# Commercial Health Ins Issues

Section 3

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Section 3

## Why Private Sector Healthcare Reforms Always Fail to Control Costs

We have a 40+ year history of healthcare system reform, and a 40+ year history of reform failures to control costs. Harvard Business School Professor Michael Porter explains why:

> With the wrong diagnosis, the attempts to treat the system have addressed the wrong issues or offered piecemeal, ultimately ineffective solutions aimed at symptoms rather than causes. [1]

Harvard Business School's Michael Porter, along with his colleague Elizabeth Teisberg, have written the Big Book About Healthcare, 400+ pages, titled **Redefining Healthcare**. Chapter 2 provides a litany of competitive dyfunctionalities. We'll use some of Porter and Teisberg's categories to articulate why we have expensive, fragmented, inappropriate and dysfunctional forms of healthcare competition.

Note when reading this: Porter is a business school professor, primarily interested in improving healthcare value. 'Value' for Porter means 'outcomes per dollar spent'. Good surgical outcomes at low cost are high value medical services, for example, while similar outcomes at higher costs represent less value.

Porter and Teisberg see as dysfunctional many healthcare regulations because these are designed to treat healthcare purchasing as different from purchasing other goods and services in our economy. **The clash between appropriate business strategies to promote patient value, and inappropriate regulations to control competition, comes through quite clearly.**

## Dysfunctional Competition in the Wrong Geographic Market

We know that some hospitals provide better value than others. The Cleveland Clinic, for example, is nationally recognized as an outstanding cardiac center, and the Mayo Clinic wins accolades for its patient care. Both provide outstanding patient value – excellent outcomes at moderate prices. From Porter's point of view, we could increase overall American patient value by allowing more patients to access these, and similar, outstanding medical facilities.

But regulations often prohibit people insured in one state from getting treatment in another state, at least, without paying hefty 'out of network' costs (essentially fines). A Massachusetts small group employee, for example, who has Massachusetts based health insurance, must pay this fine – in the form of out-of-network costs - to access the Cleveland Clinics' outstanding care.

This makes no sense. We don't do this in other economic arenas. We are not restricted from purchasing cars made in other states, or computers, or food, or clothing. That's one reason why we have a history of quality improvements and cost reductions in these products.

But in healthcare, we charge patients **more** to get better care – meaning often quicker and cheaper care.

What would happen if, for example, Massachusetts insureds could use out of state facilities without these extra charges? The short answer: it would be a win-win for the carrier, employer and employee:

- The carrier would save money;
- The employer would thus have reduced premiums;
- The employee would save money and – as an added bonus – receive better care.

The only losers – perhaps – are the Massachusetts providers who lose a patient to an out-of-state competitor. (I say lose 'perhaps' because competitive pressures from out-of-state providers might actually improve the value at Massachusetts hospitals, so they will get more insureds from other states than they lose. Inter-state competition might reward them with more patients.)

This type of geographic restriction may make no sense to people who believe that purchasing healthcare is the same as purchasing other goods and services.

But it may make perfect sense to folks who believe that purchasing healthcare is **different** from purchasing other goods and services. These people may see the state as a protector of its citizens.

Massachusetts, for example, may have significantly more stringent licensing requirements than some other states. As such, it's the Massachusetts state regulator's responsibility to dissuade its citizens from leaving the state to receive – potentially – inferior care. Yes, some people may not be able to access the Cleveland Clinic. But they are protected from receiving shoddy care in lots of other states.

Regulators, thus, may restrict people from getting the **upside** of out-of-state providers, but they also save people from getting the **downside** – shoddy treatment. That, apparently, is the justification.
Are they right? Are they wrong? The answer depends on how you define healthcare. If it's like other goods and services, then the regulators interfere with market competition to the detriment of us all. But it it's unlike other goods and services, then regulators provide a valuable function.

Regulators think that purchasing healthcare is different from purchasing other goods and services, so they regulate accordingly.

Whether or not we agree with them, we all pay the price in the form of higher costs than any other advanced industrialized country.

