systems, or lead to early retirement.

The GAO also suggests that small practices could work with partners to share in financial risk and help coordinate services, as well as work with non-partners in order to support quality reporting, patient surveys, and EHR requirements. Since many practices would like to remain independent and there is increasing evidence that small independent practices provide higher quality of care, such as fewer preventable hospital admissions, at lower cost,[341] enabling them to achieve these benefits while remaining independent is important.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the number of measures where the expected cost of collecting the measure exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.

- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that can increase the competitiveness of small practices through access to shared

resources and help build capacity for care management.

- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Enabling Consumer-Driven Healthcare

Rising healthcare spending is partly attributable to consumers' insulation from the true market price of healthcare services through the presence of third-party payment. Historically, consumers have had little reason to seek out, or price shop for, lower-cost or higher-value providers and services due to the abundance of third-party payment. Instead, reimbursement rates are negotiated between third-party payers, generally the government or insurers, and providers. And consumers generally are provided with little information on the prices of healthcare products and services.

Perhaps not surprisingly, there is a wide variation in prices charged across providers, even within a geographic area.[342] Substantial savings could be achieved if consumers actively shopped and selected lower-cost providers. For example, Table 2 demonstrates the potential savings for people who self-pay relative to the insurance rate. Unlike most industries, which typically offer relatively uniform prices to most consumers, the reimbursement of a specific service will vary significantly based on the third-party payer with which a consumer is aligned. It is also worth noting that consumers may receive a lower price by paying cash for services.[343] Yet it can be difficult for consumers to find price information.

Table 2:

The Cash Advantage

Patients who pay cash upfront for medical services can sometimes make out better than they would by using their insurance, especially if they have high-deductible plans and pay the insured rate in full. Some examples:

Patients who pay cash upfront for medical services can sometimes make out better than they would by using their insurance, especially if they have high-deductible plans and pay the insured rate in full. Some examples:

PROCEDURE	FACILITY | CITY	SELF-PAY RATE	INSURANCE RATE	INSURANCE COMPANY

MRI of the foot	**Regional Medical Imaging** | Flint, Mich.	**$379**	**$445**	Aetna
Tonsillectomy	**Banner Desert Medical Center** | Mesa, Ariz.	**$2,858***	**$5,442**	Arizona Blue Cross Blue Shield
MRI of the knee	**Boulder Community Hospital** | Boulder, Colo.	**$600**	**$1,100**	Arizona Blue Cross Blue Shield

Note: Insurers' rates may vary by plan. *Not including physicians' fees, typically $1,000 to $1,400.

Sources: the providers; insurers' cost-estimator tools

In sum, the abundance of third-party payment creates a system in which consumers generally do not shop on price and providers lack incentives to compete on price and quality to attract and retain patients. Of note, while the third-party payers have knowledge of the reimbursement schedule, price transparency at this level is inefficient for two reasons: (1) Insurers may lack incentives to obtain lower prices especially if profits are capped at a percentage of spending, and (2) Insurance introduces moral hazard and waste.

Despite the current foundational impediments to establishing a consumer-driven market, some examples provide insight into the results that might be achievable if consumers had greater incentives and ability to make informed decisions about their healthcare consumption.

Some government tax policies and payers' benefit design strategies have sought to encourage consumers to become more actively engaged in purchase decisions. As discussed earlier, consumer-directed models, such HDHP linked to HSAs, hold the promise of increasing consumer engagement in their healthcare decisions. So do initiatives that leverage the power of consumer shopping, like reference pricing. As of 2017, more than 20 million people were enrolled in an HSA-qualified plan, although only about 40 percent

of these enrollees contributed to an HSA.[344] One study found that HDHPs produce lower spending, primarily due to less utilization.[345] Combining HDHPs with consumer-driven HSAs could create more effective incentive structures than existing third-party arrangements, incentivizing patients to shop for higher-value care without forgoing necessary treatments. However, patients cannot make fully informed decisions about where to receive care without information about the cost and quality of providers. Unfortunately, consumers often lack meaningful and understandable price information.

Price Transparency in Action: in CalPERS PPO plans

Since 2011, CalPERS has used reference pricing for its PPO enrollees. Services that use reference pricing include joint replacement, arthroscopy, cataract removal, and colonoscopy.

Results:

- 9-14 percentage point increase in the use of low- price facilities.

Payers Can Improve Incentives

Empowering consumers with price information and realigning financial incentives to give consumers a greater stake in their healthcare decisions has been shown to lower prices without affecting quality. One model for increasing consumer engagement is the use of reference-based pricing. Reference pricing places an upper limit on the amount of reimbursement a payer will pay for a medical service. Generally, the reference price is set to a specific percentile of the distribution of provider reimbursements in a market, such as the median reimbursement. If an enrollee receives care from a provider that charges above the reference price, then the enrollee is responsible for the difference.

Reference pricing has been shown to reduce the variation in prices across providers, as providers increasingly compete on price. When the California Public Employees' Retirement System (CalPERS), which provides benefits to over 1.4 million enrollees, started using reference pricing, higher-cost providers soon responded by lowering their prices to attract these enrollees (Robinson 2017).[346] CalPERS distributed lists of hospitals that exceeded a certain quality threshold and had different prices for its enrollees. Consumers increasingly used lower-cost providers with no negative impact on quality.[347]

(See Figure 2.) CalPERS' experience highlights the potential for realigning incentives using reference-based pricing, to lower cost and increase value in the healthcare system.

The Centers of Excellence contracting approach is another method that many payers use to obtain value for employees. Under this approach, an employer or insurer contracts with specific high-value providers for particular services or procedures and offers its health plan enrollees lower cost sharing for using those providers. Often these arrangements rely on bundled payments, in which the payer reimburses the provider a set amount for a pre-defined episode of care.[348] Centers of Excellence contracting is often used in non-emergency situations in which a consumer can travel to obtain care from a nationally recognized physician or hospital. For example, Walmart covers its health plan enrollees at zero-cost sharing if they travel to the Mayo Clinic, Cleveland Clinic, or another select high-quality provider for cardiac, spine, and transplant surgeries.[349] In addition, Walmart covers travel and lodging costs for the patient and a caregiver.

Price Transparency in Action:

Finding Value in Imaging

In 2010, AIM Health started calling patients referred to MRI providers with substantially higher cost ($400+) or poorer quality than other sites. Patients were notified of a higher value site, but were not forced to switch.

Reduced Patient Costs

- Saved patients $220 (18.7%) per scan relative to patients in other cities.

Promoted Site Neutrality

- 30% decline in hospital price premium for MRIs
- Use of hospital-based facilities fell from 53% to 45%, 2010-2012

Current State of Price-Transparency Efforts

Meaningful and timely consumer access to prices can supplement benefit designs to help consumers choose lower-cost, higher-value providers. In a competitive, functioning insurance market, insurers would have an incentive to use such approaches. To be effective, price transparency efforts must distinguish between the charges a provider bills and the rate negotiated between payers and each provider. Some health plans and self- insured employers have developed price transparency tools for their enrollees. CalPERS uses a price transparency platform that allows patients to see providers' prices along with out-of-pocket costs. Over 90 percent of enrollees in Aetna commercial health plans have access to Aetna's Member Payment Estimator which provides personalized out-of-pocket costs for more than 600 medical services—a helpful resource because it uses negotiated plan prices instead of relatively meaningless charges,[350] and takes into account cost-sharing responsibilities such as any remaining deductible amount.

State governments purchase significant volumes of healthcare goods and services through Medicaid, departments of corrections, and public sector employees' pension and health benefit funds.[351] In this capacity, states have an incentive to reduce their healthcare spending. Realigning incentives and promoting price transparency may help states do so. Most states have some laws related to price transparency; however, states may be able to

do more.[352]

At the federal level, the ACA requires hospitals to report annually and make public a list of hospital charges for items and services. Starting in 2013, CMS publicly released average hospital-specific charges per patient and average Medicare payments for common diagnosis-related groups and ambulatory procedures. As part of the FY 2019 Inpatient Prospective Payment System Proposed Rule, CMS updated its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine readable format and to update this information at least annually, or more often as appropriate, which may make it easier for consumers to find charges and for third parties to collect and analyze data when developing value and price transparency tools or reports. This data may show the very high rates that many hospitals charge for certain services and treatments. The agency also sought comment on how to make this information available in a consumer-friendly interface.

Boosting price transparency will likely have limited utility unless the dampening effect of third-party payment on consumer engagement is also addressed. One study classified 43 percent of healthcare spending as shoppable;[353] however, third-party payment reduces the incentive to shop, resulting in low utilization of price transparency tools. Studies have found that only between 1 percent and 20 percent of patients use price transparency tools when they are available.[354] The most promising results for price transparency tools have been for services that rely less on the established physician-patient relationship and are relatively fungible and shoppable, such as imaging and laboratory tests. Price shopping for imaging services is associated with savings of up to 19 percent.[355] In addition, some evidence suggests this shopping is associated with increased price competition among providers offering these services.[356]

Further development of a consumer market for healthcare, anchored around readily available healthcare prices will likely require reforms to the third-party payment system. Research suggests that without strong financial incentives and accessible data on value (like those present in the CalPERS reference pricing example) consumers are often unwilling to change providers, overly rely on current providers for referrals, and conflate high prices with perceived quality regardless of actual outcomes. Many patients also naturally lose interest in the cost of healthcare once they meet their insurance deductible.[357]

Importantly, price information may be less useful to consumers if price comparisons do not group, or bundle, services into common episodes of care. An episode of care can include multiple services and fees, which makes it difficult for consumers to obtain accurate price estimates. Consumers may be unaware, for example, of separate physician and facility fees, resulting in higher than expected prices and surprise medical bills. By developing a standardized set of services, such as those used in bundled payment approaches, price transparency efforts could better help consumers compare providers.

Not surprisingly, many insurers and providers do not wish to publicize price information, which inhibits price transparency efforts. Employers may lack access to healthcare pricing information if providers or insurers are unwilling to release their prices. In some instances,

even self-insured employers lack access to pricing data that their administrator deems proprietary information,[358] even though the employer is paying for much of their employees' healthcare. The Labor Department has finalized a rule that enhances small employers' and sole proprietors' options for banding together to form Association Health Plans under Title I of the Employee Retirement Income Security Act.[359] Small employers and sole proprietors that form these plans may be able to gain the market power necessary to leverage providers into these pricing arrangements.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.
- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by making it easier to pay for their healthcare directly. Actions might include:
    - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
    - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Empowering Patients: Using Choice to Bring a Longer-Term View to Healthcare

Difficulty accessing price and use data is a barrier to choice and competition in healthcare. Without ready access to such data, consumers, even those with properly aligned incentives, struggle to shop for value. While a wealth of data exists in the healthcare sector, patients are often least able to benefit from it. By realigning incentives and better leveraging health data, providers, payers and researchers can help consumers choose more effective treatment options, cut down on wasteful spending, and reduce the growth in their own spending on unnecessary services or treatments.

Claims data captures information on diagnoses, procedures and therapies administered, and retail and outpatient drug dispensing, as well as site of care (provider office, hospital, etc.). When available to payers, researchers and others, such data can fuel insightful comparisons of long-term patient outcomes using different treatment options.[360] While any one data set

(claims, clinical, etc.) may not contain all facets of a patient's experience, each can add value. For example, claims data have been increasingly recognized as central to studying long-term patient outcomes and some payers already use it to monitor the effectiveness of patient management.[361] Claims data can also be used to compare population-level outcomes between different payment models and delivery systems, allowing the healthcare system to optimize patient care.[362] The healthcare system has generated claims data over decades, providing a low-cost means to shed light on long-term cost, use and outcomes, across therapeutic options.[363] Today's more advanced technology can now connect claims data across time and location in a secure manner.[364]

To better inform their healthcare decisions and allow patients and providers alike to take a holistic view of patient health, longitudinal studies will be important. These studies are more challenging if patients move across multiple payers over time, and making best use of such data would likely require cooperation among payers and providers. Of course, this data can and should be readily accessible for enrollees in Medicare and Medicaid.

Twenty-five states, in an attempt to support price transparency efforts and make information more accessible for consumers, employers, researchers and others, have established All-Payer Claims Databases (APCDs). Research on this data may generate useful findings, up-to-date price transparency tools, or other patient engagement applications, as well as allow self-insured employers to manage their own costs better. These efforts have had mixed results to date.

The eventual hope is that this data will allow payers, employers and researchers to better identify variations in pricing and quality across providers and payers. This in turn would help employers and others develop reference-pricing or center-of-excellence payment arrangements. In addition, states, academics and third parties could use these databases to develop price transparency tools, as well as research patient outcomes across providers, services and therapies. These tools may help patients find providers that offer services they value – supplementing often-outdated provider directories. They may also fill in gaps for consumers who lack access to a price transparency tool through their provider, and give employers a tool to compare prices of services across insurers.[365] Leveraging claims data may also help reduce the overuse of unnecessary or wasteful care, likely saving money for consumers, employers and taxpayers.[366]

Once claims data are accessible in a secure manner, any value-added analyses, presentations or tools built from it could be commercialized. This would leverage market forces to boost availability of insights about population health. Consumers could also access user-friendly information comparing price or value at potential sites of care.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The

administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.

- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

Healthcare Information Technology and Non-Competitive Healthcare Markets

Modern Computing and Non-Healthcare Markets

In the last two decades, we have seen transformations of many major markets, including airlines, autos, banking, brokerage, entertainment, lodging, music, printing, publishing, shipping, taxi and telephone industries driven, in part, through the availability of massive volumes of real-time price and service data. Information technology offers intriguing possibilities to transform healthcare markets as well by injecting information and competition into many points in the healthcare industry. With most American adults carrying smartphones, both the hardware and software required to assemble new combinations of real-time medical information—including data on care, nature of services, and provider prices—is widely available.

Current State of Healthcare Information Technology

Historically, healthcare IT systems have focused on revenue optimization, typically through support for large amounts of billing documentation required to maximize fee for service revenues from federal and private payers. In contrast to sectors of the economy with competitive markets where there is great focus on automation, hospitals and providers employ almost no automation. It is worthwhile to examine which non-market incentives and disincentives have driven the apparent disinterest in automation. Similarly, consumers also have very limited software tools to understand, shop for, purchase or participate in their healthcare. The limited consumer access to healthcare information has been largely limited to federally mandated portals.

A common theme throughout healthcare is the limited state of interoperability. Patients have very limited ability to obtain or move their records. Providers similarly have significant barriers to get healthcare information from other providers, including systems that cannot communicate with each other. Payers have effectively no access to electronic clinical data about their patients.

Currently, health information technology (health IT) too often facilitates anti-competitive practices. These practices include blocking clinical information exchange between

providers, as well as selectively providing minimal support for regional information sharing. Another practice common to the highest-priced delivery systems is using a single health IT vendor that systematically and preferentially shares clinical data with other high-priced providers to the exclusion of competitors.[367] At least one health IT vendor has also engaged in policies where it effectively forced smaller hospitals to buy their software installs from larger local competitors[368].

Importance of Interoperability

The ability to move the patient's clinical information from incumbent providers to competing providers is a key goal of interoperability and can promote competition and the growth of new and disruptive business models. Today this is the capability typically labeled as "interoperability." A broader model of interoperability that includes a network of patients and payers would also allow them to identify providers with best outcomes for specific procedures and treatments. It would also allow prescribers to see cost information about drugs prior to prescribing. Such interoperability would accelerate the development of consumer-facing apps that integrate medical healthcare, cost, and wellness data to help consumers make decisions about their care. Increasing interoperability may also empower consumers by lowering the switching costs that patients experience when moving from one provider to another. In its absence, providers can use the switching costs and barriers to entry associated with incompatible health information systems to impede patient mobility and competition between providers.

Barriers to Interoperability

Medical Complexity

The vast biologic complexity underlying human health is an intrinsic barrier to interoperability. This complexity means that a given diagnosis, treatment or procedure in medical records can be recorded in many different ways. Sharing the underlying biological, microbial, genetic and protein data is even harder.

Lack of Business Drivers

Most of United States healthcare employs a fee-for-service model, where clinicians and health systems bill patients or their payers for each service (test or procedure) used rather than for the value of that service. Under this model, a hospital can generate more revenue by ordering its own imaging or lab tests rather than using results previously gathered by another provider. The fee-for-service model provides little incentive to connect with other clinicians or service providers and leads to significant disconnects across the care continuum, including among long-term and post-acute care facilities, outpatient services and support providers, behavioral health providers, free-standing imaging centers, and emergency medical services.

Not surprising, health IT installations interoperate more readily with other sites under the same ownership. Across the country, large health systems are acquiring small hospitals and

provider practices, and limiting communications outside of their own network. This network effect can raise barriers to entry and provider competition. These acquisitions are designed to allow the systems to dictate prices to insurers and to craft narrow referral networks that also result in higher prices and difficult or disproportionately costly access for out-of-network services. In cases where there are less-expensive local competitors, health systems have reportedly blocked use of those services by refusing to allow electronic orders for those services, such as imaging tests, to be sent outside of their system.

Lack of Accessible Application Programming Interfaces

The consumer app economy has blossomed in recent years, due in great part to data holders publishing application programming interfaces (APIs) that open their databases to third-party software developers. For example, ride-sharing apps rely on many different APIs to offer their service (i.e., mapping APIs for location, banking APIs for payments). In contrast, most medical data captured in electronic health records (EHRs) today is not readily accessible through APIs. Typically, EHR developers have either not published their APIs, charged prohibitively high fees, or set onerous contractual conditions to use their APIs. Lack of API access discourages new market entrants and new business models. Even if API access were opened, however, different classification ontologies would limit their utility. Accordingly, this would need to be addressed as well.

Lack of Network Exchange

Most systems do not or cannot communicate with one another. There are currently more than 100 regional and state health-information networks. Additionally, some EHR developers have their own networks for their customers. Limited interoperability often affects patients who may be traveling and cannot retrieve their records from home. Typically, today's health information networks prohibit flow of information to non-providers who may also have important HIPAA-compliant[369] interests in that data, specifically insurers paying for those services.[370]

Therefore, it is often impracticable to query for information across networks for even one patient. Importantly there are also no standards-based APIs to allow payers to query provider EMR databases to get information about more than one of their patients at a time. Thus, payers have almost no computational way to get clinical data and have to rely on inference from claims data. Payers have a difficult time measuring and paying for care based on provider clinical performance and must rely on narrow quality measures or one-off data extracts to contract intelligently.

Overcoming Interoperability Barriers and the 21st Century Cures Act

Congress passed the 21st Century Cures Act in December 2016. Provisions in the act calling for usability and interoperability reflect the broad national consensus that the 2009 HITECH Act's $30 billion- plus EHR stimulus program did not materially address either usability or interoperability despite leading to widespread EHR purchases.

The 21st Century Cures Act provides powerful tools to increase the interoperability of health data and, by extension, market competition. Three pro-competitive provisions are worth noting specifically. First, the Cures Act defines information blocking broadly and outlaws it. In doing so, the Cures Act bans the practice of providers blocking access to an individual's health data. This will ease patients' ability to seek alternative providers or types of care. The legislation charged HHS with crafting a narrow set of exceptions to adequately address any concerns about privacy, security and appropriate patient care that might arise by enacting this provision.

A second major health IT provision of the Cures Act is the mandate to create a "Trusted Exchange Framework" and a "Common Agreement" to get the various health information networks to share data. ONC supervision here is needed to expand the "permitted purposes" of data sharing to facilitate data flow and more competitive markets.

The third key provision is the requirement that developers of certified electronic health records publish application programming interfaces and allow "health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces." This "open API" requirement is designed to foster plug-and-play capability with apps. The "without special effort" provision means the API must use modern industry software design and healthcare interoperability standards. Importantly, the availability of an open API should allow for population-level queries of batch data. Today there is no reasonable data standard for an insurer to get easily computable data across the population of patients a provider sees. Moreover, American healthcare providers have almost no computational accountability for the care they provide. The national discussions about "learning health systems," "big data," and machine learning are meaningless without computational access to clinical data sets. That is why many large American payers are working in conjunction with ONC and the Health Level Seven International (HL7) FHIR standards group to build out these computational accountability standards.

CMS proposed requirements that promote interoperability of health data in their 2019 payment rules and is overhauling the EHR Incentive Program (formerly known as "Meaningful Use") to an interoperability-focused program now renamed "Promoting Interoperability." In the 2019 IPPS (Inpatient Prospective Payment System) rule, CMS has incentivized a number of interoperability measures including closing the referral loop through health information exchange and providing patients electronic access to view, download and transmit their data. The IPPS and other CMS payment rules in the public comment period also provide incentives to use the electronic health records certified to the 2015 standards (which support APIs). CMS' Blue Button 2.0 initiative allows Medicare beneficiaries complete access to their Medicare claims data and will significantly improve beneficiary experience by providing this data in a universal and secure digital format that patients can share with the care provider of their choosing. Giving patients complete access to their claims data will break down barriers to interoperability by allowing patients to see a full picture of their care encounters and prescriptions on the device of their choosing as they share it with their care team. CMS is also calling on all health insurers to release their claims data in a similar fashion to the Blue Button 2.0 initiative so that all patients have the same benefits as Medicare beneficiaries.

To promote data sharing and care coordination further, CMS is ensuring that patients have access to their healthcare data after a hospital discharge, and that their data are transferred with them to their next care setting. ONC and CMS are working on identifying the key provider burdens generated by using current electronic medical records and working on strategies to address these burdens.

Recommendations: Improve Health IT

- The administration should expeditiously implement provisions of 21st Century Cures Act to prevent information blocking, make it easier for patients anywhere to get their core health information, support "Open Application Programming Interfaces" to allow patients to get data on their smart phones, and encourage support of population-level data queries to allow payers electronic access to clinical data.
- CMS and ONC should continue work on documentation burden reduction to allow EHRs to provide informative medical records rather than boilerplate text for providers and patients.
- CMS should continue its emphasis on fostering interoperability across the healthcare sector.
- CMS should continue its efforts to make data available to patients through efforts such as "MyHealthEData" and Blue Button 2.0.
- ONC should continue making standards more comprehensive and robust.

SUMMARY OF RECOMMENDATIONS TO RESTORE CHOICE AND COMPETITION TO THE HEALTHCARE SECTOR

Recommendations: Address Potential Antitrust and Provider Consolidation

- The administration should continue monitoring market competition, especially in areas that may be less competitive and thus more likely to be affected by alternative payment models.
- The administration should ascertain the impact of horizontal and vertical integration among provider practices on competition and prices.

Recommendations: Broaden Scope of Practice

- States should consider changes to their scope-of-practice statutes to allow all healthcare providers to practice to the top of their license, utilizing their full skill set.
- The federal government and states should consider accompanying legislative and administrative proposals to allow non-physician and non-dentist providers to be paid directly for their services where evidence supports that the provider can safely and effectively provide that care.
- States should consider eliminating requirements for rigid collaborative practice and supervision agreements between physicians and dentists and their care extenders (e.g., physician assistants, hygienists) that are not justified by legitimate health and safety concerns.
- States should evaluate emerging healthcare occupations, such as dental therapy, and consider ways in which their licensure and scope of practice can increase access and drive down consumer costs while still ensuring safe, effective care.