## Dysfunctional Competition over the Wrong Time Horizon

We know that most diseases, especially the chronics ones, last longer than 1 year. Lupus, multiple sclerosis and cystic fibrosis, for example, last a lifetime. Yet we finance healthcare treatments with one year health insurance policies.

These policies, underwritten by different carriers, may have different provider networks, different drug formularies and different approval criteria for various medical treatments. A patient may need to change physician, hospital, medications and treatment protocol when the employer decides to change plan.

Conceivably some patients may need to change provider, medication and treatment protocol annually. This makes no medical treatment sense - people with chronic conditions need, above all, continuity of care. This allows the treaters to monitor progress, tweek protocols as necessary and take a long term view of patient improvement.

But short term health insurance policies – i.e. 1 year plans - incent carriers and providers to seek quick hits, like eliminating certain expensive drugs or failing to invest in world-class hospital IT systems. This can be counter-productive: a patient responding to one drug may develop problems when that drug is discontinued due to a formulary difference.

Some drugs may, for example, be more expensive in the short term but reduce long term costs significantly. The VA has found this sometimes to be true. Our 1 year policy horizon and associated restrictions, however, may dissuade physicians from using the better / lower-long-term cost medication. The patient may receive sub-optimal care and the total disease treatment costs may ultimately increase.

Yet we allow, and indeed require, 1 year long insurance policies because of our weird employer based funding system. Employers, loath to take on appreciating long term liabilities, balk at committing to longer term insurance policies.

This short term funding mechanism treats healthcare purchasing as **different from** other goods and services. Your employer doesn't buy your food or auto insurance, for example. We don't subject other products designed for long term use – like automobiles – to the same short term financial review. Imagine if we purchased cars using the same 1 year time horizon as we use when purchasing healthcare!

The historical quirks that led to our employer based insurance system have generated many regulations that protect employers from potentially harmful financial obligations…sometimes to the detriment of patients, and often to the detriment of employer's own long term financial interests.

In the meantime, we choose our health insurance policies based largely on premium price. We shop for health insurance like we shop for other goods and services. But we finance healthcare very differently, using this artificially imposed 1 year time horizon.

Thus we have a financing system absurdly designed to treat healthcare purchases as **different** from other goods and services, while we try to apply routine business practices to medical treatments – restricting costs to remain within a budget, for example. This is a huge disconnect.

## Dysfunctional Competition over the Wrong Unit of Measure

We currently shop for providers, when we shop at all, seeking the 'best' doctor, the 'best' surgeon or the 'best' hospital. We typically have no clear definition of 'best'.

Some people define the best hospital as the name hospital, the research facility associated with a famous university. Some define the best doctor as the head of a department or research institute, or a graduate of a famous medical school. Others define the best surgeon as the one most frequently recommended by other doctors.

None of these definitions, typically, includes a quantification of outcomes, as in 'Dr. Smith is the best surgeon because 97% of his patients fully recover within 30 days'. We typically lack this data.

But there's a more insidious underlying issue here. Dr. Smith is but one component of a large team that provides care to a patient. The team consists of diagnosticians, nurses, pre-op professionals, surgeons, assistants, post-op professionals, rehab professionals, IT specialists, therapists, psychologists, etc. Good patient outcomes require the entire team to work together as a well oiled machine for a failure of any one component may doom the patient.

In other words, the appropriate unit of measure for medical care is **the medical condition itself** – not the individual surgeon or hospital. A great surgeon with a poor rehab team may generate poor results.
A specific hospital may be outstanding at orthopedic care, but lousy at cardiac. Or the hospital may be outstanding at certain surgical procedures but poor at chronic care. Or have a poor IT system that fails to follow patients post-discharge, leading to a high readmission rate. Or perhaps have poor post-op patient counseling that fails to prevent self destructive behavior.

A brilliant surgeon with a poor post-discharge team may generate outcomes as poor as those from a crummy surgeon with an excellent post-discharge team.

We need cost and outcome information **by medical condition** for competing hospitals in order to make wise purchasing decisions. We also need this information to make wise healthcare reform decisions. Yet this information is virtually nonexistent.