Recommendations: Improve Workforce Mobility

- States should consider adopting interstate compacts and model laws that improve license portability, either by granting practitioners licensed in one state a privilege to practice elsewhere, or by expediting the process for obtaining licensure in multiple states.
- The federal government should consider legislative and administrative proposals to encourage the formation of interstate compacts or model laws that would allow practitioners to more easily move across state lines, thereby encouraging greater mobility of healthcare service providers.

Recommendations: Facilitate Telehealth to Improve Patient Access

- States should consider adopting licensure compacts or model laws that improve license portability by allowing healthcare providers to more easily practice in multiple states, thereby creating additional opportunities for telehealth practice. Interstate licensure compacts and model laws should foster the harmonization of state licensure standards and approaches to telehealth.
- States and the federal government should explore legislative and administrative proposals modifying reimbursement policies that prohibit or impede alternatives to in-person services, including covering telehealth services when they are an appropriate form of care delivery. In particular, Congress should consider proposals modifying geographic location and originating site requirements in Medicare fee-for-service that restrict the availability of telehealth services to Medicare beneficiaries in their homes and in most geographic areas.
- States generally should consider allowing individual healthcare providers and payers to mutually determine whether and when it is safe and appropriate to provide telehealth services, including when there has not been a prior in-person visit.
- Congress and other policymakers should increase opportunities for license portability through policies that maintain accountability and disciplinary mechanisms, including permitting licensed professionals to provide telehealth service to out-of-state patients.

Recommendations: Ease Restrictions on Foreign-Trained Doctors

- The Department of Health and Human Services, in coordination with the Accreditation Council for Graduate Medical Education (GME), should identify foreign medical residency programs comparable in quality and rigor to American programs. Graduates of such equivalent programs should be granted "residency waivers," allowing them to forgo completing an American residency and instead apply directly for state licensure.
- States should create an expedited pathway for highly qualified, foreign-trained doctors seeking licensure who have completed a residency program equivalent to an American GME program.

Recommendations: Streamline Federal Funding of Medical Education

- As proposed in the FY 2019 President's Budget, the federal government should streamline federal Health and Human Services spending on graduate medical education into a single graduate medical education grant program. The budget proposal also provides the Secretary with the authority to modify amounts distributed to hospitals based on the proportion of residents training in priority specialties or programs and based on other criteria identified by the Secretary,

including addressing healthcare professional shortages and educational priorities.

- The administration should continue the work done by the HRSA's National Center for Health Workforce Analysis, which studies U. S. physician supply needs across specialties and geographic areas. HRSA should launch a study that will also assess:
    - The administration's workforce development programs.
    - Gaps between existing programs and future workforce needs and identifying actions needed to address them.

Recommendations: Repeal or Scale Back CON and COPA Requirements

- States should consider repeal of Certificate of Need (CON) statutes or, at a minimum, significantly scale back the scope of their CON regimes, for example by ensuring that competitors of CON applicants cannot weigh in on these applications.
- The FTC and its staff should make appropriate policy recommendations after completing ongoing research on the benefits and disadvantages of CON and COPA statutes and regimes.
- States should discontinue the use of COPAs to shield anti-competitive provider collaborations and mergers from antitrust scrutiny in the absence of any clear evidence that these regulatory schemes produce better results than market-based competition.

Recommendations: Amend Federal Trade Commission (FTC) Jurisdiction Over Nonprofits

- Congress should amend the Federal Trade Commission Act to extend FTC's jurisdiction to nonprofit healthcare entities to prevent unfair methods of competition.

Recommendations: Scrutinize Non-Compete Clauses and Other Restrictive Covenants

- States should scrutinize restrictive covenants such as non-compete clauses, particularly their impact on patient access to care and on the supply of providers.

Recommendations: Scrutinize Any-Willing-Provider (AWP) Laws

- Federal and state policymakers should carefully scrutinize the impact on

competition and consumers of AWP laws, rules, and proposals, along with other restraints on network formation and selective contracting.

Recommendations: Loosen Network Adequacy Requirements

- The administration should continue to provide flexible network adequacy standards for Medicare Advantage and other federally sponsored programs and avoid stringent requirements that are not conducive to innovation and modern medicine and that do not allow states flexibility to meet their specific needs.
- Similarly, states should consider loosening network adequacy standards and avoid stringent requirements.

Recommendations: Loosen Insurance Rules and Mandates

- The administration should continue to work with Congress to enact legislation that remedies key problems resulting from the ACA, that promotes greater choice and competition in healthcare markets, and that produces a sustainable government healthcare financing structure.
- Similarly, the administration should provide states with the maximum ability to expand healthcare choice and competition and create a sustainable financing structure.
- States should allow maximum consumer choice and competition in their healthcare markets, including through Association Health Plans and short-term limited-duration insurance.
- Congress should repeal the ACA's employer mandate consistent with the FY 2019 President's Budget.

Recommendations: Replace Restrictions on Physician-Owned Hospitals

- Congress should consider repealing the ACA changes to physician self-referral law that limited physician-owned hospitals.

Recommendations: Reconsider Section 1557 of the ACA

- The administration should reconsider regulations authored under Section 1557 of the ACA to ensure they do not create undue administrative burdens and serve as unnecessary barriers to entry that inhibit competition.

Recommendations: Realign Incentives

- Congress should expand consumers' abilities to benefit from Health Savings Accounts (HSAs), including by allowing a greater number of plans (e.g. any plan with an actuarial value below 70 percent) to be HSA-qualified plans, raising the contribution limit on HSAs, allowing people to use their HSA to pay HSA-qualified non-group premiums, allowing Medicare beneficiaries in enrolled high-deductible health plans to contribute to an HSA, and enabling consumers with HSAs to enter into provider-consumer fixed-fee arrangements, including direct primary-care arrangements.
- The administration should explore ways to administratively expand consumers' abilities to benefit from HSAs, including by interpreting preventive services to allow HSA-qualified plans greater ability to cover preventive low-cost treatments for chronic conditions.
- Consistent with Executive Order 13813, the administration should work through the regulatory process to increase the usability of HRAs, to expand employers' ability to offer HRAs to their employees, and to allow HRAs to be used in conjunction with non-group coverage.

Recommendations: Delivery System Reform

- The administration should focus on identifying alternative payment models that allow free markets and patients to define value, rather than rely on technical and burdensome definitions invented in Washington.

- The administration should evaluate the best metrics for measuring value and quality in the healthcare sector, eliminating unnecessary and potentially counterproductive measures and reducing the burden on providers.
- The administration should ensure that smaller physician and provider practices are not unduly harmed by delivery system reform and corresponding requirements.
- The administration should ensure that these delivery system reform models, which aim to hold providers accountable to a set of population-based metrics and total spending, foster collaboration across systems within a geographic area and do not produce harmful consolidation, particularly horizontal consolidation.
- The Administration should pursue policies and programs that encourage value, competition, and choice, such as Medicare Advantage, and move away from a fee-for-service model.

Recommendations: Positively Realigning Incentives through Payment Reform

- Congress should establish site neutral payment policies based on the anticipated clinical needs and risk factors of the patient, rather than the site of service. In

delivering these reforms, Congress should account for differing levels of patient acuity.

- State Medicaid programs should embrace site neutrality as a goal and reform their payment systems to pay for the value delivered where value is defined according to a relatively limited, straightforward, and non-gameable set of metrics. Additionally, metrics should not be designed and proposed solely by the entities to which they will ultimately apply.

Recommendations: Quality Improvement and the Measurement and Reporting of Quality

- As proposed by the Centers for Medicare and Medicaid Services' Patients over Paperwork initiative, the administration should streamline and standardize quality measures across programs to avoid duplicative reporting requirements and limit the number of measures where the expected cost of collecting the measure exceeds the expected benefit. In addition, the administration should collaborate with state Medicaid programs, private payers, and other government payers to align and streamline quality measures and reporting structures to reduce physician burden.
- The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value.
- The administration should focus on providing a framework for quality reporting in plain language that is more accessible and appealing to consumers.
- The administration should consider providing incentives and technical assistance to support the development of virtual provider groups (e.g., independent practice associations, alternative payment models, or regional quality collaboratives) that can increase the competitiveness of small practices through access to shared resources and help build capacity for care management.
- HHS should explore opportunities to initiate research into machine learning techniques that can directly access data on CMS beneficiaries from the provider Electronic Medical Records (EMRs) using open application program interfaces in order to enable quality analysis and payments based on value while reducing burden and cost and benefitting the public.

Recommendations: Facilitate Price Transparency

- It should be a priority of this administration to ensure that patients are engaged with their healthcare decisions, and have the information they need to be savvy consumers of healthcare. Federal agencies should eliminate any federal rules or policies that create unnecessary barriers to state, federal or private sector initiatives that provide price transparency.
- The administration should consider legislative proposals to empower patients as they shop for healthcare by making it easier to pay directly.
- Congress should seek to empower patients as they shop around for healthcare by

making it easier to pay for their healthcare directly. Actions might include:
    - Allowing all Americans, including Medicare beneficiaries, to maintain and contribute to a Health Savings Account, not only those enrolled in high deductible health plans.
    - Increasing flexibility for beneficiaries and providers in the Medicare program by allowing for direct negotiations between these parties so that beneficiaries can access services at a price or under a payment plan that works for them.
- Congress, federal agencies and states should incentivize providers to compete on price, including right to shop modeled on successful state efforts as well as understandable reference pricing models.

Recommendations: Using Choice to Bring a Longer-Term View to Healthcare

- The administration should continue to publicly release and increase access to claims data from taxpayer-funded federal healthcare programs and encourage the private sector and states to build consumer-friendly websites capable of displaying price information for the most common transactions. The administration should work to ensure that such data are technically and financially accessible for third-party transparency advocates, vendors, developers, researchers, employers, state and local governments, and the general public.
- States should coordinate their efforts on maximizing the utility of claims data (consistent with all relevant federal and state privacy protections), including simplifying the process for reporting data and using a standard reporting format.

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that-squelch-competition-1537281963. Accessed September 20, 2018.

46 Haas-Wilson D. *Managed Care and Monopoly Power: The Antitrust Challenge*. Cambridge: Harvard University Press; 2003; Dranove D, Lindrooth R. Hospital consolidation and costs: another look at the evidence. *J Health Econ*. 2003 Nov;22(6)983-997; Cuellar AW, Gertler PJ. Trends in hospital consolidation: the formation of local systems, *Health Aff*. 2003 Nov/Dec;22(6):77-87; Vogt WB, Town R. How has hospital consolidation affected the price and quality of hospital care? *Synth Proj Res Synth Rep.* 2006 Feb;(9):pii. https://www.ncbi.nlm.nih.gov/pubmed/22051574. Accessed August 21, 2018.

47 Chart 2.9: announced hospital mergers and acquisitions, 1998-2015. American Hospital

Association. Trendwatch Chartbook 2016 Organizational Trends. 2016.

https://www.aha.org/system/files/research/reports/tw/chartbook/2016/chart2-9.pdf. Accessed August 21, 2018.

48 15 U.S.C. § 18. Section 7 of the Clayton Act prohibits mergers if "in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."

49 See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town RJ. Competition in healthcare markets. In *Handbook of Health Economics.* Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 J *Econ Lit*. 2015;53(2):235, 294, (2015). https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

50 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 1. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018, Studies cited include Haas-Wilson D, Garmon C. *Hospital mergers and competitive effects: two retrospective analyses*. *Int J Econ Bus*. 2011:17, 30 (post-merger review of Agency methods applied to two hospital mergers; data "strongly suggests" that large price increases in challenged merger be attributed to increased market power and bargaining leverage); Dafny

L. Estimation and identification of merger effects: an application to hospital mergers. *J Law Econ*. 2009;52(3):523, 544 ("[H]ospitals increase price by roughly 40 percent following the merger of nearby rivals"); Capps C, Dranove D, Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 ("Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices."); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti- competitive price increases).

51 Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):382 (corroborating Michael G. Vita MG, Sacher S. The competitive effects of not-for-profit hospital mergers: a case study. *J Indus Econ*. 2001;49:63).

52 *Id*.

53 See, e.g., Ginsburg PB. Wide variation in hospital and physician payment rates evidence of provider market Power. Center for Studying Health System Change, Research Brief No. 16. November 2010. http://www.hschange.org/CONTENT/1162/. Accessed August 21, 2018.

54 Gaynor M. Competition policy in healthcare markets: navigating the enforcement and policy maze. *Health Aff*. 2014 Jun;33:1088.

55 Tenn S. The price effects of hospital mergers: a case study of the Sutter-Summit Transaction. *Int J Econ Bus*. 2011;18:65-82.

56 See, e.g., *In the Matter of Hospital Corp. of Am.*, 106 FTC 361 (1985), aff'd, 807 F.2d 1381 (7th Cir. 1986);

American Med. Int'l, Inc., 104 FTC 1 (1984), as modified by 104 FTC 617 (1984) and 107 FTC 310 (1986).

57 *Columbia/HCA Health* Care *Corp./Healthtrust, Inc.—The Hosp. Co.*, 120 FTC 743 (1995) (consent order); *Healthtrust, Inc.—The Hosp. Co./Holy Cross Health Servs. of Utah*, 118 FTC. 959 (1994) (consent order); *Columbia Health* Corp./HCA-Hosp. Corp. of Am., 118 FTC 8 (1994) (consent order).

58 *FTC v. Tenet Health Care Corp*., 186 F.3d 1045 (8th Cir. 1999); *FTC v. Freeman Hosp*., 911 F. Supp. 1213 (W.D.

Mo. June 9, 1995), aff'd, 69 F.3d 260 (8th Cir. 1995); *California v. Sutter Health Sys*., 84 F. Supp.2d 1057 (N.D. Cal.

2000), aff'd, 217 F.3d 846 (9th Cir. 2000), amended by 130 F. Supp. 2d 1109 (N.D. Cal. 2001); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, (E.D.N.Y. 1997); *FTC v. Butterworth Health Corp*., 946 F. Supp. 1285 (W.D. Mich. 2006), aff'd *per curiam*, 121 F.3d 708 (6th Cir. 1997); *United States v. Mercy Health Servs. & Finley Tri- States Health Group, Inc.*, 902 F. Supp. 968 (N.D. Iowa 1995), vacated as moot, 107 F.3d 632 (8th Cir. 1997).

59 See Romano PS, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health . *Int J Econ Bus*. 2011;18:45; Haas-Wilson D, Garmon C. Two hospital mergers on Chicago's North Shore: a retrospective study. *Int J Econ Bus*. 2011;18:17; Thompson A. Effect of hospital mergers on inpatient prices: a case study of the New Hanover-Cape Fear transaction. *Int J Econ Bus*. 2011;18:91; Tenn

S. The price effects of hospital mergers: a case study of the Sutter-Summit transaction. *Int J Econ Bus*. 2011;18 :65. For an overview, see Ashenfelter O, Hosken D, Vita M, Weinberg M. Retrospective analysis of hospital mergers. *Int J Econ Bus*. 2011;18:5-16; Farrell J, Pautler PA, Vita MG. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Rev Indus Org*. 2009;35:375-383.

60 *In the Matter of Evanston Northwestern Health Corp*., FTC Dkt. No. 9315 (Opinion of the Commission, Aug. 6, 2007).

61 The agencies analyze hospital mergers using the same analytical framework they use for other mergers, following the 2010 Horizontal Merger Guidelines, which specify that "mergers should not be permitted to create, enhance, or entrench market power or to facilitate its exercise." U.S. Department of Justice and Federal Trade Commission.

Horizontal Merger Guidelines. § 1. August 19, 2010. http://www.ftc.gov/os/2010/08/100819hmg.pdf. Accessed August 21, 2018.

62 P*roMedica Health System, Inc. v. FTC*, No. 12-3583 (6th Cir. Apr. 22, 2014).

63 *FTC v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *FTC v. Penn State Hershey Med. Center*, 838 F.3d 327 (3rd Cir. 2016).

64 *FTC and State of Ohio v. St. Luke's Health Sys., Ltd.*, Case No. 1:13-CV-00116-BLW (D. Idaho Jan. 24, 2014).

65 *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015). See also *FTC et al. v. Sanford Health,* No. 1-17-cv-133 (memorandum decision Dec. 15, 2017).

66 *Statement of the Commission, Phoebe Putney Health System, Inc.*, Dkt. No. 9348 (Mar. 31, 2015), https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 22, 2018.

67 As noted earlier, commonly used measures of concentration in the literature may be misleading and not as meaningful regarding the level of competition, compared to measures that take into account specific market attributes such as the set of competing suppliers in a particular local area or underlying market forces that may or may not be related to the competitiveness of a market.

68 U.S. Department of Justice and Federal Trade Commission. *Horizontal Merger Guidelines*. Section 1. August 19, 2010. http://www.ftc.gov/os/2010/08/100819hmg.pdf. Accessed August 21, 2018.

69 For example, consider 10 properly defined identical geographic markets, each served by a distinct monopolist hospital. Within the actual geographic markets, the HHIs would be 10,000. If all 10 of those hospitals were to merge into a hospital system, the post-merger HHI in each properly defined market would still be 10,000, so there would be no change. However, if the market was defined too broadly to include all of these true geographic markets, the pre- merger HHI would reflect 10 hospitals each having a 10 percent market share, or 10×102=1,000, and the post-merger HHI would be 10,000. Defining the market too broadly suggests that this merger increased concentration significantly even though it did not change the competitive landscape in any properly defined geographic market. Alternatively, suppose each of these identical geographic markets was served by two identical hospitals each, all of which are initially independent. The HHI in each geographic

market would be 502+502=5,000. Suppose a hospital system forms by combining the two hospitals in one of these geographic markets. The HHI in that geographic market would now be 10,000. Now, suppose that the market was again defined overly broadly to include all 20 hospitals in 10 geographic markets. The pre-merger HHI would reflect 20 hospitals, each with a 5 percent share, or 20× 52=500, and the post- merger HHI would be 18×52+102=550. The very significant increase in concentration in the one geographic market impacted by the merger is muted by absence of change in the nine other geographic markets.

70 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

71 See Gaynor M, Ho K, Town RJ. The industrial organization of healthcare markets. *J Econ Lit* 2015;53(2):235-284. 72 In this and similar analyses, all hospitals in the same system are treated as part of the same "firm" for purposes of evaluating market concentration indices.

73 Gaynor, et al. used a population weighted average mean in computing their mean HHI. They also dropped any MSA for which the population exceeded 3 million. They did so because in it is likely that there were multiple relevant hospital markets in these MSAs. Hence, the MSA-level HHI is more likely to be uninformative in these MSAs. See Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284.

74 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

75 See Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff*. 2017;36(9):1530-1538.

76 Methodological differences between the two studies largely explain this difference in the mean HHI. Specifically, Fulton applied an unweighted mean HHI across MSAs, whereas, as noted above, Gaynor, et al. applied a population- weighted mean. Since lower-population MSAs are generally more concentrated than higher-population MSAs, weighting the mean HHI by MSA population will likely result in a significantly lower mean HHI. This methodological difference likely explains most the jump in the mean HHI in 2006 found by Gaynor, et al. and the mean HHI in 2010 found by Fulton. Gaynor M, Ho K, Town RJ. The industrial organization of health-care markets. *J Econ Lit* 2015;53(2):235-284 and Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health Aff*. 2017;36(9):1530-1538.

77 Among specialist physicians, Fulton included cardiologists, hematologists/oncologists, radiologists, and orthopedists. To calculate the specialist-physician HHI at the MSA level, he calculated the HHI for each of the aforementioned specialties, and then calculated a weighted average of the HHI across specialties at the MSA level. Fulton, BD. Health care market concentration trends in the United States: evidence and policy responses. *Health*

Aff. 2017;36(9):1530- 1538.

78 Mathews, Anna Wilde. Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition. September 18, 2018. https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deals-that- squelch-competition-1537281963

79 See Kleiner S, Lyons S, White WD. Provider concentration in markets for physician services for patients with traditional Medicare. *Health Management, Policy and Innovation* 2012;1(1):3–18.

80 See Baker L, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending." *Health Aff*. 2014;33(5):756-763.

81 See Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. Working Paper. 2017. Available at http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html.

82 MedPAC. Report to Congress: Medicare and the health care delivery system. Policy Brief. June 2013. http://www.ipr.northwestern.edu/publications/papers/2015/ipr-wp-15-02.html. Accessed August 22, 2018.

83 Kocher R, Sahni NR. Hospitals' race to employ physicians—the logic behind a money-losing proposition. *N Engl J Med*. 2011;364(19):1790-1793.

84 See, for example, the FTC's 2013 enforcement action challenging the acquisition of Saltzer Medical Group by St. Luke's Health System. While some people characterized the transaction as a vertical one, the FTC alleged, and the court found, that the combination of the hospital's employed physicians and Saltzer's 16 primary care physicians would lead to higher reimbursement rates for adult primary care services in Nampa, Idaho. *St. Alphonsus Med. Center-Nampa Inc. v. St. Luke's Health Sys., Ltd.*, 778 F.3d 775 (9th Cir. 2015).

85 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 31-32. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

86 Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM. Occupational licensing. *J Econ. Persp* 2000;14:189,191.

87 See *Joint Hearing on Health Care and Competition Law and Policy Before the FTC and Department of Justice*, 33- 34 (Jun. 10, 2003), (statement of Dr. Morris Kleiner). http://www.ftc.gov/sites/default/files/documents/public_events/health-care-competition-law-policy- hearings/030610ftctrans.pdf. Accessed August 22, 2018.

88 Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix*. 2014;24:143,163; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 7 n.6, 31-34.

https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

89 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation 4-16. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018. 90 See, e.g., *Prepared Statement of the Federal Trade Commission on Competition and Occupational Licensure, Before the H. Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial, and Antitrust Law,* 115th Cong., 7-8 (Sept. 12, 2017).

https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_ 2017_vote.pdf. Accessed August 22, 2018; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

90 See, e.g., *Prepared Statement of the Federal Trade Commission on Competition and Occupational Licensure, Before the H. Comm. on the Judiciary, Subcomm. on Regulatory Reform, Commercial, and Antitrust Law,* 115th Cong., 7-8 (Sept. 12, 2017).

https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_ 2017_vote.pdf. Accessed August 22, 2018; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

91 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-13; Cox C, Foster S. Bureau of Economics, Federal Trade Commission. The Costs and Benefits of Occupational Regulation, at 3. 1990. http://www.ramblemuse.com/articles/cox_foster.pdf. Accessed August 22, 2018. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014, at 14-15. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018.

92 *Id. Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses, supra note 86, at 14.*; *Prepared Statement of the Federal Trade Commission on Competition and the Potential Costs and Benefits of Professional Licensure, Before the H. Comm. on Small Business*, 113th Cong. (July 16, 2014), https://www.ftc.gov/system/files/documents/public_statements/568171/140716professionallicensurehouse.pdf. Accessed August 22, 2018. Correspondingly, the adoption of regulations that recognize new provider categories can sometimes lower the average regulatory burden placed on certain healthcare services, to the extent that these newly licensed workers may compete with professionals in established licensure categories.

93 Stigler GJ. The theory of economic regulation. *Bell J Econ Man Sci.* 1971 Spring;2(1):18-20; Kleiner MM.

Occupational licensing. *J Econ. Persp*. 2000;14:13-14. By restricting the entry of competitors, licensure can restrict supply, which can increase the income of incumbents (at consumer expense) or decrease the pressure on incumbents to improve non-price aspects of their services, such as quality or convenience. See also Kleiner MM, Krueger AB. Analyzing the extent and influence of occupational licensing on the labor market. 31 *J Lab Econ*. 2013 Apr;31 S1, Part 2:73,75.

94 Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 30. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018; Gilman DJ, Fairman J. Antitrust and the future of nursing: federal competition policy and the scope of practice. *Health Matrix*. 2014;24:157.

95 *License to Compete: Occupational Licensing and the State Action Doctrine, Hearing Before the S. Comm. on the Judiciary, Subcomm. on Antitrust, Competition Pol'y and Consumer Rights*, 114th Cong., 1 (Feb. 2, 2016); *cf. N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015).

96 See, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:98-103,157- 161, annex 3-1; Eibner CE, Hussey PS, Ridgely MS, McGlynn EA. Controlling healthcare spending in Massachusetts: an analysis of options. RAND Health Report Submitted to the Commonwealth of Massachusetts. August 2009. http://www.rand.org/content/dam/rand/pubs/technical_reports/2009/RAND_TR733.pdf. Accessed August 22, 2018; National Governors Association (NGA). The role of nurse practitioners in meeting increasing demand for primary care. 2012:7-8 (study funded by U.S. Department of Health and Human Services, reviewing literature pertinent to nurse-practitioner (NP) safety and concluding: "None of the studies in the NGA's literature review raise concerns about the quality of care offered by NPs. Most studies showed that NP-provided care is comparable to physician-provided care on several process and outcome measures.")

97 U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse- Midwives: A Policy Analysis*. Health Technology Case Study 37. OTA-HCS-37. Washington, DC: U.S. Government Printing Office; December 1982:39. https://www.princeton.edu/~ota/disk2/1986/8615/8615.PDF. Accessed August 22, 2018. ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].")

98 Jorgenson D, Dalton D, Farrell B, Tsuyuki RT, Dolovish L. Guidelines for pharmacists integrating into primary care teams. *Can Pharm. J.* 2013 Nov;146(6):342-352; Durham MJ, Goad JA, Neinstein LS, Lou M. A comparison of pharmacist travel-health specialists' versus primary care providers' recommendations for travel-related medications, vaccinations, and patient compliance in a college health setting. *J Travel Med*. 2011 Jan-

Feb;18(1):20-25; Hecox N. Tuberculin skin testing by pharmacists in a grocery store setting. *J Am Pharm Assoc*. 2008 Jan-Feb;48(1):86-91.

99 FTC, Bureau of Consumer Protection. *Staff Report on Advertising of Ophthalmic Goods and Servs and Proposed Trade Reg. Rule*, 16 CFR Part 456, 17-19 (1977).

For example, dental hygienists can provide preventive dental care, while dental therapists can provide limited restorative services as well as preventive services. Dentists can provide these services as well as the full range of more complex dental services. See, e.g., *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-ohio-state-senate-regarding-competitive-effects-sb-330-increasing-access-quality/v170003_ftc_staff_comment_to_ohio_state_senate_re_ohio_sb_330_re_dental_therapists_and_hygienists.pdf (accessed September 26, 2018); *FTC Staff Comment Before the Commission on Dental Accreditation Concerning Proposed Accreditation Standards for Dental Therapy Education Programs* (2013). https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-commission-dental-accreditation-concerning-proposed-accreditation-standards-dental/131204codacomment.pdf. Accessed September 20, 2018.

101 We use the term broadly, acknowledging that "[t]he allied health workforce includes hundreds of professionals employed in different professions with different job duties and different levels of preparation, but there is no single definition of "allied health" or list of allied health occupations. All formulations exclude physicians and dentists, and most exclude nurses. Others exclude pharmacists, physician assistants, and more." IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011.

102 Institute of Medicine, National Acad. of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington DC: National Academies Press; 2011:27; see also IOM (Institute of Medicine). *Allied Health Workforce and Services: Workshop Summary*. Washington, D.C.: The National Academies of Sciences Engineering Medicine; 2011:88 ("Given current concerns about a shortage of primary care health professionals, the committee paid particular attention to the role of nurses, especially APRNs, in this area."). The extent to which APRNs and other professionals might augment the primary care workforce has been of policy interest for some time. See, e.g., U.S. Congress, Office of Technology Assessment. *Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis*. Health Technology Case Study 37. OTA-HCS-37. Washington, D.C.: U.S. Government Printing Office; December 1986. ("Most observers conclude that most primary care traditionally provided by physicians can be delivered by [nurse practitioners and physician assistants].")

103 Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:4.

104 Improving efficiency in the healthcare system: removing anti-competitive barriers for advanced practice registered nurses and physician assistants. The Hamilton Project. Policy

brief 2018-08. June 2018. http://www.hamiltonproject.org/assets/files/AM_PB_0608.pdf. Accessed August 22, 2018.

105 Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington D.C.: National Academies Press; 2011:5.

106 FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-

practice-nurses. Accessed August 22, 2018.

107 Dep't Veterans Affairs, Economic Impact Analysis for RIN 2900-AP44, Advanced Practice Registered Nurses, attachment 1, 5-7 (Nov. 9, 2016),

>https://www.va.gov/ORPM/docs/RegMgmt_ImpactAnalysis_AP44(F)_AdvancedPracticeRegisteredNurses.docx<.

108 *Id.* at 20.

109 *Id.* at 27.

110 See generally, e.g., FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission. March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation- advanced-practice-nurses. Accessed August 22, 2018, (regarding APRNs); *FTC Staff Comment to the Ohio State Senate Regarding the Competitive Effects of SB 330 in Increasing Access to Quality Dental Care* (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/03/ftc-staff-comment-ohio-state-senate-regarding- competitive. Accessed August 22, 2018 (regarding dental therapy); *FTC Staff Comments to the Iowa Board of Physician Assistants on Proposed New Rules: 645—327.8: Definition of Physician Supervision of a Physician Assistant* (2016). https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-professional-licensure- division-iowa-department-public-health-regarding-proposed/v170002_ftc_staff_comment_to_iowa_dept_of_public_health_12-21-16.pdf. Accessed August 22, 2018 (regarding physician assistants).

111 According to the American Association of Nurse Practitioners, 22 states plus the District of Columbia now grant full practice authority to APRNs. https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment. Accessed August 22, 2018. For examples of state restrictions on SOP besides supervision requirement see, e.g., Institute of Medicine, National Academy of Sciences. *The Future of Nursing: Leading Change, Advancing Health*. Washington, D.C.: National Academies Press; 2011:100-102, Box 3-1 Variation in State Licensure Requirements; FTC Staff. Policy perspectives: competition and the regulation of advanced practice nurses. Federal Trade Commission.

March 7, 2014. https://www.ftc.gov/reports/policy-perspectives-competition-regulation-advanced-practice-nurses. Accessed August 22, 2018, at notes 35-37 and accompanying

text.

112 Licensing rules are almost always state-based. See, e.g., *Dent v. West Virginia*, 129 U.S. 114 (1889) (upholding the authority of the State of West Virginia to license physicians); Health Resources and Services Administration, U.S. Department of Health and Human Services. Telehealth licensure report. Report 111-66. Special Report to the Senate Appropriations Committee (Requested by Senate). 2010. ("For over 100 years, health care in the United States has primarily been regulated by the states. Such regulation includes the establishment of licensure requirements and enforcement standards of practice for health providers, including physicians, nurses, pharmacists, mental health practitioners, etc.")

113 See, e.g., *Occupational Licensing: Regulation and Competition: Hearing Before the Subcomm. on Regulatory Reform, Commercial and Antitrust Law of the House Comm. on the Judiciary,* 115th Cong. 1, 8-9 (2017) (statement of Maureen K. Ohlhausen, Acting Chairman, Federal Trade Commission). https://www.ftc.gov/system/files/documents/public_statements/1253073/house_testimony_licensing_and_rbi_act_sept_

2017_vote.pdf. Accessed August 22, 2018; Occupational licensing: a framework for policy makers. U.S. Department of the Treasury, Council of Economic Advisors, and the Department of Labor. July 2015, at 12-16. https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf. Accessed August 25, 2018.

114 See, e.g., Health Resources & Services Administration, U.S. Department of Health & Human Services. *Special Report to the Senate Appropriations Committee, Telehealth Licensure Report, Requested by Senate* Rep't 111-66 (2010), at 9, ("The basic standards for medical and nursing licensure have become largely uniform in all states.

Physicians and nurses must graduate from nationally approved educational programs and pass a national medical and nursing licensure examination.")

115 See, e.g., American Medical Association. Obtaining a medical license. http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.page. Accessed August 22, 2018. ("The process of obtaining a medical license can be challenging and time consuming…. Physicians seeking initial licensure or applying for a medical license in another state should anticipate delays due to the investigation of credentials and past practice as well as the need to comply with licensing standards."); U.S. Department of the Treasury and U.S. Department of Defense, Supporting our military families: best practices for streamlining occupational licensing across state lines. February 2012:12-13.
http://archive.defense.gov/home/pdf/Occupational_Licensing_and_Military_Spouses_Report_vFINAL.PDF. Accessed August 22, 2018. ("Nurses moving across state lines must apply for licensure by endorsement and pay any applicable fees.")

116 See, e.g., Nicholson S, Propper C. Medical workforce. In *Handbook of Health Economics*. Vol. 2. 1st ed. Waltham, MA: North Holland; 2012:885. (In medical labor

markets, "[l]icensing is associated with restricted labor supply, an increased wage of the licensed occupation, rents, increased output prices, and no measurable effect on output quality.") 117 See, e.g., *Comment from FTC Staff to Department of Veterans Affairs*, 3 (Nov. 1, 2017), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-veterans-affairs- regarding-its-proposed-telehealth-rule/v180001vatelehealth.pdf. Accessed August 22, 2018. ("State laws and regulations that require licensure of telehealth providers licensed in another state inhibit VA employees from delivering telehealth services to beneficiaries in states in which they are not licensed.")

118 See, e.g., American Institute of Certified Public Accountants and National Association of State Boards of Accountancy. *Uniform Accountancy Act: Standards for Regulation*. 8th ed. Nashville, TN: American Institute of Certified Public Accountants; 2018. https://nasba.org/app/uploads/2018/02/Uniform-Accountancy-Act-%E2%80%93- Eighth-Edition-%E2%80%93-January-2018.pdf. Accessed August 22, 2018; Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-

_license_portability_transcript.pdf. Accessed August 22, 2018 (transcript of roundtable). (UAA mobility provisions adopted by 53 jurisdictions.) See also National Association of Boards of Pharmacy ("NABP"). *Comment to the FTC* (2017), at 1-2, https://www.ftc.gov/system/files/documents/public_comments/2017/07/00016-141084.pdf. Accessed August 22, 2018. ("As required by the *NABP Constitution and Bylaws,* all NABP members participate in e-LTP and the NABP Clearinghouse.") The number of model laws with license portability provisions is unknown because they are not tracked by any organization.

119 U.S. Constitution Art. I, § 10, cl. 3.

120 See FTC Staff. Policy perspectives: options to enhance occupational license portability. Federal Trade Commission. September 24, 2018, at 9-10. https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-

license-portability/license_portability_policy_paper.pdf. Accessed September 26, 2018.

121 See, e.g., Interstate Medical Licensure Compact. http://www.imlcc.org/. Accessed August 22, 2018, (adopted by 22 states); Physical Therapy Licensure Compact. http://www.fsbpt.org/FreeResources/PhysicalTherapyLicensurecompact.aspx. Accessed August 22, 2018, (adopted by 16 states).

122 See 42 U.S.C. §254c-18; Office for the Advancement of Telehealth, U.S. Department of Health and Human Services. Funding Opportunity Announcement HRSA-16-014. 2016. https://grants.hrsa.gov/2010/Web2External/Interface/Common/EHBDisplayAttachment.aspx?dm_rtc=16&dm_attid=2f 098e80-40a0-43ec-b4e7-2002033a031a. Accessed August 22, 2018.

123 See, e.g., Streamlining licensing across state lines: initiatives to enhance occupational licensing portability. FTC Economic Liberty Taskforce. July 27, 2017, at 11-12, 16, 18-19. https://www.ftc.gov/system/files/documents/public_events/1224893/ftc_economic_liberty_roundtable_-_license_portability_transcript.pdf. Accessed August 22, 2018.

124 See, e.g., Rheuban KS. Welcome from IOM Planning Committee. *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary*. Washington, D.C.: The National Academies Press; 2012. http://www.nap.edu/catalog/13466/the-role-of-telehealth-in-an-evolving-health-care-environment. Accessed August 22, 2018. ("[T]elehealth programs have served as innovative tools for delivery of care, linking patients and providers separated by geographic and socioeconomic barriers, all the while mitigating specialty workforce shortages"); Committee on Geographic Adjustment Factors in Medicare Payment, Institute of Medicine. *Geographic Adjustment in Medicare Payment—Phase II, Implications for Access, Quality, and Efficiency*. Washington, D.C.: The National Academies Press; 2012:8. http://iom.nationalacademies.org/Reports/2012/Geographic-Adjustment-in-Medicare-Payment-Phase-II.aspx. Accessed August 22, 2018. (Telehealth is a "very promising and rapidly developing strategy to improve access and efficiency of care" and is being used by 50 medical subspecialties.)

125 See, e.g., Hilty DM, Ferrer DC, Parish MB, Johnson B, Callahan EJ, Yellowlees PM. The effectiveness of telemental health: a 2013 review. *Telemed J E Health*. 2013 Jun;19(6):444, 449 (citing randomized controlled clinical trial of the use of telehealth services to treat depression and other mental conditions in adults). See also Gilman M, Stensland J. Telehealth and Medicare: payment policy, current use, and prospects for growth. *Medicare Medicaid Res Rev*. 2013;3(4):E1, E8. ("[O]f the 38,000 telehealth visits that Medicare beneficiaries had in 2009, most visits [62 percent] were for mental health services.")

126 See, e.g., Coates SJ, Kvedar J, Granstein RD. Teledermatology: from historical perspective to emerging techniques of the modern era. Part I: history, rationale, and current practice. *J Am Acad Derm*. 2015 Apr;72(4):563, 566-567; Coates SJ, Kvedar J, Granstein RD. From historical perspective to emerging techniques of the modern era. Part II: emerging technologies in teledermatology, limitations and future directions. *J Am Acad Derm*. 2015 Apr;72(4):577. 127 See, e.g., Fierson WM, Capone A. The American Academy of Pediatrics Section on Ophthalmology, American Academy of Ophthalmology, and the American Association of Certified Orthoptists. Telemedicine for evaluation of retinopathy of prematurity. *Pediatrics*. 2015 Jan;135(1):e238 (report providing guidance on the use of telemedicine- based retinal imaging techniques that "have the potential to allow diagnosis and monitoring of [retinopathy of prematurity] to occur in lieu of the necessity for some repeated on-site examinations in" neonatal intensive care units);

Silva PS, Aiello LP. Telemedicine and eye examinations for diabetic retinopathy: a time to maximize real-world outcomes. *JAMA Ophthalmol*. 2015 May;133(5):525 ("a telemedicine approach for diabetic retinopathy evaluation can effectively increase the rates of eye examinations, thereby potentially reducing the rates of blindness and vision loss in the diabetic population").

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129 See, e.g., Mehrotra A. The convenience revolution for treatment of low-acuity conditions. *JAMA*. 2013;310:35, 36; Mehrotra A, Paone S, Martich GD, Albert SM, Shevchik GJ. A comparison of care at e-visits and physician office visits for sinusitis and urinary tract infections. *JAMA Int. Med*. 2013 Jan 14;173(1):72, 73.

130 See, e.g., *Comment from FTC Staff to Steve Thompson, Representative, Alaska State Legislature* (March 25, 2016). https://www.ftc.gov/policy/policy-actions/advocacy-filings/2016/03/ftc-staff-comment-alaska-state-legislature- regarding. Accessed August 23, 2018. (Regarding telehealth provisions in Senate Bill 74, which would allow licensed Alaska physicians located out-of-state to provide telehealth services.) *See also* Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-

365. 2017. Highlights, at 21 ("[P]rovider and regional medical specialty shortages can be addressed through telehealth.") https://www.gao.gov/products/GAO-17-365#summary. Accessed August 23, 2018.

131 See generally Committee on Pediatric Workforce, Marcin JP, Rimsza ME, Moskowitz WB. The use of telemedicine to address access and physician workforce shortages. *Pediatrics*. 2015 Jul;136(1):202, 203 ([U]rban as well as rural children "face significant disparities in access and time-distance barriers, which could be partly alleviated by the use of telehealth"); Bashshur RL, Shannon GW, Smith BR, Alverson DC, Antoniotti N, Barsan WG, et al. The empirical foundations of telemedicine interventions for chronic disease management. *Telemed J E Health*. 2014 Sep;20(9):769, 770 ("Differences in *access* to care reflect economic, geographic, and functional as well as social, cultural, and psychological factors….[M]any residents of the inner city have limited access to medical resources for economic reasons."); Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. *Ann Intern Med*. 2015 Nov 17;163(10):787 ("Limited access to care is not an issue specific to rural communities; underserved patients in urban areas have the same risks as rural patients if they lack primary or specialty care….")

132 See, e.g., Fish EM, Hickman SA, Chaudhry HJ. *SciTech Lawyer*. 2014;10:n.p. https://www.americanbar.org/content/dam/aba/publications/scitech_lawyer/2014/spring/state_licensure_regulations_ev

olve_to_meet_demands_modern_medical_practice.authcheckdam.pdf. Accessed August 23, 2018. ("Fifty-seven state medical and osteopathic boards and the District of Columbia Board of Medicine now require physicians engaging in telemedicine to be licensed in the state in which the patient is located."); Fleisher LD, Dechene JC. *Telemedicine and E-Health Law. N.p: Law Journal Press; 2014, 1.02[2] ("A large number of states require out-of-state telemedicine physicians to obtain a full, unrestricted medical license in order to 'see' patients in the state via telemedicine.")*

133 See, e.g., Thomas L, Capistrant, G. 50 state telemedicine gaps analysis: psychologist clinical practice standards & licensure. American Telemedicine Association. June 2016. https://higherlogicdownload.s3.amazonaws.com/AMERICANTELEMED/3c09839a-fffd-46f7-916c-692c11d78933/UploadedImages/Policy/State%20Policy%20Resource%20Center/Psychol%20-%2050-state-telehealth- gaps-analysis-pysch-pgl_final.pdf. Accessed August 23, 2018. ("Across the care spectrum, inadequate licensure portability and arbitrary scope of practice standards challenge telehealth adoption and utilization….Mental and behavioral health providers are not spared from this fragmented policy landscape.")

134 See, e.g., Daniel H, Sulmasy LS, Health and Public Policy Committee of the American College of Physicians. Policy recommendations to guide the use of telemedicine in primary care settings: an American College of Physicians position paper. Ann Intern Med. 2015 Nov 17;163(10):App. ("One of the most significant challenges to wide-spread telemedicine adoption is reimbursement."); Burke BL, Hall WR, Section on Telehealth Care. Telemedicine: pediatric applications. Pediatrics. 2015 Jul;136(1):e294, e303 ("The most significant barriers are payment, licensing across state borders, and liability.")

135 See 42 U.S.C. § 1395m(m)(4)(C)(ii); 42 C.F.R. § 410.78(b)(3).

136 See 42 U.S.C. § 1395m(m)(4)(C)(i); 42 C.F.R. § 410.78(b)(4). See also Health care: telehealth and remote patient monitoring use in Medicare and selected federal programs. U.S. Government Accountability Office. GAO-17-365. 2017. Highlights, at 8-9, 21-25. https://www.gao.gov/products/GAO-17-365#summary. Accessed August 23, 2018. (Medicare telehealth coverage restrictions that limit the geographic and practice settings in which beneficiaries may receive services are barriers to the use of telehealth). Legislators have been cautious about expanding coverage of telemedicine services in part because of concerns that its ease of use could lead to overutilization. In practice, however, Medicare telemedicine-related spending is very low. See ibid. at 14, 18 (in 2014, Medicare paid 175,000 telehealth claims for a total of about $14 million, less than 0.01 percent of the approximately $257 billion in total annual Medicare expenditures on Part B services); Neufeld JD, Doarn CR. Telemedicine spending by Medicare: a snapshot from 2012. Telemed J E Health. 2015 Aug;21(8):686-693. In addition, concerns about improper claims for reimbursement of telehealth services have been overblown. An Office of Inspector General (OIG) audit found that the Centers for Medicare and Medicaid Services (CMS) paid for some telehealth services that did not meet Medicare requirements, but most claims for telehealth services were appropriate. To reduce the number of unallowable claims, OIG recommended post-payment reviews to detect errors, and education and training of practitioners on Medicare telehealth requirements. See CMS paid practitioners for

telehealth services that did not meet Medicare requirements. Department of Health and Human Services, Office of Inspector General. A-05-16-00058. April 2018. https://oig.hhs.gov/oas/reports/region5/51600058.pdf. Accessed August 23, 2018.

137 See, e.g., Comment from FTC Staff to the Delaware Bd. of Speech/Language Pathologists, Audiologists & Hearing Aid Dispensers 6 & nn.57, 59 (Nov. 29, 2016). https://www.ftc.gov/system/files/documents/advocacy_documents/ftc- staff-comment-delaware-board-speech/language-pathologists-audiologists-hearing-aid-dispensers-regarding-its- proposed-revisions-its/161130_ftc_dealers_final_.pdf. Accessed August 23, 2018. (Discussing initial in-person evaluation requirements before speech/language/pathology or audiology services may be provided by telehealth in Kentucky and Texas.) It is difficult to draw a bright line between services for which health and safety considerations warrant a prior in-person examination and those that do not, in part because rapid changes in technology and healthcare priorities may lead to changing views of the need for an in-person visit. See, e.g., Letter from Jonathan Linkous, chief executive officer, American Telemedicine Association, to Imelda L. Paredes, executive assistant, Drug Enforcement Administration, Department of Justice 8-11 (October 6, 2015). (Discussing changing views on telemedicine prescribing of controlled substances without a prior in-person examination). See also *FTC Staff Comment to Washington State Rep. Paul Graves, regarding S.S.B. 5411/H.B. 1473*, 4-5 (Feb. 9, 2018), https://www.ftc.gov/policy/advocacy/advocacy- filings/2018/02/ftc-staff-comment-washington-state-rep-paul-graves. Accessed August 23, 2018. This letter explains why allowing a practitioner to determine whether the use of telehealth care is appropriate is better than a rigid in-person examination requirement.