The costs and value of each individual treatment component cannot be assessed in isolation, as each component is but a part of the larger team effort. Our attempts to control a portion of the treatment costs – surgical costs, for example, or rehab therapy costs – backfire as a result.

Healthcare reforms that consider any unit of measure other than the specific medical condition will almost certainly also fail.

## Dysfunctional Competition to Amass Wealth

Our various medical care providers – primary care physicians, specialists, hospitals, diagnosticians, allied medical professionals, etc – all share a client who is not their patient. Their real client: the insurance carrier who pays the bills!

I have no doubt that medical care professionals would each, personally, like to help their patient's get better. Many went into the profession to help people.

But I equally have no doubt that medical professionals also seek to maximize their incomes, as do all rational business people in a capitalist environment. In the healthcare field, we call this 'supply induced demand'. It correlates with moral hazard – the healthcare problem we discussed in Chapter 8. Here's how it works:

Physicians know that someone besides the patient – i.e. an insurer - will ultimately pay the bill. The physician also knows the criteria that each insurer uses to approve payments. It's a simple step – and probably unconscious for most medical professionals - then, to design a treatment plan that generates the highest payments.

Take this process one step further. Each hospital has an economic self interest in providing the most reimbursable treatment to each patient. Providers also have economic interests in not referring that patient out. This would mean that another provider benefits economically.
Providers – both specialists and hospitals - compete to provide the most care to each patient and refrain from referring patients to other providers. Again, probably not even consciously.

Now add one more step. Providers assemble themselves in networks, often affiliated with hospital systems. When referrals are necessary, they refer 'in-network'. Not to the 'best' specialist or, necessarily, to the cheapest. Instead, to an in-network affiliate, to keep the carrier's payments within their group. Compensation, bonuses, etc may rest on physicians' abilities to keep patients in-network.

And add a final step. Provider groups negotiate rates against carriers. The carriers want to pay less; the providers want to earn more. The larger and more powerful the provider group, the higher the rates.

Rates become a function of negotiating power, not of outcomes, not of efficiency, and not of patient satisfaction.

Providers thus compete with carriers and with each other to amass wealth. Whether or not patients get good treatment or enjoy good outcomes becomes a side issue in the compensation competition.

Hospitals typically do not support their claim for higher payments with data showing that their 30-day readmission rate is lower than another's. Nor do they show that their diabetic patients reduce their blood sugar levels more in a given time period. They generally don't argue that they should get paid more because their treatment quality is better.

Instead, they threaten not to accept a carrier's payment schedule. Here's Rick Weisblatt, Senior Vice President for Health Services at Harvard Pilgrim Health Care in Massachusetts, describing how geographically isolated hospitals (for example, on an island) negotiate fees. They use their geographic monopoly

> To leverage higher reimbursement. The employers in that community generally want that hospital in the network. And the hospitals are not shy about threatening termination [of the carrier's contract] [1]

The competition is to amass wealth, not provide better value.

Healthcare competition is <u>like</u> competition in other arena where the parties negotiate fees and prices to maximize their wealth. But it is <u>different from</u> other goods and services which compete on value – in our case, cost per patient outcome.

Instead, in healthcare, the parties compete simply via power relationships.

**Dysfunctional Competition over the Wrong Hospital Strategies**

Most American hospitals are General Hospitals, providing all medical services from ER to cancer treatment to open heart surgery, to all patients in a geographic area. These broadline general hospitals compete with each other.

Yet numerous studies have demonstrated that specialty hospitals – orthopedic, cardiac, etc – generate better outcomes at lower prices. The literature is full of case studies of this. [1]

Indeed, Harvard Business School Professor Regina Herzlinger – who has taught accounting to budding MBAs for years – claims bluntly:

> Specialty hospitals generally provide better, cheaper healthcare than the everything-for-everybody general hospital. [1]

General hospitals, rather than competing with specialty hospitals on **value** (best outcomes per dollar spent) instead obtain political redress.

Some states – about 35 currently – have Certificate of Need regulations on the books. CON laws restrict hospital expansion or construction unless the hospitals can demonstrate a 'need' for the additional services to government regulators – at a public hearing. A new specialty hospital looking to enter a market must similarly face this requirement.