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142 The Complexities of Physician Supply and Demand: Projections from 2014 to 2025. Prepared for Association of American Medical Colleges. 2016 Apr 5: 5.

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U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250 (2016). https://www.justice.gov/atr/file/812606/download. Accessed August 23, 2018. For selected FTC and Division comments regarding state CON laws from 2008 - 2016, see *Joint Statement of the Fed. Trade Comm'n and the Antitrust Div. of the U.S. Dep't Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would*

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and Practice. Vol. 2. N.p.:Thomson Reuters; 2003: §16:2, at 16-9.

173 Compare, e.g., OHIO ADMIN. CODE ANN. 3701-12-23, 23.2 (regarding certain activities by "long-term care" facilities

in Ohio) with OR. REV. STAT. § 442.315(1) (2017) (regarding "any new hospital or new skilled nursing or intermediate care service or facility" in Oregon, subject to certain exclusions).

174 For example, Connecticut generally requires a CON for establishment or acquisition of new healthcare facilities, Conn. Gen. Stat. § 19a-638(a), but exempts, e.g., residential care homes, nursing homes and rest homes, *ibid.* at § 19a- 638(b)(4), outpatient chronic dialysis services, *id.* at § 19a-638(b)(9), and transplant services, *ibid.* at § 19a-638(b)(10), among others. *See* Conn. Gen. Stat. § 19a-638(b)(1)-(22) (exemptions).

175 For example, Delaware requires a CON for a new facility, but only for capital expenditures by existing facilities in excess of $5.8 million (or a higher amount based on inflation). See 16 Del. C. § 9304.

176 For example, provisions of the Delaware Code requiring review, 16 Del. C. § 9304., are "[e]ffective until Dec. 31, 2020."

177 See, e.g., Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018 (synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M, Town RJ. Competition in healthcare markets. In *Handbook of Health Economics.* Vol 2, 1st ed. Waltham, MA: North Holland; 2012:499, 637 (2012). Gaynor M, Ho K, Town R. The industrial organization of health-care markets. 53 J *Econ Lit*. 2015;53(2):235, 294, (201u5). https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets.

Accessed August 21, 2018 (critical review of empirical and theoretical literature regarding markets in healthcare services and insurance).

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Hospital consolidation and negotiated PPO Prices. *Health Aff*. 2004 Mar-Apr;23:175, 179 ("Overall, our results do not support the argument that efficiencies from consolidations among competing hospitals lead to lower prices. Instead, they are broadly consistent with the opposing view that consolidations among competing hospitals lead to higher prices."); see also, e.g., Farrell J, Pautler P, Vita M. Economics at the FTC: retrospective merger analysis with a focus on hospitals. *Ref Indus Org* 2009;35(4):369 (Mergers between not-for-profit hospitals can result in substantial anti- competitive price increases).

179 Sherman D. The effect of state certificate-of-need laws on hospital costs: an economic policy analysis. Federal Trade Commission. January 1988. https://www.ftc.gov/reports/effect-state-certificate-need-laws-hospital-costs- economic-policy-analysis. Accessed August 23, 2018 (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data on 3,708 hospitals, that strong CON programs do not lead to lower costs but may actually increase costs); Noether M. Competition among hospitals. Federal Trade Commission. May 1987. https://www.ftc.gov/reports/competition-among-hospitals-0. Accessed August 23, 2018 (empirical study concluding that CON regulation led to higher prices and expenditures); Anderson KB, Kass DI. Certificate of need regulation of entry into home healthcare: a multi-product cost function analysis. Federal Trade Commission. January 1986.

180 *Health Care and Competition Law and Policy Hearings*. Federal Trade Commission. https://www.ftc.gov/news- events/events-calendar/2003/02/health-care-competition-law-policy-hearings. Accessed Dec. 2, 2015.

181 Federal Trade Commission and the U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 1-6. http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed August 23, 2018. 182 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*. October 26, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust- division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf.

Accessed August 23, 2018; Letter from Marina Lao, Director, Office of Policy Planning, Federal Trade Commission, et al., to The Honorable Marilyn W. Avila, N.C. House of Representatives. July 10, 2015. https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-concurring-comment- commissioner-wright-regarding-north-carolina-house-bill-200/150113ncconadv.pdf. Accessed August 23, 2018; *Prepared Statement of the Federal Trade Commission Before the Florida State Senate*. April 2, 2008. https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf. Accessed August 23, 2018; *Statement of the Antitrust Division, U.S. Department of Justice, Before the Florida Senate Committee on Health & Human Services*. March 25, 2008. http://www.justice.gov/atr/comments-competition-healthcare-and-certificates-need. Accessed August 23, 2018; *Joint Statement of the Fed. Trade Comm'n and the Antitrust*

Div. of the U.S. Dep't Justice Regarding Certificate-of- Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program (2017) https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-antitrust- division. Accessed August 23, 2018; S*tatement of the Antitrust Division, U.S. Department of Justice, Before a Joint Session of the Health & Human Services Committee of the State Senate and the CON Special Committee of the State House of Representatives of the General Assembly of the State of Georgia*. February 23, 2007. *http://www.justice.gov/atr/competition-healthcare-and-certificates-need.* Accessed August 23, 2018.

183 See, e.g., Bloom N, Propper C, Seiler S, Van Reenen JV. The impact of competition on management quality: evidence from public hospitals. *Rev Econ. Studies*. 2015 Apr 1;82(2):457, 457. ("We find that higher competition results in higher management quality.")

184 Vivian Ho & Meei-Hsiang Ku-Goto, State Deregulation and Medicare Costs for Acute Cardiac Care, 70 MED. CARE RES. & REV. 185, 202 (2012) (finding an association between the lifting of CON laws and a reduction in mean patient costs for coronary artery bypass graft surgery, and finding that these cost savings slightly exceed the fixed costs of new entrants); Patrick A. Rivers et al., The Effects of Certificate of Need Regulation on Hospital Costs, 36 J. HEALTH CARE FIN. 1, 11 (2010) (finding a positive relationship between the stringency of CON laws and healthcare costs per adjusted admission and concluding that the "results, as well as those of several previous studies, indicate that [CON] programs do not only fail to contain [hospital costs], but may actually increase costs as well" (emphasis in original)). While other studies evaluate the impact of repealing CON laws (with varying results), many of these studies are less persuasive because they do not account for preexisting cost differences between the states. Compare Michael

D. Rosko & Ryan L. Mutter, The Association of Hospital Cost-Inefficiency with Certificate-of-Need Regulation, 71 MED. CARE RES. & REV. 1, 15 (2014) (finding "a plausible association between CON regulation and greater hospital cost-efficiency"), with Gerald Granderson, The Impacts of Hospital Alliance Membership, Alliance Size, and Repealing Certificate of Need Regulation on Cost Efficiency of Non-profit Hospitals, 32 MANAGE. DECIS. ECON. 159, 167-68 (2011) ("[R]epealing state CON programs contributed to an improvement in hospital cost efficiency.").

185 Some papers find that CON laws are associated with lower utilization of hospital beds. These studies, however, do not address the critical question of whether the lower bed utilization in states with CON laws is a result of preventing over-investment or restricting beneficial investment. See, e.g., Delamater PL, Messina JP, Grady SC, WinklerPrins V, Shortridge AM. Do more hospital beds lead to higher hospitalization rates? A spatial examination of Roemer's Law. *PLOS ONE.* 2013;8:13-14 (finding "a positive, significant association between hospital bed availability and hospital utilization rates"); Hellinger FJ. The effect of certificate-of-need laws on hospitals beds and healthcare expenditures: an empirical analysis. *Am J Man Car*e. 2009;15:737 (finding that CON laws "have reduced the number of hospital beds by about 10%").

186 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250* (2016), at text accompanying notes 14-25 (detailing lengthy application, hearing, and appeal process in South Carolina). https://www.justice.gov/atr/file/812606/download. Accessed August 23, 2018.

187 See Halm EA, Lee C, Chassin MR. Is volume related to outcome in health care? A systematic review and methodological critique of the literature. *Ann Intern Med*. 2002 Sep 17;137(6):511, 514. ("We found the most consistent and striking differences in mortality rates between high- and low-volume providers for several high-risk procedures and conditions, including pancreatic cancer, esophageal cancer, abdominal aortic aneurysms, pediatric cardiac problems, and treatment of AIDS. The magnitude of volume-outcome relationships for more common procedures, such as [coronary artery bypass graft surgery], coronary angioplasty, and carotid endarterectomy, for which selective referral and regionalization policies have been proposed, was much more modest.")

188 *See* Gaynor M, Seider H, Vogt WB. The volume-outcome effect, scale economies, and learning-by-doing. *Am Econ Rev*. 2005;95(2):243, 244.

189 See, e.g., Ho V, Ku-Goto M, Jollis JG. Certificate of need (CON) for cardiac care: controversy over the contributions of CON. *Health Serv Res*. 2009 Apr;44(2 Pt 1):483, 483 (2009) ("States that dropped CON experienced lower [coronary artery bypass graft surgery] mortality rates relative to states that kept CON, although the differential is not permanent.")

190 See Li S, Dor A. How do hospitals respond to market entry? Evidence from a deregulated market for cardiac revascularization. *Health Econ*. 2015;24:990, 1006 (finding that repeal of Pennsylvania's CON program improved "the match between underlying medical risk and treatment intensity"); Ho V, Ku-Goto M. State deregulation and Medicare costs for acute cardiac care. *Med Care Res Rev*. 2012;70:199 (finding association between lifting of CON laws and shorter lengths of stay and fewer strokes during admission for coronary artery bypass patients, finding no significant association between lifting CON laws and three other complications during admission for coronary artery bypass graft patients, and finding no significant associations between lifting of CON laws and length of stay or need for coronary artery bypass graft surgery for percutaneous coronary intervention patients); Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):51, 52 (finding that new entry after repeal of Pennsylvania's CON program "had a salutary effect on the market for cardiac surgery by directing more volume to better doctors and increasing access to treatment").

191 Gaynor M, Town R. The impact of hospital consolidation—update. Robert Wood Johnson Foundation, The Synthesis Project. Policy Brief No. 9. June 2012, at 3. http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261. Accessed August 21, 2018; *see also* Romano P, Balan DJ. A retrospective analysis of the clinical quality effects of the acquisition of Highland Park Hospital by Evanston Northwestern Health care. *Int J Econ Bus*. 2011;18:45, 64 (2011).

192 Cutler DM, Huckman RS, Kolstad JT. Input constraints and the efficiency of entry: lesson from cardiac surgery. *Am Econ J.: Econ Policy* 2010;2(1):63 (finding that, following repeal of Pennsylvania's CON program, incumbent hospitals "were not put in a precarious position by the elimination of CON"); The Lewin Group. An evaluation of Illinois' Certificate of Need Program: prepared for the State of Illinois Commission on Government Forecasting and Accountability. 2007 Feb 15;ii:27-28. http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf. Accessed August 23, 2018. ("Through our research and analysis we could find no evidence that safety-net hospitals are financially stronger in CON states than other states.")

193 Garmon C. Hospital competition and charity care. *Forum Health Econ Policy*. 2009;12:1, 13.

194 See Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. July 2004, ch. 8, at 4. http://www.ftc.gov/reports/healthcare/040723health carerpt.pdf. Accessed August 23, 2018 (discussing examples of how CON programs limited access to new cancer treatments and shielded incumbents from competition from innovative newcomers).

195 See, e.g., *Joint Statement of the Federal Trade Commission and the Antitrust Div. of the U.S. Department of Justice Regarding Certificate-of-Need (CON) Laws and Alaska Senate Bill 62, Which Would Repeal Alaska's CON Program*, 6-7 (2017). https://www.ftc.gov/policy/advocacy/advocacy-filings/2017/04/joint-statement-federal-trade-commission-

antitrust-division. Accessed August 23, 2018.

196 *United States v. Charleston Area Med. Ctr., Inc.*, No. 2:06-0091 (S.D. W.Va. 2006). In a separate but similar case, informal suggestions by state CON officials led closely competing West Virginia hospitals to agree that one hospital would seek a CON for open heart surgery and the other for cancer treatment. *United States v. Bluefield Reg'l Med. Ctr., Inc*., No. 1:05-0234 (S.D. W.Va. 2005). While the Division secured consent decrees prohibiting these agreements between competitors to allocate services and territories, such conduct indicates that CON laws can provide the opportunity for anti-competitive agreements. See, e.g., U.S. Department of Justice, Department of Justice Statement on the Closing of the Vermont Home Health Investigation. Press Release. November 23, 2005. http://www.justice.gov/archive/opa/pr/2005/November/05_at_629.html. Accessed August 23, 2018.

197 See generally *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348 (March 31, 2015). https://www.ftc.gov/enforcement/cases-proceedings/111-0067/phoebe-putney-health-system-inc-phoebe-putney- memorial. Accessed August 23, 2018.

198 FTC v. Phoebe Putney Health Sys., 793 F. Supp. 2d 1356, 1361-1362 (M.D. Ga. 2011).

199 *FTC v. Phoebe Putney Health Sys.*, 663 F.3d 1369 (11th Cir. 2011).

200 *FTC v. Phoebe Putney Health Sys.*, 133 S. Ct. 1003, 1007 (2013).

201 The Eleventh Circuit had dissolved the stay that had prevented the parties from consummating the merger. With the stay dissolved, the parties had consummated their merger before the Supreme Court resolved the state-action question. *FTC v. Phoebe Putney Health Sys. Inc.*, 133 S. Ct. at 1011.

202 *Statement of the Federal Trade Commission*, at 1, *In the Matter of Phoebe Putney Health Sys., Inc.*, Dkt. No. 9348, (March 31, 2015):1.

https://www.ftc.gov/system/files/documents/public_statements/634181/150331phoebeputneycommstmt.pdf. Accessed August 23, 2018.

203 Several states have passed COPA statutes since the 1990s, and there appears to be a recent resurgence in the implementation of COPA regulations. The following hospital mergers have been permitted to proceed pursuant to COPA oversight: HealthSpan Hospital System (Minnesota, 1994); Mission Health System (North Carolina, 1995); Benefis Health System (Montana, 1996); Palmetto Health System (South Carolina, 1998); Cabell Huntington Hospital/St. Mary's Medical Center (West Virginia, 2016); and Mountain States Health Alliance/Wellmont Health System (Tennessee and Virginia, 2017). In addition, the Staten Island Performing Provider System in New York recently received a COPA for certain collaborative activities (2016). See COPA Application #COPA-SIPPS Staten Island PPS. New York Department of Health, Public Health and Health Planning Council.
https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2016-11-17/docs/copa- sipps_staten_island_pps.pdf. Accessed August 23, 2018.

204 To obtain antitrust immunity for conduct that might otherwise violate the federal antitrust laws, the state action doctrine requires both a clear articulation of the state's intent to displace competition in favor of regulation and that the state provide active supervision over the regulatory scheme or body. *See N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S. Ct. 1101, 1114 (2015); *FTC v. Phoebe Putney Health Sys., Inc.*, 133 S. Ct. 1003, 1013 (2013).

205 Benefits typically considered by the states include cost efficiencies, quality improvements, population health improvements, preservation of hospital facilities and resources, and increased patient access to healthcare services. Disadvantages typically considered by the states include price increases, an inability of health plans to negotiate reasonable contract terms with providers, and reduced quality and access for healthcare services attributable to a reduction in competition.

206 For example, the Federal Trade Commission recently dismissed an administrative complaint filed in the matter of Cabell Huntington Hospital's proposed acquisition of St. Mary's Medical Center, after the West Virginia state legislature passed a COPA statute intended to shield the transaction from an antitrust challenge, and the West Virginia Health Care Authority approved the hospitals' COPA application. See Statement of the Federal Trade Commission In the Matter of Cabell Huntington Hospital, Inc., Dkt. No. 9366 (Jul. 6, 2016).
https://www.ftc.gov/system/files/documents/public_statements/969783/160706cabellcommstmt.pdf. Accessed September 26, 2018.

207 In 2015, the North Carolina legislature repealed the state's COPA statute, leaving no effective constraint on Mission Health System, which had operated under a COPA since 1995. See S.B. 698, Gen. Assemb., 2015-16 Session, Session Law 2015-288 (N.C. 2015), http://www.ncleg.net/Sessions/2015/Bills/Senate/PDF/S698v5.pdf. Accessed August 23, 2018 (ratified by General Assembly Sept. 29, 2015; signed into law by Governor Oct. 29, 2015, repealing Article 9A of Chapter 131E of the NC General Statutes, relating to Certificate of Public Advantage, effective Jan. 1, 2018); H.B.

1030, Gen. Assemb., 2015-2016 Session, Session Law 2016-94, at 93 (N.C. 2016), http://www.ncga.state.nc.us/Sessions/2015/Bills/House/PDF/H1030v8.pdf. Accessed August 23, 2018. (revising the effective date of repeal from January 1, 2018 to September 30, 2016). In 2007, the Montana state legislature revised the state's COPA statute to limit the duration of COPAs to ten years, effectively terminating the COPA that Benefis Health System had operated under since 1996. See Mont. Code Ann. § 50-4-603(5) (amended 2007). http://leg.mt.gov/bills/mca/50/4/50-4-603.htm. Accessed August 23, 2018 (limiting the duration of a COPA to no more than 10 years from the date of issuance).

208 See, e.g., FTC staff submissions regarding the proposed merger and COPA applications of Mountain States Health Alliance and Wellmont Health System. https://www.ftc.gov/enforcement/cases-proceedings/151-0115/wellmont-healthmountain-states-health. Accessed August 23, 2018; Submission of Amerigroup Tennessee Inc. to the Tennessee Department of Health on the review of the application for a Certificate of Public Advantage from Wellmont Health System and Mountain States Health Alliance (Nov. 18, 2016). November 18, 2016. https://www.tn.gov/content/dam/tn/health/documents/COPA_AmeriGroup_Submission_to_Tennessee_DOH_with_Ex hibits_11.18.16.pdf. Accessed August 23, 2018; Written Comments of America's Health Insurance plans submitted to the Tennessee Department of Health – COPA Index Advisory Group. April19, 2016. https://www.tn.gov/content/dam/tn/health/documents/AHIP_COPA_Comments_041819.pdf. Accessed August 23, 2018; Letter submitted by professors and academic economists to the Tennessee Department of Health. November 21, 2016. https://www.tn.gov/content/dam/tn/health/documents/Comment_on_Wellmont-MSHA_COPA_Application_by_Professors_and_Academic_Eco.pdf. Accessed August 23, 2018; Public comments submitted to the Virginia Department of Health regarding the cooperative agreement application of Mountain States Health Alliance and Wellmont Health System. http://www.vdh.virginia.gov/licensure-and-certification/cooperative-agreement/public-comment/. Accessed August 23, 2018.

209 See FTC staff notice of COPA assessment: request for empirical research and public comments. November 1, 2017. https://www.ftc.gov/system/files/attachments/press-releases/ftc-staff-seeks-empirical-research-public-comments- regarding-impact-certificates-public-advantage/p181200_copa_assessment_comment_notice_11-1-17.pdf. Accessed August 23, 2018.

210 See, e.g., *FTC Staff Comment to New York State Department of Health, Concerning Certificate of Public Advantage Applications, Intended to Exempt Performing Provider Systems from the Antitrust Laws* (April 22, 2015), at 3.

https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy- resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf. Accessed August 23, 2018. ("The antitrust laws already recognize, and, indeed, have long stood for the proposition that competitor collaborations can be procompetitive. As explained in numerous sources of guidance issued by the federal antitrust agencies, this position extends to collaborations among competing healthcare providers.")

211 15 U.S.C. § 45(a)(2).

212 15 U.S.C. § 44.

213 For example, the Commission generally cannot challenge anti-competitive conduct, such as collusive behavior, by nonprofit hospitals. In three past enforcement actions, the Commission alleged that groups of physicians and hospitals had participated in unlawful price-fixing arrangements but was able to sue only the physicians and a for-profit hospital. See Piedmont Health Alliance.138 F.T.C. 675 (2004) (consent order), https://www.ftc.gov/enforcement/cases- proceedings/0210119i/piedmont-health-alliance-inc-et-al-matter. Accessed August 24, 2018; Tenet Healthcare Corp./Frye Regional Medical Center. 137 F.T.C. 219 (2004) (consent order). https://www.ftc.gov/enforcement/cases- proceedings/0210119h/tenet-healthcare-corporation-frye-regional-medical-center-inc. Accessed August 24, 2018; Maine Health Alliance, 136 F.T.C. 616 (2003) (consent order). https://www.ftc.gov/enforcement/cases-proceedings/0210017/maine-health-alliance-william-r-diggins-matter. Accessed August 24, 2018.

214 Philipson TJ, Posner RA. Antitrust in the not-for-profit sector. *J Law Econ*. 2009 Feb;52(1): 1-18.

215 15 U.S.C. § 18.

216 See, e.g., *Fed. Trade Comm'n v. Sanford Health*, No. 1:17 CV-133 (N.D. 2017); *Fed. Trade Comm'n v. Penn State Hershey Med. Ctr.*, 838 F.3d 327 (3d Cir. 2016); *Fed. Trade Comm'n v. Advocate Health Care Network*, 841 F.3d 460 (7th Cir. 2016); *ProMedica Health Sys., Inc. v. FTC*, 749 F.3d 559 (6th Cir. 2014), cert. denied, 135 S. Ct. 2049 (2015); *St. Alphonsus Med. Ctr.-Nampa Inc. v. St. Luke's Health Sys.*, 778 F.3d 775 (9th Cir. 2015).

217 See, e.g., *Fed. Trade Comm'n v. OSF Health Care Sys.*, 852 F. Supp. 2d 1069, 1081 (N.D. Ill. 2012) ("[T]he evidence in this case reflects that nonprofit hospitals do seek to maximize the reimbursement rates they receive."); *Fed. Trade Comm'n v. ProMedica*, No. 3:11 CV 47, 2011 WL 1219281, at *22 (N.D. Ohio Mar. 29, 2011) (finding that a nonprofit hospital entity "exercises its bargaining leverage to obtain the most favorable reimbursement rates possible from commercial health plans."); *United States v. Rockford Mem'l Corp.*, 898 F.2d 1278, 1284-87 (7th Cir. 1990) (rejecting the contention that nonprofit hospitals would not seek to maximize profits by exercising their market power); *Fed. Trade Comm'n v. Univ. Health, Inc.*, 938 F.2d 1206, 1213-14 (11th Cir. 1991) ("[T]he district court's assumption that University Health, as a nonprofit entity, would not act anticompetitively was improper."); *Hospital Corp. of*

America v. Fed. Trade Comm'n, 807 F.2d 1381, 1390-91 (7th Cir. 1986) (rejecting the contention that nonprofit hospitals would not engage in anticompetitive behavior).