Imagine the hearing. I, for example, want to open Gary's Coronary Hospital, perhaps in conjunction with an out-of-state hospital (or even, heaven forbid, a foreign hospital). I think I can provide better value – better outcomes at lower costs – than the current hospitals in my region. I'm willing to invest my money in this venture.

I make my proposal at the public hearing. 'Why,' I wonder, 'do I need to convince regulators about the validity of my proposal? I wouldn't have to go through this if I wanted to open or expand a shoe store. Or if I was a university president and wanted to expand my business school or chemistry department. I'm looking for the same tax treatment as the university, but I have a far more difficult regulatory hurdle to overcome.'

After I outline my business plan, the local incumbents speak in turn. They all explain to the regulators that there is no 'need' for my new coronary facility. They all, it turns out, have sufficient capacity to cover all the cases that I'm hoping to get. They try to convince regulators that there is no need for my services.

I, in this case, see purchasing healthcare as **like** purchasing other goods and services. I'll invest my money and take my chances. If I'm wrong about the need for my service, I'll fail and go out of business. I'm willing to take that risk.

But the regulators see purchasing healthcare as **different from** most other economic activities. They perceive a need to avoid wasting resources – potential tax losses from another non-profit entity, perhaps. They may want to avoid generating excess expensive medical capacity, so seek to protect hospitals from themselves. They may want to prohibit me from 'cherry-picking' profitable services from existing broadline general hospitals, using the totally fallacious argument that hospitals need the profitable patients to subsidize the unprofitable ones. [1]

Regulators may also perceive a need to protect the local incumbents, perhaps on the theory that 'they do such good work' for the local community - even if this raises medical costs to state inhabitants. In Michael Porter's terms, CON laws serve to

> Protect local incumbents from competition that could drive improvements in the diagnosis and treatment of specific medical conditions. [1]

Hospital systems tend to be very large local employers, often the largest or second largest in a local market. Physician and hospital campaign contributions are also

generally quite significant, especially at the local level. One wonders the impact of this electoral and campaign contribution clout in the Certificate of Need decisions.

This situation played out at the national level in, for example, the Medicare Modernization Law of 2003. That Law prohibited establishment of new specialty hospitals for 18 months. Congress passed a second 6-month ban in 2005.

Now that's a good way to stifle competition!

Note the tension between those who see healthcare as like, and unlike, other economic activities. Contrast the regulations governing private hospital expansion with the regulations governing private college expansion. A private college (also generally a non-profit, like a hospital) can open a new department or expand an existing one without receiving state permission. But a hospital cannot….to our cost disadvantage.

## Dysfunctional Competition Based on the Wrong Information

Wise shoppers need quality information – both price and outcomes – about the products they're considering. Neither is available in healthcare.

Contrast the purchase of a tennis racquet with the purchase of any medical service, even one as simple as an MRI.

You can comparison shop for tennis racquets. You can determine price, weight, color, string tension, hand grip size and construction material. You might even – depending on where you purchase – hit a few balls with it. You can get all this information about a product that costs a couple hundred dollars and plays a minor or inconsequential role in most people's lives.

Contrast this with available medical provider information. We'll use an MRI example, because this is a relatively straight-forward, discrete test.

You can't determine the MRI price – it's a function of carrier discounts, which in turn are a product of power negotiations. You can't determine radiologist quality. You can't learn how many misdiagnoses have been generated from this facility – either false positives or false negatives. You can't determine if this particular machine is the most current incarnation of MRI. You can't even learn how many people with your medical condition have used this radiological facility.

In short, you can't learn anything about this procedure's cost or quality, even though it may have life impacting consequences for you.

Not only is this type of quality information unavailable to shoppers, but it's also typically unavailable to physicians. Indeed, according to Porter, 'most physicians lack any objective evidence of whether their results are average, above average or below average…they generally lack information on their own efficiency.' [1]

Imagine lacking quality feedback about your own competence and outcomes in other profession! Porter goes even further:

> The information that is available – health plan overviews, subscriber satisfaction surveys, and reputation surveys…has modest value. Much more relevant is information about…results.[1]

The hospital rankings currently available, in, for example, US News and World Report or Money magazine 'fall far short of the types of information really needed to support comparisons of value'. [1]

This differs, of course, from auto, food or other product information.