218 15 U.S.C. § 4. See *United States v. Charleston Area Med. Ctr. et al*., No. 2-16-cv-03664 (stipulated final judgment Oct. 21, 2016), which describes a Herman Act case involving an illegal agreement between two nonprofit hospitals to allocate marketing territories.

219 Minda G. The common law, labor and antitrust. *Berk J Employ Labor Law*. 1989 Dec;11(4):461-539. https://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1189 &context=bjell. Accessed August 24, 2018.

220 Gilson RJ. The legal infrastructure of high technology industrial districts: Silicon Valley, Route 128, and covenants not to compete. *NY Univ Law R*. 1999 Jun:74(3):575-629. https://law.stanford.edu/index.php?webauth-document=publication/256234/doc/slspublic/NYULawReview-74-3-Gilson.pdf. Accessed August 24, 2018.

221 Goold SD. Report of the Council on Ethical and Judicial Affairs. CEJA Report 3-A-14. https://www.ama-assn.org/sites/default/files/media-browser/public/about-ama/councils/Council Reports/council-on-ethics-and-judicial- affairs/ceja-3a14.pdf. Accessed August 24, 2018.

222 Lavetti K, Simon C, and White WD. The Impacts of Restricting Mobility of Skilled Service

Workers: Evidence from Physicians. Forthcoming *Journal of Human Resources*. http://kurtlavetti.com/UIPNC_vf.pdf. Accessed November 27, 2018.

223 *Ibid* at 41.

224 *Murfreesboro Medical Clinic, P.A., v. David Udom*, S.C.T. M2003-00313-SC-CV (June 29, 2005). https://caselaw.findlaw.com/tn-supreme-court/1058188.html. Accessed August 24, 2018.

225 *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).

https://www.leagle.com/decision/19851183138illapp3d104511046. Accessed August 24, 2018.

226 Horton RW. Restrictive covenants in physician employment relationships. American Health Lawyers Association— Member Briefing. April 2013. http://www.bassberry.com/~/media/Files/Publications/2013/05/AHLA_Article_Horton_and_Padgett_April_2013.pdf. Accessed August 24, 2018.

227 Garmaise JM. Ties that truly bind: noncompetition agreements, executive compensation, and firm investment. *J Law Econ Org*. 2011 Aug;27(2):376-425. https://academic.oup.com/jleo/article-abstract/27/2/376/2194339. Accessed August 24, 2018.

228 See, e.g., Federal Trade Commission and U.S. Department of Justice. *Improving Health Care: A Dose of Competition*. Ch. 6. July 2004: 29-30. http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf. Accessed August 23, 2018; Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing- provider" regulations. *J Health Econ*. 2011;20:955, 956; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:192, 196-197.

229 *McRand, Inc. v. Van Beelen*, 138 Ill. App.3d 1045 (1985).

https://www.leagle.com/decision/19851183138illapp3d104511046. Accessed August 24, 2018.

230 State AWP (and FOC) laws vary substantially in scope – e.g., applying to some types of plans but not others, or some types of providers but not others. They also vary in stringency and may impose greater or lesser restraints, via varied enforcement mechanisms, on plan contracting and benefits design. Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of 'any-willing-provider' regulations. *J Health Econ*. 2011;20:959; Klick J, Wright JD. The effect of any willing provider and freedom of choice laws on healthcare expenditures. *Am Law Econ Rev*.

2015;17:198-200. For example, some states have adopted AWP laws for pharmacy services. See, e.g., Carroll A, Ambrose JM. Any-willing-provider laws: their financial effect on HMOs. *J Health Polit Policy Law*. 2002;27:928. Depending on these variables, AWP and FOC laws may have greater or lesser economic impact. See, e.g., Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*. 2011;20:959.

231 See generally, e.g., Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*. 2010;29(11):2009; Robinson JC. Hospital tiers in health insurance: balancing consumer choice with financial incentives, *Health Aff*. 2003 Jan-Jun Suppl Web Exclusives:W3-135; Yegian JM. Tiered hospital networks. *Health Aff*. 2003;147:W3. Coverage for the non-preferred tier is therefore lower – in some limiting cases, zero.

232 See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*. 2010;29(11):2010.

233 Often—not always—drug benefits are designed to encourage substitution of lower-cost generic versions of branded products. See Robinson JC. Applying value-based insurance design to high-cost health services. *Health Aff*.

2010;29(11):2011.

234 Beneficiaries or subscribers might generally prefer more choice rather than less, all other things being equal. Providers might also have more self-interested reasons for favoring AWP or FOC laws to the extent that they suffer financially when excluded from preferred tiers of provider networks and/or to the extent that competitive bidding can otherwise diminish profits, say, in significantly concentrated provider markets. See, e.g.,

Vita MG, Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*.

2011;20:956.

235 42 USCS § 1395w-104(b)(1). See, e.g., CMS. Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs. 79 *Fed Reg* 1918, 1978-1982 (Jan. 10, 2014) (discussing proposed "any-willing-pharmacy" rules).

236 See Medicare Program. Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 *Fed Reg*. 16440, 16440-16757 (Apr. 16, 2018).

237 The limited literature on this issue tends to look at the effect of any-willing-provider laws on total spending, instead of prices. Because the quantity of healthcare is generally measured to have a negative, though small, relationship with healthcare prices, these studies likely understate the effect of AWP laws on prices. See, e.g., *Fed. Trade Comm'n Staff Comment to the Ctrs. for Medicare & Medicaid Servs.*, 8, n.15 (March 2014). https://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers- medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf. Accessed August 24, 2018.

238 Klick J, Wright JD. The effect of any-willing-provider and freedom-of-choice laws on healthcare expenditures. *Am Law Econ Rev*. 2015;17:204-05. Klick & Wright find smaller, and not statistically significant effects associated with FOC laws. That may be due, they suggest, to the commonly weaker restraints provided by FOC laws that, in effect, permit beneficiaries to leave the bounds of a network by forgoing the savings gleaned by selective contracting on an *ad hoc* basis, doing less general damage to selective contracting. *Ibid.,* at 194.

239 Durrance CP. The impact of pharmacy-specific any-willing-provider legislation on prescription drug expenditures.

Atlantic Econ J. 2009;37:409.

240 Vita M. Regulatory restrictions on selective contracting: an empirical analysis of "any-willing-provider" regulations. *J Health Econ*. 2001;20:955, 960-66. Panel data show, e.g., that states with highly restrictive AWP/FOC laws spent approximately 2 percent more on healthcare than states without such policies.

241 Gaynor M, Mostashari F, Ginsburg PB. Making healthcare markets work: competition policy for healthcare. Brookings. April 13, 2017. >https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report- v11.pdf< at 24, n.34. Accessed September 26, 2018.

242 See Maryland Health Care Commission and Maryland Insurance Administration. Mail order purchase of maintenance drugs: impact on consumers, payers, and retail pharmacies.

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Expansion of Health Reimbursement Accounts and ICHRAs

Since HSAs are the property of the individual, increasing consumers' ability to use HSAs is likely the best way to encourage first-party payment. Expanding HRAs could also encourage more efficiency through greater consumer control over their healthcare and somewhat reduced third-party payment.

Originally described in IRS guidance in 2002, HRAs allow employers to reimburse their employees' medical expenses. An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical expenses incurred by the employee or his or her family up to a maximum dollar amount for a period. Historically, HRAs have often been used by employers that did not choose to offer group insurance to their workers, as well as to supplement group coverage.

As a result of the interpretation of some ACA provisions, HRAs can currently only be offered if employers also offer ACA-compliant group health insurance plans. In implementing the ACA, the Obama administration determined that standalone HRAs violated the ACA prohibition on annual dollar limits and the requirement that group health plans provide certain preventive care without cost sharing. Although the Obama administration issued regulations allowing HRAs to be offered as long as the employee had other group health insurance coverage, the Obama administration restricted individuals' ability to use an HRA to purchase individual market insurance of their own choosing, even if the insurance did not have annual and lifetime dollar limits and covered preventive care without cost sharing.

The following two expansions of HRAs, both proposed in a notice of proposed rule-making issue on October 23, 2018, would increase their usability and provide employers, and their employees, with a greater set of alternatives for financing health coverage. First, reversing the Obama administration restriction on HRAs for individuals with individual market insurance would encourage more employers to offer HRAs, increase consumer choice, and provide equal tax treatment for employee-selected coverage in the individual market as for traditional employer-selected group coverage.[304] In essence, allowing HRAs to be integrated with non-group coverage that does not have annual dollar limits and that covers the necessary preventive care without cost sharing would allow employers to provide a tax-advantaged, defined contribution arrangement for each employee to select the health insurance that best works for his or her circumstances. In addition to the benefit for workers, the proposed rule would better enable businesses to focus on what they do best—serve their customers—and not on navigating and managing complex health benefit designs.

This proposed rule is increasingly important as fewer employees at small and mid-sized firms are enrolled in employer coverage and most employers that do offer a plan only provide their workers a single option. For firms that employ 3-24 workers, the percentage of workers covered by employer health benefits has fallen from 44% in 2010 to 30% in 2018. For firms that employ 25-49 workers, the percentage of workers covered by employer health benefits has fallen from 59 percent in 2010 to 44 percent in 2018. 81

percent of small to midsized employers (fewer than 200 employees), and even 42 percent of larger employers (at least 200 employees), offering health benefits only provide a single coverage option for their employees. Economists have found that increasing plans available to employees is extremely valuable, providing the median consumer equivalent benefit as a 13 percent premium reduction.[305]

An additional way to expand the use of HRAs is to allow a limited "excepted benefit" HRA that, as with all excepted benefits, would not be subject to the ACA's market rules (such as the prohibition on annual dollar limits and the requirement to cover preventive care without cost sharing) or certain other requirements for group health plans under the Code and the Employee Retirement Income Security Act of 1974 (ERISA). Providing an excepted benefit HRA would reduce the bias toward comprehensive ESI and allow employees another tax-advantaged arrangement to finance limited healthcare expenses. The proposed regulation would permit employers that offer traditional group coverage to provide an HRA of up to $1,800 per year (indexed to inflation) to reimburse an employee for certain qualified medical expenses, including standalone dental benefits and premiums for a short-term health insurance plan.

According to preliminary estimates from the Treasury Department, once fully phased in, roughly 800,000 employers are expected to provide HRAs to pay for individual health insurance coverage to over 10 million employees. Some experts, such as Harvard Business School professor Regina Herzlinger, suggest the effect could be larger since expanded HRAs will create a more efficient healthcare system as consumerism will be unleashed.[306] This phenomenon could lead to increased workforce investment and higher wages as less is spent on health insurance and could spur innovation among providers and insurers as they directly compete for consumer dollars.

Individual Coverage Health Reimbursement Accounts (ICHRAs)

This Question and Answer section comes from New Health Coverage Options for Employers and Employees Individual Coverage and Excepted Benefit Health Reimbursement Arrangements, June 2019 jointly published by the US Departments of the Treasury and Labor.

https://www.irs.gov/pub/irs-utl/health_reimbursement_arrangements_faqs.pdf

Q1. What are the benefits of offering an Individual Coverage HRA to employees?

Individual Coverage HRAs can help enable businesses to focus on what they do best—serve their customers—and not on navigating and managing complex health benefit designs. Individual Coverage HRAs provide tax advantages because the reimbursements provided to employees do not count toward the employees' taxable wages. In effect, Individual Coverage HRAs extend the tax advantage for traditional group health plans

(exclusion of premiums, and benefits received, from federal income and payroll taxes) to HRA reimbursements of individual health insurance premiums. Employers may also allow employees to pay for off-Exchange health insurance on a tax-favored basis, using a salary reduction arrangement under a cafeteria plan, to make up any portion of the individual health insurance premium not covered by the employee's Individual Coverage HRA.

In most cases, the Individual Coverage HRA rule will increase worker options for health insurance coverage, allowing workers to shop for plans in the individual market and select coverage that best meets their needs. It will also result in coverage being more portable for many workers. 81% of small to midsized employers (fewer than 200 employees) and 42% of larger employers (at least 200 employees) offering health benefits in 2018 provided only one type of health plan to their employees.

Q2. How does an Individual Coverage HRA work?

An Individual Coverage HRA reimburses employees for their medical care expenses (and sometimes their family members' medical care expenses), up to a maximum dollar amount that the employer makes available each year. The employer can allow unused amounts in any year to roll over from year to year. Employees must enroll in individual health insurance (or Medicare) for each month the employee (or the employee's family member) is covered by the Individual Coverage HRA. This can be individual health insurance offered on or off an Exchange. However, it cannot be short-term, limitedduration insurance (STLDI) or coverage consisting solely of dental, vision, or similar "excepted benefits." There are other important requirements too. An employer that wants to offer an Individual Coverage HRA should review the HRA rule for more information on the conditions the HRA must meet.

Q3. Why is the HRA rule important for small businesses and their workers?

The HRA rule will provide hundreds of thousands of businesses a better way to offer health insurance coverage and millions of workers and their families a better way to obtain coverage. The HRA rule will especially help small employers, who face larger administrative costs from offering a traditional group health plan, compete for talent. Many small employers struggle to offer coverage to their employees, and a significant number of small employers have stopped offering coverage since 2010. Between 2010 and 2018, the percentage of firms offering coverage declined from 59% to 47% at firms with 3-9 workers, from 76% to 64% at firms with 10-24 workers, from 92% to 71% at firms with 25-49 workers, and from 95% to 91% at firms with 50-199 workers.

Q4. What are the expectations for take-up of the Individual Coverage HRA?

The Departments estimate that once employers fully adjust to the new rules, roughly 800,000 employers will offer Individual Coverage HRAs to pay for insurance for more than 11 million employees and family members, providing these Americans with more

options for selecting health insurance coverage that better meets their needs. The Departments estimate that, once fully phased in, about 800,000 people who were uninsured will gain coverage.

The HRA rule, combined with the Administration's rules to expand Association Health Plans (AHPs) and STLDI has been projected to increase private insurance coverage by nearly 2 million people. (Source: The HRA rule regulatory impact analysis combined with the Congressional Budget Office January 2019 estimates of the AHP and STLDI rule).

Q5. I am an employer. To whom can I offer an Individual Coverage HRA?

If you offer an Individual Coverage HRA, you must offer it on the same terms to all individuals within a class of employees, except that the amounts offered may be increased for older workers and for workers with more dependents. You cannot offer an Individual Coverage HRA to any employee to whom you offer a traditional group health plan. However, you can decide to offer an individual coverage HRA to certain classes of employees and a traditional group health plan (or no coverage) to other classes of employees.

Employers may make distinctions, using classes based on the following status:

• Full-time employees, • Part-time employees, • Employees working in the same geographic location (generally, the same insurance rating area, state, or multi-state region), • Seasonal employees, • Employees in a unit of employees covered by a particular collective bargaining agreement, • Employees who have not satisfied a waiting period, • Non-resident aliens with no U.S.-based income, • Salaried workers, • Non-salaried workers (such as hourly workers), • Temporary employees of staffing firms, or • Any group of employees formed by combining two or more of these classes.

To prevent adverse selection in the individual market, a minimum class size rule applies if you offer a traditional group health plan to some employees and an Individual Coverage HRA to other employees based on: full-time versus part-time status; salaried versus non-salaried status; or geographic location, if the location is smaller than a state. Generally, the minimum class size rule also applies if you combine any of these classes with other classes. The minimum class size is:

- Ten employees, for an employer with fewer than 100 employees,
- Ten percent of the total number of employees, for an employer with 100 to 200 employees, and
- Twenty employees, for an employer with more than 200 employees.

Also, through a new hire rule, employers can offer new employees an Individual Coverage HRA, while grandfathering existing employees in a traditional group health plan.

Q6. How do my employer contributions work?

Employers can contribute as little or as much as they want to an Individual Coverage HRA. However, an employer must offer the HRA on the same terms to all employees in a class of employees, except that employers can increase the amount available under an Individual Coverage HRA based on the employee's age or number of dependents. Also, see Q7 for employers subject to the employer mandate.

Q7. Can an employer offer an Individual Coverage HRA to satisfy the employer mandate?

First, only certain employers – in general, those with at least 50 full-time employees, including full-time equivalent employees, in the prior year – are applicable large employers subject to the employer mandate.

An offer of an Individual Coverage HRA counts as an offer of coverage under the employer mandate. In general, whether an applicable large employer that offers an Individual Coverage HRA to its full-time employees (and their dependents) owes a payment under the employer mandate will depend on whether the HRA is affordable. This is determined under the premium tax credit rule being issued as part of the HRA rule and is based, in part, on the amount the employer makes available under the HRA. Therefore, if you are an applicable large employer and want to avoid an employer mandate payment by offering an Individual Coverage HRA, in general, you will need to contribute a sufficient amount for the offer of the Individual Coverage HRA to be considered affordable.

The Internal Revenue Service will provide more information on how the employer mandate applies to Individual Coverage HRAs soon. For more information on the employer mandate, see https://www.irs.gov/affordable-care-act/employers/employershared-responsibility-provisions.

Q8. What other responsibilities do I, the employer, have?

Individual Coverage HRAs must provide a notice to eligible participants regarding the Individual Coverage HRA and its interaction with the premium tax credit. The HRA must also have reasonable procedures to substantiate that participating employees and their families are enrolled in individual health insurance or Medicare, while covered by the HRA. The Appendix to this document includes a model notice and a model substantiation form that you can use. Employees must also be permitted to opt out of an Individual Coverage HRA at least annually so they may claim the premium tax credit if they are otherwise eligible and if the HRA is considered unaffordable.

You generally will not have any responsibility with respect to the individual health insurance itself that is purchased by the employee, because it will not be considered part of

your employer-sponsored plan, provided:

• An employee's purchase of any individual health insurance is completely voluntary. • You do not select or endorse any particular insurance carrier or insurance coverage. • You don't receive any cash, gifts, or other consideration in connection with an employee's selection or renewal of any individual health insurance. • Each employee is notified annually that the individual health insurance is not subject to the Employee Retirement Income Security Act (ERISA), which is the federal law governing employer-provided health coverage.

Q9. May an employer allow employees to pay any portion of the premium for their individual health insurance that is not covered by the Individual Coverage HRA on a tax-preferred basis by using a salary reduction arrangement under a cafeteria plan?

It depends on whether the employee buys the individual health insurance on an Exchange or off an Exchange. The Internal Revenue Code provides that an employer may not permit employees to make salary reduction contributions to a cafeteria plan to purchase coverage offered through an Exchange. However, that restriction does not apply to coverage that is purchased off an Exchange. Therefore, if an employee buys individual health insurance outside an Exchange and the HRA doesn't cover the full premium, the employer could permit the employee to pay the balance of the premium for the coverage on a pre-tax basis through its cafeteria plan, subject to other applicable regulations.

Q10. Can large employers offer Individual Coverage HRAs too?

Yes. Although the Departments expect that the rule will especially benefit small and mid-sized employers, employers of all sizes may offer an Individual Coverage HRA, subject to the conditions in the HRA rule.

Q11. What are the benefits of offering an Excepted Benefit HRA?

There may be scenarios in which you wish to offer an HRA in addition to a traditional group health plan, for example to help cover the cost of copays, deductibles, or noncovered expenses. Excepted Benefit HRAs generally allow for higher levels of employer contributions than health flexible spending arrangements (FSAs) and can permit rollover of unused amounts from year to year.

Beginning in 2020, HRAs can be offered as "excepted benefits" which are exempt from many federal health care requirements that don't work well for account-based plans. Employees may use these Excepted Benefits HRAs even if they do not enroll in the traditional group health plan (or in any other coverage), which distinguishes the Excepted Benefit HRA from other HRAs.

To qualify as excepted benefits:

- The annual HRA contribution must be limited to $1,800 per year (indexed for inflation beginning in 2021).
- The HRA must be offered in conjunction with a traditional group health plan, although the employee is not required to enroll in the traditional plan.
- The HRA cannot be used to reimburse individual health insurance premiums, group health plan premiums (other than COBRA), or Medicare premiums, although it can reimburse premiums for excepted benefits, such as dental and vision coverage, as well as for STLDI.
- The HRA must be uniformly available to all similarly situated individuals (as defined under the Health Insurance Portability and Accountability Act, which generally permits bona fide employment-based distinctions unrelated to health status).

In particular, the Excepted Benefit HRA will benefit some of the growing number of employees who have been opting out of their employer's traditional group health plan because the employee's share of premiums is too expensive. In 1999, 17 percent of workers eligible for employer coverage at small and midsized firms (those with 3 to 199 workers) turned down the offer of employer coverage. By 2011, this share had climbed to 22 percent, and in 2018 it was 27 percent.

Note that Excepted Benefit HRAs, which can reimburse medical care expenses other than excepted benefits, are different from an HRA that reimburses only excepted benefits. Employers can continue to offer HRAs that reimburse only excepted benefits, and those HRAs need not meet the requirements for Excepted Benefit HRAs.

Association Health Plans

This section comes from the CBO Paper: INCREASING SMALL-FIRM HEALTH INSURANCE COVERAGE THROUGH ASSOCIATION HEALTH PLANS AND HEALTHMARTS, January 2000. https://www.cbo.gov/publication/12066

Numbers in the text and tables of this paper may not add up to totals because of rounding.

All dollar values are expressed as 1999 dollars. All footnotes are at the end of this section.

SUMMARY AND INTRODUCTION

The rising number of people who lack health insurance continues to be a major concern to policymakers. According to the Census Bureau's Current Population Survey, about 43 million people under age 65 were uninsured in 1997. That estimate represents about 18 percent of the nonelderly population, compared with less than 15 percent who were uninsured a decade earlier.1

Given that the primary source of private health insurance coverage in the United States is employment, one might reasonably assume that people who lack insurance also lack jobs. Yet most uninsured people are members of families with at least one full-time worker. Uninsured workers are usually employees of small firms (those with fewer than 50 employees), and small firms typically face higher costs for health insurance than do larger firms, which may make small firms less likely to offer it. In 1996, 42 percent of small-firm establishments offered health insurance to their employees (see Table 1). (An establishment is a single geographic location of a firm.)2 By contrast, more than 95 percent of establishments in firms with 100 or more employees offered insurance. Another reason for lower rates of health insurance coverage for workers in small firms is lower take-up rates when insurance is offered. In 1996, about 81 percent of employees in small firms accepted insurance coverage when it was offered by their employers, compared with 87 percent of employees in firms with at least 100 employees.3

Concerns about low rates of coverage for employees of small firms have led to a number of initiatives at both the state and federal levels as well as in the private sector. One example is the formation of group purchasing cooperatives, some private and some sponsored by state or local governments, in which firms join together to purchase insurance in larger volumes at more affordable prices. By one estimate, almost a third of small firms purchase their health insurance through some form of cooperative purchasing arrangement.4 Even so, concerns persist about the affordability of insurance coverage and the lack of sufficient alternatives for reducing its cost. Recently, the House passed H.R. 2990, the Quality Care for the Uninsured Act of 1999, which among other things calls for establishing association health plans (AHPs) and HealthMarts, two new vehicles for offering health insurance coverage to small employers. (The House passed similar legislation—H.R. 4250—in the 105th Congress, but the bill was never considered by the Senate.) Several other proposals for AHPs and HealthMarts have also been introduced in the House.5

This paper considers how the introduction of AHPs and HealthMarts would affect premiums and

coverage in the small-group health insurance market.6 (Although entities known as association health plans already exist, all of the legislative proposals would create federally certified AHPs operating under a different set of rules.) The new entities would be exempt from some state insurance regulations that apply to insurance plans offered in the small-group market. Such regulations tend to increase premiums for those traditional plans.