Why is medical information so unavailable? One short answer: government regulators treat healthcare differently from the way they treat providers of other goods and services. They don't require it.

We require auto manufacturers to publish lots of information about their products, including crash test ratings. But not hospitals. Why?

Some claim that hospital lobbies are too powerful. This seems an unsatisfactory answer, for the auto industry also has lobbyists, is also powerful and would probably be delighted to avoid publicizing crash test ratings and other comparative information that might cast them in a poor light. Ditto for the food industry.

Instead, I think, regulators see medical service provision as essentially different from provision of other goods and services, and thus subject to a different set of rules. They allow medical providers to withhold comparative information from the public, apparently with the justification that ordinary people would not be able to understand this data. (OK, political pressures and lobbying are a consideration here also.)

Interestingly, regulators have no problem mandating certain kinds of services for sick people – minimum nursing staffing ratios, for example, or mental health parity. They do this because they believe that the market alone will not provide adequate services to sick people. They typically regulate based on political influences – the nurses lobby, for example, demanding certain minimum staffing rates – rather than on rigorous, extensive studies comparing various nurse-to-patient ratios and patient outcomes.

But regulators balk at requiring price and outcome transparency. They require it for autos, but not for healthcare. They require it for food products, but not for healthcare. They require it for financial services, but not for healthcare. They even require it, more or less, for life, homeowners and auto insurance – but not for healthcare.

The best way to understand these discrepancies? Understand that many regulators see healthcare as essentially different from other goods and services.

This conflict – between regulations based on one set of assumptions, and competition based on another – leads to dysfunctional competition that raises medical service prices without simultaneously improving patient outcomes.
Porter and Teisberg note several other kinds of inappropriate and dysfunctional competition in the healthcare arena. We've presented enough above to make our underlying point: our lack of consensus about whether healthcare is like or not like other goods and services leads to a poor regulatory framework and dysfunctional, costly competition.

## Our Lack of Consensus Is Expensive

As our medical providers compete for business in this poorly regulated, dysfunctional marketplace, we have more and more people ***administering*** our healthcare. In 2006, for example, we had some 470,000 health insurance employees – that's 1 for every 2 physicians! [1]

These numbers don't include the number of hospital and physician office employees who coordinate with these insurance employees. Surveys find that both doctors and nurses spend between one-third and one-half of their time on paperwork and that health insurance administration alone is a staggering 30% of all healthcare spending. [1]

Why are these costs so astonishingly high? Because we lack a consensus on whether healthcare is like or dislike other goods and services. As a result, we have an overly complicated, confused and often internally contradictory regulatory and administrative system.

We could reduce administrative costs, complications and confusion if we all agreed that healthcare is like other goods and services – or dislike.

If, for example, we let the market alone dictate healthcare system evolution, then we could eliminate many mandates and healthcare access restrictions, referral costs and requirements and inappropriate geographical competition. We could probably eliminate the expensive and inappropriate medical arms race by focusing on outcomes per dollar.

Alternatively, if we agreed that healthcare is a government function – not a market function – then we could eliminate many of our current costly types of provider competition, like individual underwriting and pre-existing condition exclusions and network restrictions. We could also eliminate the massive private insurance overheads that serve no useful economic function in a public healthcare system.

But since we lack consensus, we have the worst of both worlds. We have expensive private insurance overhead. We have expensive provider overheads whose only function is to deal with the various insurance carriers and complications. Yet we don't have the benefits of true market competition that would lower costs and improve outcomes.

Indeed, our current convoluted healthcare billing system is so complex and confusing that carrier and provider *billing offices themselves* often cannot understand the process. Errors and double billing abound. [1] Partially as a result, insurers find reasons to reject up to 30% of all the bills they receive from physicians and hospitals [1] – leading to more administrative time and expense to straighten all this out.

Our lack of consensus about how to treat healthcare – is it like or dislike other goods and services? – is hugely expensive for all of us.

## Overview of Health Insurance Reforms Since 2000

The US has enjoyed spurts of health insurance reforms for the past 60 years at least. Medicare and Medicaid, the first major public health insurance programs since World War II, passed Congress in the 1960s. Nixon's HMO Act of 1973 followed, presenting a major private sector reform about 6 years later. Both dramatically changed our health insurance landscape for years to come.

After 3 decade major healthcare reform lull, the W. Bush administration passed the Medicare Modernization Act in 2003 and the Obama administration the Affordable Care Act 7 years later. Both also dramatically changed our health insurance landscape for years to come.

But did either the MMA or Aca have the impacts their authors desired? Did either improve the health status of Americans? Did either cut medical costs? Did either dramatically expand coverage? This chapter will address those questions and propose some startling and perhaps unsettling answers. It will then suggest some changes to our healthcare system, already in the works, that *could* have the dramatic systemic impacts that the healthcare reformers had hoped to have.

### The Two Major Healthcare Reforms Since 2000

The Medicare Modernization Act of 2003, passed by the George W. Bush administration, represented the ***market based*** reformers vision of an improved healthcare system. Among its key components, this legislation enhanced the so-called 'consumerism' movement in American health insurance by codifying Health Savings Accounts and Health Reimbursement Accounts into our income tax and health insurance systems.

- Health Savings Accounts (HSAs) allow insured folks to invest tax deductible money into special accounts called Health Savings Accounts that they own personally. This money grows tax free until needed, when it can be withdrawn tax free to spend on medical care. HSAs are the only triple tax free investments available under the IRS code; they're tax deductible when initiated, grow tax free and are not taxed when withdrawn for qualified medical expenses.
  HSAs have grown tremendously, totaling over $80 billion by 2022 with some individual accounts reaching $100,000 or more.

  Health Savings Accounts are closely tied into high deductible health plans, both legislatively and economically. Insured people could originally only invest an amount equal to their annual health insurance deductible into their HSA. Overtime, this requirement has changed; in 2021, the contribution limits were $3600 for an individual plan and $7200 for a family plan.

  Economically and philosophically, these accounts were designed to help medical care consumers think of medical payments as being made with their own money.

The Medicare Modernization Act authors hoped that this change in consumer attitude – from thinking of medical payments as someone else's money (the health insurance company's) to thinking of medical payments as their own money – would motivate patients to shop more wisely for medical care, compare prices and choose the least expensive care, in other words, act like purchasers of other consumer products. This consumer driven movement would, in turn, force medical providers to cut prices and therefore reduce healthcare spending by billions of dollars.

That, at least, was the theory.

- Health Reimbursement Accounts (HRAs) are funded by employers. These were designed, originally, to cushion the impact of high deductible plans on employees by covering all or part of the deductible. Operationally, the employee pays for a medical treatment, then submits a receipt to his / her employer for reimbursement. Overtime this became mechanically simpler, with employees paying for medical services with their HRA card.
  HRA payments are tax deductible to the employer and tax free to the employee.

  HSAs and HRAs have become integrated into our health insurance landscape since 2003 and have also become far more complicated and intricate than outlined here. My purpose in this chapter is simply to introduce them as components of the Medicare Modernization Act of 2003.

The Medicare Modernization Act also introduced Parts C and D of Medicare.

Medicare Part C, often called Medicare Advantage, operates like an old-fashioned HMO. These plans are offered by private insurance companies under Medicare's guidance and with Medicare's approval. Medicare pays a fixed amount to the companies that offer Medicare Advantage Plans. These companies must follow rules set by Medicare. However, each Medicare Advantage Plan can charge different out-of-pocket costs, have different rules for how to get services like specialist referrals or specific hospital and physician networks, and sometimes include additional benefits. That introduces additional consumerism into the marketplace; different Medicare beneficiaries can choose different Part C plans according to their own different insurance plan preferences.

The MMA authors hoped that competition among health insurers – the folks who actually offer various Part C plans – would force prices down. Part C subscribers would, again in theory, choose the lowest cost / most attractive insurance options. As these plans grew in popularity, the offering insurance companies could negotiate lower and lower prices with participating doctors and hospitals.