Currently, about 48 million people either work for a small firm or are a dependent of someone who does. Under the most likely scenario for AHPs and HealthMarts, the Congressional Budget Office (CBO) estimates that approximately 4.6 million of those people might obtain their coverage through the proposed new insurance arrangements. But overall enrollment in employer-sponsored health insurance would increase by only about 330,000 people, because most firms purchasing coverage through an AHP or HealthMart would be switching from traditional insurance coverage—that is, insurance plans subject to the full array of state insurance regulations.7 On average, premiums paid by small firms that purchased health insurance through an AHP or HealthMart would be about 13 percent lower than the premiums they would otherwise pay under current law. With AHPs and HealthMarts in place, the firms that continued to purchase traditional coverage would face an average increase in premiums of about 2 percent.

THE HEALTH INSURANCE MARKET FOR SMALL GROUPS

As noted earlier, small firms are less likely than large employers to offer health insurance coverage to their employees, and small-firm employees are less likely to take up coverage when it is offered. Factors contributing to those lower rates of coverage include the characteristics of workers in small firms, firms' costs for providing insurance benefits, and state insurance regulations.

The earnings of employees in small firms are one of the chief reasons for lower rates of health insurance coverage among small employers. Compared with employees in large firms, those in small firms tend to be paid lower wages and have lower family income, although some employees are members of households with higher-paid workers. Given their lower income, employees of small firms may be unwilling to accept the even lower wages that would result if their employer sponsored a health benefits plan. Furthermore, because lower-income workers probably have fewer assets to protect in the event of a large medical expense, they may place less value on having insurance. Their lower wages also mean that smallfirm employees have less of a tax incentive to purchase insurance than do higher-paid workers. (Because employees are not taxed on their employer's contribution for health insurance, workers in higher tax brackets gain a larger subsidy for health insurance than do workers in lower tax brackets.)8

The cost of health insurance for small firms may be another factor in their lower rates of coverage. Health insurance premiums for equivalent benefit packages are higher for small firms than for large ones. The premiums themselves do not differ consistently on the basis of firm size, but the benefit packages that large firms offer their employees are more generous than those offered by small firms.9 In addition, the administrative costs included in the premium are higher for small firms because they have fewer employees among whom to spread the fixed costs of a health benefits plan, including costs for marketing and enrollment. Premiums are also likely to be higher for small firms because they do not have as much purchasing power as large firms, which limits their ability to bargain for lower rates from providers and insurers.

State insurance regulations may also contribute to higher premiums for small firms. For example, premium compression regulations, although reducing premiums for some firms, have raised premiums for others. Because of their size, small firms may experience much greater variation than large firms in their expenses for health benefits. One employee's serious illness can dramatically boost a small firm's health expenses, and in the absence of regulatory intervention, the firm's health insurance premiums could also rise substantially (since, in general, premiums are set to reflect those expenses).10 Such significant rate variation, and even cancellation of policies, characterized the small-group market during the late 1980s.11 In response, many states imposed new regulations that guaranteed availability and renewability of insurance and limited the degree to which premiums could vary among small firms.12 In California, for example, the highest premium that an insurer may charge for a particular policy can be no more than 20 percent above its lowest premium for that policy. To comply with that kind of regulation, known as premium (or rate) compression, the insurer must increase the premiums it charges its lowest-cost, or healthiest, firms and reduce the premiums it charges its highest-cost firms. The result is cross-subsidization—the increased premiums paid by the healthiest firms are used to help pay for the expenses of less healthy firms, whose premiums are no longer high enough to cover their expected costs.

Another way in which state regulations may have boosted premiums for small firms is by mandating the inclusion of certain benefits in all health insurance plans. (In a number of states, those mandates cover treatment for alcoholism, drug abuse, and mental illness as well as chiropractic care and bone marrow transplants.) If such regulations force insurers in the small-group market to provide benefits that firms would not otherwise purchase, the mandates will, in effect, push up premiums by more than the additional coverage's value to employees. Mandates may also discourage some small employers from offering coverage, particularly firms with employees who are relatively healthy and who—given the choice—would probably forgo at least some of the mandated benefits to obtain lower premiums. Another way in which state regulations may increase premiums is through premium taxes, which are paid by insurers. In 1996, such taxes ranged from less than 1 percent to as much as 4 percent of premiums.13

Although, in principle, mandates and premium taxes affect the premiums of any firm (regardless of size) that purchases insurance from a licensed insurer, they frequently have a greater impact on small firms. The reason is that larger firms can avoid such regulations by self-insuring—that is, by bearing the financial risks of their employees' health care costs themselves rather than purchasing coverage from a health insurer or health plan. The federal Employee Retirement Income Security Act (ERISA) exempts firms' self-insured health plans from most state insurance regulations. However, small firms are less likely than large firms to self-insure because they have fewer potential enrollees (employees and their dependents) among whom to spread expenditures and as a result are vulnerable to greater financial risk (see Table 1 on page 2). Small firms that offer coverage are much more likely to purchase it from a health insurer and must therefore bear the full cost of state insurance regulation.14

ASSOCIATION HEALTH PLANS AND HEALTHMARTS

AHPs and HealthMarts are intended to reduce the cost of health insurance for small employers. Like group purchasing cooperatives, they could enhance the purchasing power of their members, and they might reduce some administrative costs. But AHPs and HealthMarts would have two additional advantages compared with cooperatives: they would be exempt from most state benefit

mandates, and they could avoid the full effect of state regulation of insurance premiums.

Association Health Plans

AHPs would operate subject to several important requirements. Trade, industry, or professional associations that had been in existence for at least three years could sponsor an AHP, which would have to offer its insurance products to all member firms. Those products could constitute a full range of health plans, including a selfinsured plan, under certain conditions: generally, the AHP would have to offer at least one fully insured plan (purchased from a licensed health insurer), and the sponsoring association would have to meet other qualifying criteria designed to limit favorable selection (attracting enrollees that are healthier than average) and the risk of financial insolvency. Both the AHP's self-insured and fully insured plans would be exempt from state benefit mandates, but they would not be exempt from state premium taxes.15

Because of their structure, AHPs would be subject in only a limited way to state laws that regulate premiums in the small-group health insurance market. In general, AHPs would have to abide by the premium-setting regulations of each state for their enrollees who resided in that state. Some states require insurers that offer small-group policies to community-rate their premiums (a practice in which the price for a given health policy must be the same for all purchasers despite variations in those purchasers' expected costs per enrollee). Other states limit the degree to which premiums for a particular policy can vary among firms. AHPs would have to follow the state's rating rules, but the premiums they offered would be based on the average expected costs per enrollee of only the association's member firms—not on the costs of the broader (and potentially more expensive) groups that insurers offering traditional coverage serve. As a result, AHP premiums are likely to be lower than they would be if they reflected the availability rules applying to traditional (fully regulated) plans.

HealthMarts

In many respects, HealthMarts would be similar to AHPs, but certain features—in particular, eligibility based on geographic location rather than association membership—would set them apart. HealthMarts would be nonprofit organizations that offered health insurance products to all small firms within their geographic service area, which would have to cover at least one county or an area of equivalent size. All of the health benefits plans that a HealthMart offered would be available to any small employer within its service area. Employers who chose to participate would have to agree to purchase health insurance only from the HealthMart. (That is, participating employers could not offer their employees plans from the traditional market in addition to HealthMart plans.)

Like AHPs, health plans offered through HealthMarts would be exempt from most state benefit mandates but would have to pay state premium taxes. HealthMarts would also be subject to state premium regulations that applied within their service area.16 Unlike AHPs, however, HealthMarts could offer only fully insured plans from insurance issuers licensed in the state; self-insurance would not be an option.

HOW AHPs AND HEALTHMARTS WOULD AFFECT PREMIUMS AND COVERAGE

The effects of AHPs and HealthMarts on the premiums of and number of people enrolled in

traditional plans would depend on the response of small firms to health insurance policies comprising fewer benefits coupled with lower premiums. Coverage might increase if AHPs and HealthMarts could offer plans with premiums that were lower than those for traditional coverage. Firms that do not currently offer insurance to their employees might choose to do so if the price was lower, even if the benefits were not as comprehensive as in some plans. Yet that response is only part of the coverage picture. Firms that already purchase traditional coverage might instead seek lower-cost coverage through an AHP or HealthMart. If the firms that dropped traditional coverage had healthier-than-average employees, and thus lower costs for insurance, fewer of those so-called low-cost firms would remain to subsidize the premiums of higher-cost firms. As a result, premiums for at least some firms purchasing traditional plans would have to rise, which could lead those firms to drop coverage.

Premiums in the AHP/HealthMart Market

AHPs and HealthMarts could offer premiums that were lower than those for traditional coverage to the extent that they were exempt from state benefit mandates and could avoid some of the effects of state premium-setting regulations. Group purchasing of health insurance through AHPs and HealthMarts could also lower the cost of health insurance for small firms if it reduced administrative costs or increased firms' purchasing power. AHP premiums might undergo further paring depending on whether a particular AHP could achieve savings through self-insurance.

Avoiding State Regulation. According to their advocates, reducing the cost of state regulation is one of the principal attractions of AHPs and HealthMarts. Unlike the purchasing cooperatives that can now be found in many states, AHPs and HealthMarts would not be subject to state benefit mandates and might also avoid some restrictions on premiums. (Box 1 briefly discusses several kinds of purchasing cooperatives.) For example, small firms could obtain lower premiums if AHPs and HealthMarts dropped some of the benefits that states required insurers to cover and offered less generous benefit packages than were available in traditional plans. The extent of such savings and their effect on premiums would depend on whether employees of small firms still desired some of those mandated benefits. Firms take into account the preferences of their employees in designing their benefit packages and will not necessarily sponsor policies that omit all mandated benefits. (One study of self-insured employers found that many of those firms offered mandated benefits despite their exemption from state regulations under ERISA.)17

Exempting AHPs and HealthMarts from offering mandated benefits might substantially affect selection. With the exemption, AHPs and HealthMarts could design benefit packages that had fewer benefits and were relatively unattractive to firms whose employees had costly health care needs. Those firms would want more extensive benefit packages and would probably maintain their enrollment in traditional (fully regulated) plans. As a result, their high health care costs would not affect the premiums offered by AHPs and HealthMarts, which might allow those plans to lower their costs by more than the savings from the mandates exemption alone. Lower-priced plans with leaner benefit packages would appeal more to healthy firms (with lower-than-average expected health care costs)—both those that offered no coverage at all to their employees and those that already offered insurance. Some firms with higher-than-average expected health costs might also be attracted by the lower premiums, but they would be less likely to participate because of the leaner benefits.

Health insurance purchase cooperatives

Health insurance purchasing cooperatives are relatively popular among small firms. A recent study estimated that 33 percent of establishments in firms with fewer than 10 employees and 28 percent of establishments in firms with 10 to 49 employees purchase health insurance through some type of group purchasing cooperative.1 Such group purchasing arrangements can be divided into three broad categories: state-sponsored health insurance purchasing alliances, multiple-employer welfare arrangements (MEWAs), and multiemployer union-sponsored plans (also known as Taft-Hartley plans).

To encourage small firms to purchase health insurance, a handful of states sponsored health insurance purchasing alliances beginning in the early 1990s.2 (An example is California's Health Insurance Purchasing Cooperative.) Typically, state alliances offer a variety of plans, including one or more managed care options, to any qualifying employer who wishes to purchase insurance through the alliance, and employees then enroll in the plan of their choice. The health plans that alliances offer are subject to normal state insurance regulations, including premium-setting rules and benefit mandates, although a few states exempt alliance plans from some of those requirements.

MEWAs can take many different forms including privately sponsored alliances, which function like the state-sponsored type, and association health plans, which can offer coverage only to members of their sponsoring association. (Those existing association health plans should not be confused with the proposed association health plans that are the focus of this paper.) The association-sponsored plans are employee benefit plans as defined by the Employee Retirement Income Security Act, or ERISA. They are more likely than purchasing alliances to offer a limited selection of health insurance options, and they can self-insure if they choose. In general, both fully insured and self-insured MEWAs are subject to state insurance regulations, including benefit mandates and premium-setting rules.

Union-sponsored plans are the only type of purchasing cooperative that does not have to adhere to state insurance regulations. Even though Taft-Hartley plans may involve many employers, ERISA classifies them separately from MEWAs and exempts them from state regulations such as benefit mandates and premium-setting rules.

There is little direct evidence about the effect of cooperatives on premiums. According to a study of a major purchasing alliance in California, the premiums that participating insurers offered to qualifying small employers were not as low as those offered to large firms.3 Long and Marquis's analysis of a national survey of small firms found that premiums for cooperatives were roughly the same as those offered by traditional plans. The advantages of alliances appear to be primarily choice and information. For about the same premium, firms purchasing their coverage through a cooperative are more likely than other small firms to offer a choice of health plans to their employees. They also have better access to information about those plans, such as the benefits offered and the quality of care provided.

In the long run, one would expect the most successful AHPs to be sponsored by associations whose members had lower-than-average health care costs. Similarly, the most successful HealthMarts would probably be located in lower-cost areas of the country or areas where the costs of regulation

and mandates were high.

Group Purchasing.

To a limited extent, the advantages offered by group purchasing might enable AHPs and HealthMarts to offer premiums that were lower than those for traditional coverage. Like other group purchasing arrangements, AHPs and HealthMarts would probably have more negotiating power with health insurers than would small employers negotiating on their own. The larger the number of potential enrollees, the more willing health insurers and provider networks would be to discount their rates to attract business. Another advantage of group purchasing that might be reflected in lower premiums would be lower administrative costs—with group purchasing, some fixed costs would be shared among a larger number of enrollees.

Savings from group purchasing, however, are unlikely to induce many small firms to add coverage, because the group purchasing option, with its associated advantages, is already available to them through purchasing cooperatives. One exception may be AHPs and HealthMarts in states that have not been particularly supportive of cooperative purchasing arrangements.

Self-Insuring Through AHPs.

Although AHPs would be able to offer self-insured plans, several factors would limit the attractiveness of that option. For example, all plans offered by AHPs, whether self-insured or fully insured, would be exempt from benefit mandates and would have to pay premium taxes. As a result, selfinsured AHP plans would offer no advantage in those areas over fully insured AHP plans.18 Other advantages of self-insuring might also go unrealized. For example, firms that self-insure can retain and earn interest on the money that they would ordinarily pay in premiums to a health insurer until the money is needed to pay medical claims.19 But small firms enrolling in an AHP's self-insured plan would still have to pay premiums to a third party—the AHP. Moreover, to curb favorableselection practices, some of the proposals being considered would restrict the selfinsurance option to AHPs sponsored by associations whose member firms had higher-than-average health expenditures or represented a broad cross-section of industries (such as a chamber of commerce).
The option to self-insure jointly with other firms is not new. ERISA already allows small firms to self-insure by joining together with other firms in so-called multiple-employer welfare arrangements (MEWAs). However, MEWAs might not be as attractive a vehicle for self-insuring as AHPs would be. Unlike AHPs, MEWAs must comply with some state regulations, including benefit mandates. In addition, some small firms may consider participation in a MEWA to be too risky. Overlapping state and federal laws have made regulating MEWAs a complicated and difficult task. According to the General Accounting Office, "MEWAs have proven to be a source of regulatory confusion, enforcement problems, and, in some instances, fraud."20 As of December 1998, the Department of Labor had initiated 358 civil and 70 criminal investigations of MEWAs that affected over 1.2 million enrollees and involved monetary violations of more than $83.6 million.21

To bypass such problems, all of the AHP proposals include requirements to facilitate effective regulation of small firms that self-insure collectively. AHPs that offered self-insured plans would be subject to federal solvency standards, including requirements to set aside adequate reserves and

to purchase stop-loss and indemnification insurance. Stop-loss insurance, which insures against the risk of unusually high claims, would apply to claims for a specific enrollee as well as aggregate claims for the plan as a whole. Indemnification insurance would pay outstanding claims if the plan was unable to meet its obligations. Thus, although self-insured AHP plans might not offer many advantages over their fully insured counterparts, they might still be more attractive to small firms than self-insuring through a MEWA.

Premiums for Traditional Insurance Plans

If firms with healthier-than-average employees switched from traditional insurance to AHPs and HealthMarts, premiums for some firms' traditional policies would rise. Moreover, that selection effect could be exacerbated by recently enacted federal requirements regarding the portability of insurance coverage. The Health Insurance Portability and Accountability Act of 1996 limits exclusions for preexisting conditions when purchasers of insurance switch from one policy to another. That provision could lead to the sorting of "healthy" and "sick" firms into AHP/HealthMart and traditional plans, respectively. For example, a firm with healthy employees (and thus relatively low expected health costs) might purchase a relatively inexpensive policy (covering few mandated benefits) in the AHP/HealthMart market. If one or more of its employees subsequently developed a serious illness, the firm could switch back to a traditional plan to obtain a more comprehensive policy, and its employees would face no exclusion (or only a limited exclusion) for preexisting conditions.22

To discourage favorable-selection practices, the proposals covering AHPs and HealthMarts generally include requirements that would limit their ability to attract healthier-than-average groups. For example, AHPs would have to offer their plans to any small firm that qualified for membership in the sponsoring association. Similarly, HealthMarts would have to make their plans available to any small firm located in their designated geographic area. A further factor tempering favorableselection efforts may be that increasingly aggressive attempts by AHPs and HealthMarts to attract low-cost firms would add to administrative costs. Moreover, premium-setting regulations would still apply.

Even if AHPs and HealthMarts were successful in attracting primarily low-cost firms, the resulting premium increases for traditional plans would be relatively small. High-cost firms would be a small minority of those firms retaining traditional coverage, even though some lower-cost firms would switch to less costly AHP or HealthMart options. The low-cost firms that continued to purchase traditional health insurance would cross-subsidize the higher-cost firms, just as they do now.

Coverage

How AHPs and HealthMarts affected coverage would depend on how small firms responded to changes in premiums and benefits and, more specifically, on the differential responses by low-cost and high-cost firms. The effect on coverage of reforms in the small-group market that were enacted by many states in the early 1990s—reforms that AHPs and HealthMarts would weaken—may provide some insight into the potential impact of the proposed new insurance vehicles. Although the reforms may have stabilized premiums and made health insurance more available in the small-group market, they may also have led to reduced coverage: between 1987 and 1996, enrollment of small-firm employees in employer sponsored health insurance declined by about 3 to

4 percentage points. 23

New insurance laws—including benefit mandates and premium compression requirements—that raised premiums for low-cost firms in the small-group market probably contributed to that loss of coverage. Benefit mandates may have caused firms to pay for benefits that their employees did not value highly. When those mandates resulted in higher-priced insurance policies, some losses in coverage probably occurred. Premium compression requirements, which lead to low-cost firms cross-subsidizing the coverage of higher-cost firms, raise the cost of insurance for firms with healthier employees and lower it for firms with less healthy employees.24 Some empirical studies suggest that because low-cost firms and their employees have less immediate need for health insurance, they may be more sensitive to price changes than high-cost firms and their employees (see the appendix). Consequently, the studies show that the number of employees in lowcost firms who dropped coverage when their premiums rose was greater than the number of employees in high-cost firms who gained coverage when their premiums fell.

The differential responses to changes in premiums by firms with different expected health care costs is key to understanding the net effect of AHPs and HealthMarts on coverage. AHPs and HealthMarts would weaken some of the effects of state premium reforms; as a result, some low-cost firms would gain access to lower premiums, but some high-cost firms would see their premiums rise.25 If, indeed, high-cost firms respond less to price changes than do low-cost firms, the resulting net coverage loss among high-cost firms would probably be less than the net coverage gain among low-cost firms, so overall coverage levels would probably increase. In addition, the mandates exemption of the AHPs and HealthMarts would allow them to offer plans with fewer benefits and at a lower price than the traditional plans can offer. The new plans are likely to be particularly attractive to low-cost firms, which would encourage some firms and workers to add coverage.

ESTIMATING THE EFFECTS OF AHPs AND HEALTHMARTS ON PREMIUMS AND COVERAGE

CBO constructed an analytical model to project how small firms and their employees would respond to the introduction of AHPs and HealthMarts. Two measures of the potential impact of those proposed new insurance arrangements are the net increase in the number of people covered by insurance and the increase in total premiums paid to insurers. The latter measure reflects both the additional people covered by insurance and the net overall changes in the value of benefits offered to people with coverage. Changes in coverage might accompany either an increase or decrease in the total premiums paid. The estimates reported here indicate the long-term changes in premiums and coverage that would occur after the market had fully adjusted to the introduction of AHPs and HealthMarts.

Main Findings

The model's main findings rely on assumptions that were developed from the results of empirical studies about how firms and employees respond to changes in premiums and insurance regulations (see the appendix for details). Under those assumptions, the introduction of AHPs and HealthMarts would increase net coverage through small firms by about 1.3 percent, or 330,000 people, including employees and their dependents (see Table 2). The increase in the overall number of people with

insurance, however, would be slightly lower, because some of those who gained employer-sponsored coverage through AHPs and HealthMarts would have otherwise obtained coverage through the individual market. The 330,000 figure represents a net increase of about 340,000 enrollees among low-cost firms that would be slightly offset by a net drop of 10,000 people among higher-cost firms. (For these estimates, low-cost firms are those with expected claims costs per enrollee in the lower 90 percent of the distribution for all small firms.) Altogether, CBO estimates that about 4.6 million people would be insured through AHPs and HealthMarts, with most of those people switching from the fully regulated market to the new plans.

Once AHPs and HealthMarts were in full operation, total premiums paid annually by small firms and their employees would be approximately $150 million more than they otherwise would be, which represents about a 0.3 percent increase in total spending for health insurance in the small-group market (see Table 3). Firms that continued to purchase traditional health insurance plans would pay an additional $800 million in premiums. That increase would be more than offset by the $1.2 billion in net premium savings that would result because firms faced lower premiums in AHP and HealthMart plans. In addition, the net increase in coverage among low-cost firms would add $600 million in premiums; among higher-cost firms, the increase in the price of traditional plans would lead to a cut of about $50 million worth of coverage.

The price of a policy would be lower for some firms as a result of introducing AHPs and HealthMarts. On average, premiums paid by firms that participated in AHPs and HealthMarts would be about 13 percent lower than the premiums they would pay in the small-group market under current law (see Table 4). Five percentage points of that reduction come from the benefit mandate exemption and savings from group purchasing (see the appendix). The other 8 percentage points stem from the expected health costs of firms in the AHP and HealthMart market that are generally lower than average and that allow participating firms to avoid some of the premium-boosting effects of rate compression laws.

Once AHPs and HealthMarts became available, firms that continued to purchase traditional plans would, on average, see some increases in their premiums arising from the shift of some low-cost firms to the new insurance vehicles. CBO's projections indicate a net transfer of approximately 4.3 million enrollees in low-cost firms from fully regulated plans to an AHP or HealthMart plan. Those transfers would cause premiums offered to firms with traditional coverage to rise, on average, by 2 percent. The increase is relatively small because low-cost firms would continue to be a substantial part of the market for traditional plans.

Findings Under Alternative Assumptions

To determine a plausible range of possible outcomes once AHPs and HealthMarts were introduced, CBO varied its assumptions about the behavioral responses of firms and employees (see the appendix). At one extreme, the model estimated that coverage through small firms would increase by only 10,000 enrollees. That figure is associated with a negligible increase in premiums for small firms purchasing traditional insurance and a 9 percent reduction in premiums for participants in AHPs and HealthMarts. At the upper end of the range, the model estimated that coverage could increase by as many as 2 million people. The accompanying changes in premiums would be an increase of 2 percent for firms retaining traditional coverage and a reduction of 25 percent for firms participating in AHPs and HealthMarts. Under those alternative scenarios, the total number of

enrollees in AHPs and HealthMarts ranges from less than 1 million to 5.7 million.

CONCLUSIONS

CBO projects that the introduction of AHPs and HealthMarts would have only slight effects on insurance coverage nationwide, increasing the number of people insured through small firms by about 330,000. Although about 4.6 million people would enroll in the new plans, the net boost in the number of people insured through small firms would be far smaller because many enrollees in the new plans would otherwise have been insured through traditional plans and because the increase in enrollees from some firms (those that gained coverage through AHPs and HealthMarts) would be offset by the decrease in enrollees from others (those that dropped their traditional coverage). Although coverage among small firms would grow by about 1.3 percent, total spending for health insurance would actually rise by only 0.3 percent, for two reasons: some coverage would be less comprehensive—because AHPs and HealthMarts are exempt from most statemandated benefit requirements—and the mix of low-cost and high-cost firms with coverage would change.

If low-cost firms moved to AHPs and HealthMarts, some firms with traditional coverage would see their premiums rise because fewer low-cost firms would remain to cross-subsidize the high-cost firms. In response, some firms and workers covered under traditional plans would drop coverage, but most would continue to be covered and pay slightly higher premiums. After summing the changes in enrollment in both AHP/HealthMart and traditional plans, CBO estimates that, on balance, high-cost firms would drop coverage and low-cost firms would add coverage. Consequently, among firms that have coverage, the proportion of low-cost firms would increase, and the share of high-cost firms would decrease.

Among the states, the impact of AHPs and HealthMarts would probably be uneven because states differ in the extent and intensity of their regulations. States that have imposed relatively strict premium compression rules would be likely to attract more of the new plans than states that allow insurers to charge a wider range of premiums. The reason is that in states with more tightly compressed premiums—where the most cross-subsidization occurs—low-cost firms would face the greatest potential difference in price between traditional and AHP/HealthMart plans. Similarly, states with benefit mandates that are more costly or that cover benefits perceived as having little value to the average employee would be riper markets for AHPs and HealthMarts, as would areas with greater concentrations of small firms. In addition to considering who would gain and who would lose under these proposed new insurance arrangements, policymakers must address issues of regulatory authority and solvency standards. Much uncertainty attends the overlapping of federal and state jurisdiction over AHPs and HealthMarts. States, for example, would exercise considerable regulatory authority over HealthMart plans—which could only be fully insured products offered by state-licensed insurers. But the Department of Health and Human Services would also be given regulatory authority over HealthMarts. States would have some authority over AHPs but might rely on the Department of Labor to oversee those plans—especially since self-insured AHPs would have to comply with federal solvency standards. How great a role the federal government or the states played in regulating the new entities would depend, in part, on the resources that the two designated federal oversight agencies devoted to that function.

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

Chapter 5

Biden's Build Back Better Proposals

In late 2021, the Biden administration introduced the Build Back Better program to address climate change, various social equity issues and improve the Affordable Care Act. The ultimate fate of each component is unclear as of the publication date of this text. Below, we summarize the Affordable Care Act section of the Plan as passed by the US House of Representatives on November 19, 2021.

Read this as the Biden administration's vision for healthcare reform.

The summary below comes from KFF, the Kaiser Family Foundation article Potential Costs and Impact of Health Provisions in the Build Back Better Act | KFF

Major Provisions of the Build Back Better Act and their Potential Costs and Impact

1. ACA Marketplace Subsidies

BACKGROUND

Under the Affordable Care Act, people purchasing Marketplace coverage could only qualify for subsidies if they met other eligibility requirements and had incomes between one and four times the federal poverty level. People eligible for subsidies would have to contribute a sliding-scale percentage of their income toward a benchmark premium, ranging from 2.07% to 9.83%. Once income passed 400% FPL, subsidies stopped and many individuals and families were unable to afford coverage.

In 2021, the American Rescue Plan Act (ARPA) temporarily expanded eligibility for subsidies by removing the upper income threshold. It also temporarily increased the dollar value of premium subsidies across the board, meaning nearly everyone on the Marketplace paid lower premiums, and the lowest income people pay ***zero*** premium for coverage with very low deductibles. The ARPA also made people who received unemployment insurance (UI) benefits during 2021 eligible for zero-premium, low-deductible plans.

However, the ARPA provisions removing the upper income threshold and increasing tax credit amounts are only in effect for 2021 and 2022. The unemployment provision is only in effect for 2021.

PROVISION DESCRIPTION

Section 137301 of The Build Back Better Act would extend the ARPA subsidy changes that eliminate the income eligibility cap and increase the amount of APTC for individuals across the board through the end of 2025.

Additionally, Section 30605 of The Build Back Better Act would extend the special Marketplace subsidy rule for individuals receiving UI benefits for an additional 4 years, through the end of 2025.

Section 137303 of the Act would, for purposes of determining eligibility for premium tax credits, disregard any lump sum Social Security benefit payments in a year. This provision would be permanent and effective starting in the 2022 tax year. Starting in 2026, people would have the option to have the lump sum benefit included in their income for purposes of determining tax credit eligibility.

Finally, Section 137302 modifies the affordability test for employer-sponsored health coverage. The ACA makes people ineligible for marketplace subsidies if they have an offer of affordable coverage from an employer, currently defined as requiring an employee contribution of no more than 9.61% of household income in 2022. The Build Back Better Act would reduce this affordability threshold to 8.5% of income, bringing it in line with the maximum contribution required to enroll in the benchmark marketplace plan. This provision would take effect for tax years starting in 2022 through 2025. Thereafter the affordability threshold would be set at 9.5% of household income with no indexing.

PEOPLE AFFECTED

CBO projects that the enhanced tax credits in Section 137301 would reduce the number of uninsured by 1.2 million people. As of August 2021, 12.2 million people were actively enrolled in Marketplace plans – an 8% increase from 11.2 million people enrollees as of the close of Open Enrollment for the 2021 plan year. HealthCare.gov and all state Marketplaces reopened for a special enrollment period of at least 6 months in 2021, enrolling 2.8 million people (not all of whom were necessarily previously uninsured). Of these, 44% selected plans with monthly premiums of $10 or less.

The US Department of Health and Human Services (HHS) reports that ARPA reduced Marketplace premiums for the 8 million existing Healthcare.gov enrollees by $67 per month, on average. If the ARPA subsidies are allowed to expire, these enrollees will likely see their premium payments double.

HHS also reports that between July 1 and August 15, more than 280,000 individuals received enhanced subsidies due to the ARPA UI provisions. Individuals eligible for these UI benefits can continue to enroll in 2021 coverage through the end of this year.

The ARPA changes made people with income at or below 150% FPL eligible for zero-premium silver plans with comprehensive cost sharing subsidies. 40% of new consumers who signed up during the SEP are in a plan that covers 94% of expected costs (with average deductibles below $200). As a result of the ARPA, HHS reports the median deductible for new consumers selecting plan during the COVID-SEP decreased by more than 90% (from $750 in 2020 to $50 in 2021).

With the ARPA and ACA subsidies, as well as Medicaid in states that expanded the program, we estimate that at least 46% of non-elderly uninsured people in the U.S. are eligible for free or nearly-free health plans, often with low or no deductibles.

BUDGETARY IMPACT

CBO estimates that extension of the ARPA marketplace subsidy improvements through 2025 (Section 13701) will cost $73.9 billion over the ten-year budget window, with "cost" reflecting both direct spending and on-budget revenue losses. This total also includes the cost of modifying the affordability threshold for employer-sponsored coverage (Section 13602)

CBO further estimates the cost of extending the enhanced marketplace subsidies for people receiving unemployment benefits (Section 13705) will be $1.8 billion over the ten-year budget window.

The cost of disregarding lump sum Social Security benefits payments for purposes of determining premium tax credit eligibility (Section 13703) is $416 million over the ten-year budget window.

2. New Medicare Hearing Benefit

BACKGROUND

Medicare currently does not cover hearing services, except under limited circumstances, such as cochlear implantation when beneficiaries meet certain eligibility criteria. Hearing services are typically offered as an extra benefit by Medicare Advantage plans, and in 2021, 97% of Medicare Advantage enrollees in individual plans, or 17.1 million people, are offered some hearing benefits, but according to our analysis, the extent of that coverage and the value of these benefits varies. Some beneficiaries in traditional Medicare may have private coverage or coverage through Medicaid for these services, but many do not.

PROVISION DESCRIPTION

Section 30901 of the Build Back Better Act would add coverage of hearing services to Medicare Part B, beginning in 2023. Coverage for hearing care would include hearing rehabilitation and treatment services by qualified audiologists, and hearing aids. Hearing aids would be available once per ear, every 5 years, to individuals diagnosed with moderately severe, severe, or profound hearing loss. Hearing services would be subject to the Medicare Part B deductible and 20% coinsurance. Hearing aids would be covered similar to other Medicare prosthetic devices and would also be subject to the Part B deductible and 20% coinsurance. For people in traditional Medicare who have other sources of coverage such as Medigap or Medicaid, their cost sharing for these services might be covered. Payment for hearing aids would only be on an assignment-related basis. As with other Medicare-covered benefits, Medicare Advantage plans would be required to cover these hearing benefits.

Effective Date: The Medicare hearing benefit provision would take effect in 2023.

PEOPLE AFFECTED

Adding coverage of hearing services, including hearing aids, to Medicare would help beneficiaries with hearing loss who might otherwise go without treatment by an audiologist or hearing aids, particularly those who cannot afford the cost of hearing aids. It would also lower out-of-pocket costs for some beneficiaries who would otherwise pay the full cost of their hearing aids without the benefit.

Among beneficiaries who used hearing services in 2018, average out-of-pocket spending according to our analysis was $914, although many hearing aids are considerably more expensive than the average.

While the majority of enrollees in Medicare Advantage plans have access to a hearing benefit, a new defined Medicare Part B benefit could also lead to enhanced and more affordable hearing benefits for Medicare Advantage enrollees. Because costs are often a barrier to care, adding this benefit to Medicare could increase use of these services, and contribute to better health outcomes.

BUDGETARY IMPACT

CBO estimates that the new Medicare Part B hearing benefit would increase federal spending by $36.7 billion over 10 years (2022-2031).

3. Lowering Prescription Drug Prices and Spending

BACKGROUND

Currently, under the Medicare Part D program, which covers retail prescription drugs, Medicare contracts with private plan sponsors to provide a prescription drug benefit. The law that established the Part D benefit includes a provision known as the "noninterference" clause, which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." For drugs administered by physicians that are covered under Medicare Part B, Medicare reimburses providers 106% of the Average Sales Price (ASP), which is the average price to all non-federal purchasers in the U.S, inclusive of rebates, A recent KFF Tracking Poll finds large majorities support allowing the federal government to negotiate and this support holds steady even after the public is provided the arguments being presented by parties on both sides of the legislative debate (83% total, 95% of Democrats, 82% of independents, and 71% of Republicans).

In addition to the inability to negotiate drug prices under Part D, Medicare lacks the ability to limit annual price increases for drugs covered under Part B (which includes those administered by physicians) and Part D. In contrast, Medicaid has an inflationary rebate in place. Year-to-year drug price increases exceeding inflation are not uncommon and affect people with both Medicare and private insurance. Our analysis shows that half of all covered Part D drugs had list price increases that exceeded the rate of inflation between 2018 and 2019.

PROVISION DESCRIPTION

Drug Price Negotiations. Sections 139001, 139002, and 139003 of the Build Back Better Act would amend the non-interference clause by adding an exception that would allow the federal government to negotiate prices with drug companies for a small number of high-cost drugs lacking generic or biosimilar competitors covered under Medicare Part B and Part D. The negotiation process would apply to no more than 10 (in 2025), 15 (in 2026 and 2027), and 20 (in 2028 and later years) single-source brand-name drugs lacking generic or biosimilar competitors, selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending (for 2027 and later years). The negotiation process would also apply to all insulin products.

The legislation exempts from negotiation drugs that are less than 9 years (for small-molecule drugs) or 13 years (for biological products, based on the Manager's Amendment) from their FDA-approval or licensure date. The legislation also exempts "small biotech drugs" from negotiation until 2028, defined as those which account for 1% or less of Part D or Part B spending and account for 80% or more of spending under each part on that manufacturer's drugs.

The proposal establishes an upper limit for the negotiated price (the "maximum fair price") equal to a percentage of the non-federal average manufacturer price: 75% for small-molecule drugs more than 9 years but less than 12 years beyond approval; 65% for drugs between 12 and 16 years beyond approval or licensure; and 40% for drugs more than 16 years beyond approval or licensure. Part D drugs with prices negotiated under this proposal would be required to be covered by all Part D plans. Medicare's payment to providers for Part B drugs with prices negotiated under this proposal would be 106% of the maximum fair price (rather than 106% of the average sales price under current law).

An excise tax would be levied on drug companies that do not comply with the negotiation process, and civil monetary penalties on companies that do not offer the agreed-upon negotiated price to eligible purchasers.

Effective Date: The negotiated prices for the first set of selected drugs (covered under Part D) would take effect in 2025. For drugs covered under Part B, negotiated prices would first take effect in 2027.

Inflation Rebates. Sections 139101 and 139102 of the Build Back Better Act would require drug manufacturers to pay a rebate to the federal government if their prices for single-source drugs and biologicals covered under Medicare Part B and nearly all covered drugs under Part D increase faster than the rate of inflation (CPI-U). Under these provisions, price changes would be measured based on the average sales price (for Part B drugs) or the average manufacturer price (for Part D drugs). For price increase higher than inflation, manufacturers would be required to pay the difference in the form of a rebate to Medicare. The rebate amount is equal to the total number of units multiplied by the amount if any by which the manufacturer price exceeds the inflation-adjusted payment amount, including all units sold outside of Medicaid and therefore applying not only to use by Medicare beneficiaries but by privately insured individuals as well. Rebate dollars would be deposited in the Medicare Supplementary Medical Insurance (SMI) trust fund.

Manufacturers that do not pay the requisite rebate amount would be required to pay a penalty equal to at least 125% of the original rebate amount. The base year for measuring price changes is 2021.

Effective Date: These provisions would take effect in 2023.

Limits on Cost Sharing for Insulin Products. Sections 27001, 30604, 137308, and 139401 would require insurers, including Medicare Part D plans and private group or individual health plans, to charge no more than $35 for insulin products. Part D plans would be required to charge no more than $35 for whichever insulin products they cover for 2023 and 2024 and all insulin products beginning in 2025. Coverage of all insulin products would be required beginning in 2025 because the drug negotiation provision (described earlier) would require all Part D plans to cover all drugs that are selected for price negotiation, and all insulin products are subject to negotiation under that provision. Private group or individual plans do not have to cover all insulin products, just one of each dosage form (vial, pen) and insulin type (rapid-acting, short-acting, intermediate-acting, and long-acting) for no more than $35.

Effective Date: These provisions would take effect in 2023.

Vaccines. Section 139402 would require that adult vaccines covered under Medicare Part D that are recommended by the Advisory Committee on Immunization Practices (ACIP), such as for shingles, be covered at no cost. This would be consistent with coverage of vaccines under Medicare Part B, such as the flu and COVID-19 vaccines.

Effective Date: This provision would take effect in 2024.

Repealing the Trump Administration's Drug Rebate Rule. Section 139301 would prohibit implementation of the November 2020 final rule issued by the Trump Administration that would have eliminated rebates negotiated between drug manufacturers and pharmacy benefit managers (PBMs) or health plan sponsors in Medicare Part D by removing the safe harbor protection currently extended to these rebate arrangements under the federal anti-kickback statute. This rule was slated to take effect on January 1, 2022, but the Biden Administration delayed implementation to 2023 and the infrastructure legislation passed by the House and Senate includes a further delay to 2026.

Effective Date: This provision would take effect in 2026.

PEOPLE AFFECTED

The number of Medicare beneficiaries and privately insured individuals who would see lower out-of-pocket drug costs in any given year under these provisions would depend on how many and which drugs were subject to the negotiation process, and how many and which drugs had lower price increases, and the magnitude of price reductions relative to current prices under each provision.

Neither CBO nor the Biden Administration have published estimates of beneficiary premium and out-of-pocket budget effects associated with the provision to allow the HHS Secretary to negotiate drug prices. An earlier version of the negotiations proposal in H.R.3 that passed the House of Representatives in 2019 would have lowered cost sharing for Part D enrollees by $102.6 billion in the aggregate (2020-2029) and Part D premiums for Medicare beneficiaries by $14.3 billion. Based on our analysis of the H.R. 3 version of this provision, the negotiations provision in H.R. 3 would have reduced Medicare Part D premiums for Medicare beneficiaries by an estimated 9% of the Part D base beneficiary premium in 2023 and by as much as 15% in 2029. However, the effects on beneficiary premiums and cost sharing under the drug negotiation provision in the BBBA are expected to be more modest than the effects of H.R. 3 due to the smaller number of drugs eligible for negotiation and a different method of calculating the maximum fair price.

While it is expected that some people would face lower cost sharing under these provisions, it is also possible that drug manufacturers could respond to the inflation rebate by increasing launch prices for new drugs. In this case, some individuals could face higher out-of-pocket costs for new drugs that come to market, with potential spillover effects on total costs incurred by payers as well.

In terms of insulin costs, a $35 cap on monthly cost sharing for insulin products could lower out-of-pocket costs for many insulin users with private insurance and those in Medicare Part D without low-income subsidies. While formulary coverage and tier placement of insulin products vary across Medicare Part D plans, our analysis shows that in 2019, a large number of Part D plans placed insulin products on Tier 3, the preferred drug tier, which typically had a $47 copayment per prescription during the initial coverage phase. However, once enrollees reach the coverage gap phase, they face

a 25% coinsurance rate, which equates to $100 or more per prescription in out-of-pocket costs for many insulin therapies, unless they qualify for low-income subsidies. Paying a flat $35 copayment rather than 25% coinsurance could reduce out-of-pocket costs for many people with diabetes who use insulin products.

In terms of vaccines, providing for coverage of adult vaccines under Medicare Part D at no cost could help with vaccine uptake among older adults and would lower out-of-pocket costs for those who need Part D-covered vaccines. Our analysis shows that in 2018, Part D enrollees without low-income subsidies paid an average of $57 out-of-pocket for each dose of the shingles shot, which is generally free to most other people with private coverage.

BUDGETARY IMPACT

Drug Price Negotiations. CBO estimates $78.8 billion in Medicare savings over 10 years (2022-2031) from the drug negotiation provisions.

Inflation Rebates. CBO estimates a net federal deficit reduction of $83.6 billion over 10 years (2022-2031) from the drug inflation rebate provisions in the BBBA. This includes net savings of $49.4 billion ($61.8 billion in savings to Medicare and $7.7 billion in savings for other federal programs, such as DoD, FEHB, and subsides for ACA Marketplace coverage, offset by $20.1 billion in additional Medicaid spending) and higher federal revenues of $34.2 billion.

Limits on Cost Sharing for Insulin Products. CBO estimates additional federal spending of $1.4 billion ($0.9 billion for Medicare and $0.5 billion in other federal spending) and a reduction in federal revenues of $4.6 billion over 10 years associated with the insulin cost-sharing limits in the BBBA.

Vaccines. CBO estimates that this provision would increase federal spending by $3.3 billion over 10 years (2022-2031).

Repealing the Trump Administration's Drug Rebate Rule. Because the rebate rule was finalized (although not implemented), its cost has been incorporated in CBO's baseline for federal spending. Therefore, repealing the rebate rule is expected to generate savings. CBO estimates savings of $142.6 billion from the repeal of the Trump Administration's rebate rule between 2026 (when the BBBA provision takes effect) and 2031. In addition, CBO estimated savings of $50.8 billion between 2023 and 2026 for the three-year delay of this rule included in the Infrastructure Investment and Jobs Act.

4. Medicare Part D Benefit Redesign

BACKGROUND

Medicare Part D currently provides catastrophic coverage for high out-of-pocket drug costs, but there is no limit on the total amount that beneficiaries pay out-of-pocket each year. Medicare Part D enrollees with drug costs high enough to exceed the catastrophic coverage threshold are required to pay 5% of their total drug costs unless they qualify for Part D Low-Income Subsidies (LIS). Medicare pays 80% of total costs above the catastrophic threshold and plans pay 15%. Medicare's reinsurance payments to Part D plans now account for close to half of total Part D spending (45%), up from 14% in 2006.

Under the current structure of Part D, there are multiple phases, including a deductible, an initial coverage phase, a coverage gap phase, and the catastrophic phase. When enrollees reach the coverage

gap benefit phase, they pay 25% of drug costs for both brand-name and generic drugs; plan sponsors pay 5% for brands and 75% for generics; and drug manufacturers provide a 70% price discount on brands (there is no discount on generics). Under the current benefit design, beneficiaries can face different cost sharing amounts for the same medication depending on which phase of the benefit they are in, and can face significant out-of-pocket costs for high-priced drugs because of coinsurance requirements and no hard out-of-pocket cap.

PROVISION DESCRIPTION

Sections 139201 and 139202 of the Build Back Better Act amend the design of the Part D benefit by adding a hard cap on out-of-pocket spending set at $2,000 in 2024, increasing each year based on the rate of increase in per capita Part D costs. It also lowers beneficiaries' share of total drug costs below the spending cap from 25% to 23%. It also lowers Medicare's share of total costs above the spending cap ("reinsurance") from 80% to 20% for brand-name drugs and to 40% for generic drugs; increases plans' share of costs from 15% to 60% for both brands and generics; and adds a 20% manufacturer price discount on brand-name drugs. Manufacturers would also be required to provide a 10% discount on brand-name drugs in the initial coverage phase (below the annual out-of-pocket spending threshold), instead of a 70% price discount.

The legislation also increases Medicare's premium subsidy for the cost of standard drug coverage to 76.5% (from 74.5% under current law) and reduces the beneficiary's share of the cost to 23.5% (from 25.5%). The legislation also allows beneficiaries the option of smoothing out their out-of-pocket costs over the year rather than face high out-of-pocket costs in any given month.

Effective Date: The Part D redesign and premium subsidy changes would take effect in 2024. The provision to smooth out-of-pocket costs would take effect in 2025.

PEOPLE AFFECTED

Medicare beneficiaries in Part D plans with relatively high out-of-pocket drug costs are likely to see substantial out-of-pocket cost savings from this provision. While most Part D enrollees have not had out-of-pocket costs high enough to exceed the catastrophic coverage threshold in a single year, the likelihood of a Medicare beneficiary incurring drug costs above the catastrophic threshold increases over a longer time span.

Our analysis shows that in 2019, nearly 1.5 million Medicare Part D enrollees had out-of-pocket spending above the catastrophic coverage threshold. Looking over a five-year period (2015-2019), the number of Part D enrollees with out-of-pocket spending above the catastrophic threshold in at least one year increases to 2.7 million, and over a 10-year period (2010-2019), the number of enrollees increases to 3.6 million.

Based on our analysis, 1.2 million Part D enrollees in 2019 incurred annual out-of-pocket costs for their medications above $2,000 in 2019, averaging $3,216 per person. Based on their average out-of-pocket spending, these enrollees would have saved $1,216, or 38% of their annual costs, on average, if a $2,000 cap had been in place in 2019. Part D enrollees with higher-than-average out-of-pocket costs could save substantial amounts with a $2,000 out-of-pocket spending cap. For example, the top 10% of beneficiaries (122,000 enrollees) with average out-of-pocket costs for their medications

above $2,000 in 2019 – who spent at least $5,348 – would have saved $3,348 (63%) in out-of-pocket costs with a $2,000 cap.

BUDGETARY IMPACT

CBO estimates the benefit redesign and smoothing provisions of the BBBA would reduce federal spending by $1.5 billion over 10 years (2022-2031), which consists of $1.6 billion in lower spending associated with Part D benefit redesign and $0.1 billion in higher spending associated with the provision to smooth out-of-pocket costs.

5. Medicaid Coverage Gap

BACKGROUND

There are currently 12 states that have not adopted the ACA provision to expand Medicaid to adults with incomes through 138% of poverty. The result is a coverage gap for individuals whose below-poverty-level income is too high to qualify for Medicaid in their state, but too low to be eligible for premium subsidies in the ACA Marketplace.

PROVISION DESCRIPTION

Section 137304 of the Build Back Better Act would allow people living in states that have not expanded Medicaid to purchase subsidized coverage on the ACA Marketplace for 2022 through 2025. The federal government would fully subsidize the premium for a benchmark plan. People would also be eligible for cost sharing subsidies that would reduce their out-of-pocket costs to 1% of overall covered health expenses on average.

Section 30608 includes adjustments to uncompensated care (UCC) pools and disproportionate share hospital (DSH) payments for non-expansion states. These states would not be able draw down federal matching funds for UCC amounts for individuals who could otherwise qualify for Medicaid expansion, and their DSH allotments would be reduced by 12.5% starting in 2023.

Section 30609 would increase the federal match rate for states that have adopted the ACA Medicaid expansion from 90% to 93% from 2023 through 2025, designed to discourage states from dropping current expansion coverage.

PEOPLE AFFECTED

We estimate that 2.2 million uninsured people with incomes under poverty fall in the “coverage gap”. Most in the coverage gap are concentrated in four states (TX, FL, GA and NC) where eligibility levels for parents in Medicaid are low, and there is no coverage pathway for adults without dependent children. Half of those in the coverage gap are working and six in 10 are people of color.

CBO estimates that provisions to address the coverage gap would result in 1.7 million fewer uninsured people.

BUDGETARY IMPACT

CBO estimates that the net federal cost of extending Marketplace coverage to certain low-income people would increase federal spending by $57 billion over the next decade (this reflects $43.8 billion in federal costs and a loss of federal revenues of $13.2 billion).

CBO estimates provisions to limit DSH and uncompensated care pool funding for non-expansion states would reduce federal costs by $18.3 billion over 5 years and $34.5 billion over the next 10 years and federal costs would increase by $10.4 billion due to the increase in the match rate for current expansion states from 90% to 93% for expansion states for 2023 through 2025.

6. Maternity Care and Postpartum Coverage

BACKGROUND

Medicaid currently covers almost half of births in the U.S. Federal law requires that pregnancy-related Medicaid coverage last through 60 days postpartum. After that period, some may qualify for Medicaid through another pathway, but others may not qualify, particularly in non-expansion states. In an effort to improve maternal health and coverage stability and to help address racial disparities in maternal health, a provision in the American Rescue Plan Act (ARPA) of 2021 gives states a new option to extend Medicaid postpartum coverage to 12 months. This new option takes effect on April 1, 2022 and is available to states for five years.

PROVISION DESCRIPTION

Section 30721 of the Build Back Better Act would require states to extend Medicaid postpartum coverage from 60 days to 12 months, ensuring continuity of Medicaid coverage for postpartum individuals in all states. This requirement would take effect in the first fiscal quarter beginning one year after enactment and also applies to state CHIP programs that cover pregnant individuals.

Section 30722 would create a new option for states to coordinate care for Medicaid-enrolled pregnant and post-partum individuals through a maternal health home model. States that take up this option would receive a 15% increase in FMAP for care delivered through maternal health homes for the first two years. States that are interested in pursuing this new option can receive planning grants prior to implementation.

Sections 31031 through 31048 of the Build Back Better Act provide federal grants to bolster other aspects of maternal health care. The funds would be used to address a wide range of issues, such as addressing social determinants of maternal health; diversifying the perinatal nursing workforce, expanding care for maternal mental health and substance use, and supporting research and programs that promote maternal health equity.

PEOPLE AFFECTED

Largely in response to the new federal option, at least 26 states have taken steps to extend Medicaid postpartum coverage. Pregnant people in non-expansion states could see the biggest change as they are more likely than those in expansion states to become uninsured after the 60-day postpartum coverage period. For example, in Alabama, the Medicaid eligibility level for pregnant individuals is 146% FPL, but only 18% FPL (approximately $4,000/year for a family of three) for parents.

Some states have piloted maternal health homes and seen positive impacts on health outcomes. The federal grant provisions related to maternal health could affect care for all persons giving birth, but the focus of these proposals is on reducing racial and ethnic inequities. There were approximately 3.7 million births in 2019, and nearly half were to women of color. There are approximately 700-800 pregnancy-related deaths annually, with the rate 2-3 times higher among Black and American Indian

and Alaska Native women compared to White women. Additionally, there are stark racial and ethnic disparities in other maternal and health outcomes, including preterm birth and infant mortality.

BUDGETARY IMPACT

CBO estimates that requiring 12 month postpartum coverage in Medicaid and CHIP would have a net federal cost of $1.2 billion over 10 years (new costs of $2.2 billion offset by new revenues of $1.0 billion. CBO estimates that the option to create a maternal health home would increase federal spending by $1.0 billion over 10 years.

CBO estimates that federal outlays for the grant sections in the Build Back Better Act related to maternal health care outside of the postpartum extension and maternal health homes are $1.1 billion.

7. Other Medicaid and Children's Health Insurance (CHIP) Changes

BACKGROUND

Under current law, states have the option to provide 12-months of continuous coverage for children. Under this option, states allow a child to remain enrolled for a full year unless the child ages out of coverage, moves out of state, voluntarily withdraws, or does not make premium payments. As such, 12-month continuous eligibility eliminates coverage gaps due to fluctuations in income over the course of the year.

To help support states and promote stability of coverage during the COVID-19 pandemic, the Families First Coronavirus Response Act (FFCRA) provides a 6.2 percentage point increase in the federal share of certain Medicaid spending, provided that states meet maintenance of eligibility (MOE) requirements that include ensuring continuous coverage for current enrollees.

Under current law, Medicaid is the base of coverage for low-income children. CHIP complements Medicaid by covering uninsured children in families with incomes above Medicaid eligibility levels. Unlike Medicaid, federal funding for CHIP is capped and provided as annual allotments to states. CHIP funding is authorized through September 30, 2027. While CHIP generally has bipartisan support, during the last reauthorization funding lapsed before Congress reauthorized funding.

PROVISION DESCRIPTION

Section 30741 of the Build Back Better Act would require states to extend 12-month continuous coverage for children on Medicaid and CHIP.

Section 30741 of the Build Back Better Act would phase out the FFCRA enhanced federal funding to states. States would continue to receive the 6.2 percentage point increase through March 31, 2022, followed by a 3.0 percentage point increase from April 1, 2022 through June 30, 2022, and a 1.5 percentage point increase from July 1, 2022 through September 30, 2022.

Section 30741 also would modify the FFCRA MOE requirement for continuous coverage. From April 1 through September 30, 2022, states could continue receiving the enhanced federal matching funds if they only terminate coverage for individuals who are determined no longer eligible for Medicaid and have been enrolled at least 12 consecutive months. The legislation includes other rules for states about conducting eligibility redeterminations and when states can terminate coverage.

Section 30801 of the Build Back Better Act would permanently extend the CHIP program.

PEOPLE AFFECTED

As of May 2021, there were 39 million children enrolled in Medicaid and CHIP (nearly half of all enrollees). As of January 2020, 34 states provide 12-month continuous eligibility to at least some children in either Medicaid or CHIP. A recent MACPAC report found that the overall mean length of coverage for children in 2018 was 11.7 months, and also that rates of churn (in which children disenroll and reenroll within a short period of time) were lower in states that had adopted the 12-month continuous coverage option and in states that did not conduct periodic data checks. Another recent report shows that children with gaps in coverage during a year are more likely to be children of color with lower incomes.

As of May 2021, there were 6.9 million people (mostly children) enrolled in CHIP.

BUDGETARY IMPACT

CBO estimates that Section 30741 would reduce federal costs by a net $3.5 billion over 10 years. This 10 year number reflects $17.1 billion in federal savings in FY 2022 that is likely related to the provisions to end the enhanced fiscal relief and the continuous coverage requirements and then federal costs starting in FY 2024. CBO estimates that permanently extending the CHIP program would reduce federal costs by $1.2 billion over 10 years.

8. Other Medicaid Financing and Benefit Changes

BACKGROUND

Unlike in the 50 states and D.C., annual federal funding for Medicaid in the U.S. Territories is subject to a statutory cap and fixed matching rate. The funding caps and match rates have been increased by Congress in response to emergencies over time.

Vaccines are an optional benefit for certain adult populations, including low-income parent/caretakers, pregnant women, and persons who are eligible based on old age or a disability. For adults enrolled under the ACA's Medicaid expansion and other populations for whom the state elects to provide an "alternative benefit plan," their benefits are subject to certain requirements in the ACA, including coverage of vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) with no cost sharing.

Under the Families First Coronavirus Response Act, coverage of testing and treatment for COVID-19, including vaccines, is required with no cost sharing in order for states to access temporary enhanced federal funding for Medicaid which is tied to the public health emergency. The American Rescue Plan Act (ARPA) clarified that coverage of COVID-19 vaccines and their administration, without cost sharing, is required for nearly all Medicaid enrollees, through the last day of the 1st calendar quarter beginning at least 1 year after the public health emergency ends. The ARPA also provides 100% federal financing for this coverage.

PROVISION DESCRIPTION

Section 30731 of the Build Back Better Act would increase the Medicaid cap amount and match rate for the territories. The FMAP would be permanently adjusted to 83% for the territories beginning in FY 2022, except that Puerto Rico's match rate would be 76% in FY 2022 before increasing to 83%

in FY 2023 and subsequent years. The legislation would also require a payment floor for certain physician services in Puerto Rico with a penalty for failure to establish the floor.

Section 30751 of the Build Back Better Act would establish a 3.1 percentage point FMAP reduction from October 1, 2022 through December 31, 2025 for states that adopt eligibility standards, methodologies, or procedures that are more restrictive than those in place as of October 1, 2021 (except the penalty would not apply to coverage of non-pregnant, non-disabled adults with income above 133% FPL after December 31, 2022, if the state certifies that it has a budget deficit).

Section 139405 of the Build Back Better Act would require state Medicaid programs to cover all approved vaccines recommended by ACIP and vaccine administration, without cost sharing, for categorically and medically needy adults. States that provide adult vaccine coverage without cost sharing as of the date of enactment would receive a 1 percentage point FMAP increase for 8 quarters.

PEOPLE AFFECTED

In June 2019 there were approximately 1.3 million Medicaid enrollees in the territories (with 1.2 million in Puerto Rico).

From February 2020 through May 2021 Medicaid and CHIP enrollment has increased by 11.5 million or 16.2% due to the economic effects of the pandemic and MOE requirements.

All states provide some vaccine coverage for adults enrolled in Medicaid who are not covered as part of the ACA's Medicaid expansion, but as of 2019, only about half of states covered all ACIP-recommended vaccines.

BUDGETARY IMPACT

CBO estimates that the changes in Medicaid financing for the Territories would increase federal spending by $9.5 billion over 10 years.

CBO estimates that the provision to impose a penalty in the match rate if states implement eligibility or enrollment restrictions through 2025 would increase federal costs by $7.0 billion.

CBO estimates that extending vaccines to adults on Medicaid would increase federal spending by $2.8 billion over 10 years.

9. Medicaid Home and Community Based Services and the Direct Care Workforce

BACKGROUND

Medicaid is currently the primary payer for long-term services and supports (LTSS), including home and community-based services (HCBS), that help seniors and people with disabilities with daily self-care and independent living needs. There is currently a great deal of state variation as most HCBS eligibility pathways and benefits are optional for states.

PROVISION DESCRIPTION

Sections 30711-30713 of the Build Back Better Act would create the HCBS Improvement Program, which would provide a permanent 6 percentage point increase in federal Medicaid matching funds for HCBS. To qualify for the enhanced funds, states would have to maintain existing HCBS eligibility, benefits, and payment rates and have an approved plan to expand HCBS access, strengthen

the direct care workforce, and monitor HCBS quality. The bill includes some provisions to support family caregivers. In addition, the Act would include funding ($130 million) for state planning grants and enhanced funding for administrative costs for certain activities (80% instead of 50%).

Section 30714 of the Build Back Better Act would require states to report HCBS quality measures to HHS, beginning 2 years after the Secretary publishes HCBS quality measures as part of the Medicaid/CHIP core measures for children and adults. The bill provides states with an enhanced 80% federal matching rate for adopting and reporting these measures.

Sections 30715 and 30716 of the Build Back Better Act would make the ACA HCBS spousal impoverishment protections and the Money Follows the Person (MFP) program permanent.

Sections 22301 and 22302 of the Build Back Better Act would provide $1 billion in grants to states, community-based organizations, educational institutions, and other entities by the Department of Labor Secretary to develop and implement strategies for direct service workforce recruitment, retention, and/or education and training.

Section 25005 of the Build Back Better Act would provide $20 million for HHS and the Administration on Community Living to establish a national technical assistance center for supporting the direct care workforce and family caregivers.

Section 25006 of the Build Back Better Act would provide $40 million for the HHS Secretary to award to states, nonprofits, educational institutions, and other entities to address the behavioral health needs of unpaid caregivers of older individuals and older relative caregivers.

PEOPLE AFFECTED

The majority of HCBS are provided by waivers, which served over 2.5 million enrollees in 2018. There is substantial unmet need for HCBS, which is expected to increase with the growth in the aging population in the coming years. Nearly 820,000 people in 41 states were on a Medicaid HCBS waiver waiting list in 2018. Though waiting lists alone are an incomplete measure, they are one proxy for unmet need for HCBS. Additionally, a shortage of direct care workers predated and has been intensified by the COVID-19 pandemic, characterized by low wages and limited opportunities for career advancement. The direct care workforce is disproportionately female and Black.

A KFF survey found that, as of 2018, 14 states expected that allowing the ACA spousal impoverishment provision to expire would affect Medicaid HCBS enrollees, for example by making fewer individuals eligible for waiver services.

Over 101,000 seniors and people with disabilities across 44 states and DC moved from nursing homes to the community using MFP funds from 2008-2019. A federal evaluation of MFP showed about 5,000 new participants in each six month period from December 2013 through December 2016, indicating a continuing need for the program.

BUDGETARY IMPACT

CBO estimates that all of the Medicaid-related HCBS provisions together will increase federal spending by about $150 billion in the 10-year budget window. The new HCBS Improvement Program (Section 30712) accounts for most of this spending ($146.5 billion).

CBO scores the Department of Labor direct care workforce provisions according to the amount of spending authorized for each in the bill: $1 billion for grants to support the direct care workforce (Section 22302), $20 million for a technical assistance center for supporting direct care and caregiving (Section 25005), and $40 million for funding to support unpaid caregivers (Section 25006).

10. Paid Family and Medical Leave

BACKGROUND

The U.S. is the only industrialized nation without a minimum standard of paid family or medical leave. Although six states and DC have paid family and medical leave laws in effect, and some employers voluntarily offer these benefits, this has resulted in a patchwork of policies with varying degrees of generosity and leaves many workers without a financial safety net when they need to take time off work to care for themselves or their families.

PROVISION DESCRIPTION

Section 130001 of the Build Back Better Act would guarantee four weeks per year of paid family and medical leave to all workers in the U.S. who need time off work to welcome a new child, recover from a serious illness, or care for a seriously ill family member. Annual earnings up to $15,080 would be replaced at approximately 90% of average weekly earnings, plus about 73% of average weekly earnings for annual wages between $15,080 and $32,248, capping out at 53% of average weekly earnings for annual wages between $32,248 and $62,000. While all workers taking qualified leave would be eligible for at least some wage replacement, the progressive benefits formula means that the share of pay replaced while on qualified leave is highest for workers with lower wages. The original Act called for 12 weeks of paid leave for similar qualified reasons, plus three days of bereavement leave, and benefits began at 85% of average weekly earnings for annual wages up to $15,080 and were capped at 5% of average weekly earnings for annual wages up to $250,000.

PEOPLE AFFECTED

According to the Bureau of Labor Statistics (BLS), approximately one in four (23%) workers has access to paid family leave through their employer. Data on the share of workers with access to paid medical leave for their own longer, serious illness are limited, although BLS also reports that 40% of workers have access to short-term disability insurance.

It is estimated that 53 million adults are caregivers for a dependent child or adult and 61% of them are women. Sixty percent (60%) of caregivers reported having to take a leave of absence leave from work or cut their hours in order to care for a family member. Workers who take leave do so for different reasons: Half (51%) reported taking leave due to their own serious illness, one-quarter (25%) for reasons related to pregnancy, childbirth, or bonding with a new child, and one-fifth (19%) to care for a seriously ill family member. In total, four in ten (42%) reported receiving their full pay while on leave, one-quarter (24%) received partial pay, and one-third (34%) received no pay.

BUDGETARY IMPACT

CBO estimates that the federal cost of these provisions would be about $205.5 billion over the 2022-2031 period. The estimate accounts for funding the paid leave benefits and administration, grants for

the state administration option for states that already have a comprehensive paid leave law, and partial reimbursements for employers that provide equally comprehensive paid leave as a benefit to all their workers. The CBO estimate is modestly offset by application fees paid by employers participating in the reimbursement option for employer-sponsored paid leave benefits.

11. Consumer Assistance, Enrollment Assistance, and Outreach

BACKGROUND

Consumer Assistance in Health Insurance – The Affordable Care Act (ACA) established a new system of state health insurance ombudsman programs, also called Consumer Assistance Programs, or CAPs. These programs are required to conduct public education about health insurance consumer protections and help people resolve problems with their health plans, including filing appeals for denied claims. By law, private health plans, including employer-sponsored plans, are required to include contact information for CAPs on all explanation-of-benefit statements (EOB) with notice that CAPs can help consumers file appeals.

To help inform oversight, CAPs are also required to report data to the Secretary of HHS on consumer experiences and problems. The ACA permanently authorized CAPs and appropriated seed funding of $30 million in 2010. Forty state CAPs were established that year; since then, Congress has not appropriated CAP funding.

Enrollment Assistance and Outreach in the Marketplace – The Affordable Care Act also requires marketplaces to establish Navigator programs that help consumers apply for and enroll in coverage through the marketplace. And it requires marketplaces to conduct public education and outreach about the availability of coverage and financial assistance. As noted above, the Build Back Better Act would create new eligibility for marketplace coverage and financial assistance for low-income adults in states that have not expanded Medicaid.

PROVISION DESCRIPTION

Section 30603 appropriates $100 million for state consumer assistance programs (CAPs) over the 4-year period, 2022-2025.

Section 30601(d) appropriates $105 million to conduct public education and outreach in non-expansion states so people will learn about new coverage and subsidy options. $15 million is appropriated for 2022 and $30 million for each of 2023-2025. In addition, this section requires the Secretary to obligate no less than $70 million of marketplace user-fee revenues for additional Navigator funding to support enrollment assistance for the new coverage-gap population (at least $10 million in FY 2022 and at least $20 million in each of FY 2023-2025).

PEOPLE AFFECTED

CAP Funding – More than 175 million Americans are covered by private health insurance plans today. Consumers generally find health insurance confusing and have limited understanding of even basic health insurance terms and concepts. Four-in-ten have difficulty understanding what their health plan will cover or how much they will have to pay out-of-pocket for needed care; when faced with unaffordable bills, only one-in-ten even try to get providers to lower their price. When claims are denied, consumers rarely appeal. These are the kinds of problems CAPs could help address with

expanded funding. Most of the state CAPs established in 2010 continue to operate today, though at reduced capacity without federal financial support; programs rely on state funding (many CAPs are housed in state Insurance Departments or Attorney General offices) and philanthropic support today. With recent enactment of the federal No Surprises Act, as well as amendments to the Mental Health Parity and Addiction Equity Act (MHPAEA), CAPS can help consumers understand and navigate new federal health insurance protections and inform oversight by federal and state agencies.

Marketplace Enrollment Assistance and Outreach – After years of cuts in funding for Navigator enrollment assistance and outreach, the Biden Administration took steps this year to restore federal marketplace funding for these activities. During the 2021 COVID special enrollment opportunity, when expanded subsidies enacted by ARPA first became available, more than 2.2 million people newly signed up for marketplace coverage. However, KFF found only 1 in 4 people who are uninsured or buy their own health insurance checked to see if they would qualify for affordable coverage. This finding is consistent with earlier KFF surveys that find 3 in 4 uninsured don't look for health coverage because they assume it is not affordable. Investments in public education, outreach, and enrollment assistance can help inform the 2.2 million uninsured adults in the coverage gap of new affordable health coverage options through the marketplace.

BUDGETARY IMPACT

New appropriations for Consumer Assistance Programs would cost $100 million over 5 years.

New appropriations for marketplace outreach would cost $105 million over 5 years. Additional funding for Navigator enrollment assistance in coverage gap states would not come from new appropriations; these resources will come from user fee revenue collected by the marketplace.