Again, in theory.

- Medicare Part D covers outpatient prescription drugs, previously not covered by Medicare.

Our purpose in this chapter is less to describe components of the Medicare Modernization Act or, later, the Affordable Care Act, but more to discuss their impacts on the American healthcare system. To that end, we'll move now to commentaries on the state of American healthcare post-MMA. I'll use summarizes from well known academics representing various disciplines – medicine, business, economics and public policy – to make my points.

In 2005 – two years after passage of the MMA – two Harvard Medical School professors, Jules Richmond and Rashi Fein representing for our purposes the medical school perspective, called our healthcare system a 'mess' in the title of their lengthy book on the state of American healthcare entitled 'The Healthcare Mess'. Interestingly Richmond was a former US Surgeon General and exceptionally well placed to understand the issues he discussed.

In 2010 – seven years after passage of the MMA – Regina Herzslinger, a well known Harvard Business School professor and, for our purposes representing the business school perspective, called our healthcare system 'insane'. That was at a Boston area lecture I attended, though my notes are somewhat confusing on this point; she may have called our system 'stupid'. The distinction doesn't matter.

Others from various academic disciplines offered similar commentaries.

Seven years after passing the Medicare Modernization Act and seeing an obvious need to correct some perceived fatal flaws in our healthcare system, the Obama administration passed the Affordable Care Act, a set of government based health insurance reforms. These differed markedly from the market based reforms encompassed in the 2003 Medicare Modernization Act. The ACA's primary goal was to expand insurance coverage, not to enhance consumer / patient power. Among the key ACA provisions, it

- Introduced income based subsidies for health insurance premiums, so lower income folks could afford to purchase private plans,
- Introduced health insurance exchanges or online marketplaces, where consumers could view all health insurance plans available in their area and comparison shop based on price and benefits,
- Introduced employer mandates, requiring employers to offer health insurance to their employees under various circumstances and conditions,
- Introduced an individual mandate, requiring everyone to have health insurance, again under various circumstances and conditions,
- Introduced community rating, so everyone in the same area paid the same amount for health insurance with some minor condition differences, like age and smoking status. This ended 'individual underwriting' where the insurance carrier priced policies differently based on a host of individual risk factors. Individual

underwriting made health insurance unaffordable to very sick people, a situation the Obama administration wanted to avoid.

- Eliminated annual or lifetime policy payment ‘caps’ or amounts of money a person could receive in insurance payments per year or per lifetime. Caps protected insurance carriers from extremely high payouts but, again according to ACA authors, did not serve severely sick patient interests as well.
- Medicaid expansion in which the Feds paid states to cover more low income people.

The commentators continued.

In 2014 – four years after passing the ACA and 11 after passing the Medicare Modernization Act, Ezekiel Emanuel, perhaps the primary author of the ACA and brother of President Obama’s Chief of Staff Rahm Emanuel, called our healthcare system “terribly complex, blatantly unjust, outrageously expensive, grossly inefficient and error prone”. Remember – this summary came from a supporter of healthcare reform.

In 2016 – six years after passing the ACA and 13 after passing the MMA, Jonathan Engle from Columbia University’s School of Public Heath called our system “uniquely dysfunctional”.

In 2020 – ten years after passing the ACA and 17 after passing the MMA, Angus Deaton and Anne Case, two Princeton economics professors, called our system a “calamity”. Deaton won the Nobel Prize for Economics in 2015 for his work in this field.

Other academics and healthcare commentators chimed in along the same general lines.

The summary of our selected healthcare commentaries above, described US healthcare system evolutions through 2 major reforms – the Medicare Modernization Act of 2003 and the Affordable Care Act of 2010 – as moving from a ‘mess’ to a ‘dysfunction calamity’. Not a ringing success by any means.

Interestingly, this fiasco (my word) is taxpayer subsidized since employer paid premiums are tax deductible to the employer and not taxable to the employee - the biggest tax break allowed by the IRS. This raises questions to me, at least, about the purpose of our healthcare system. Is it designed to get people healthy? Is it designed to be benefit sick people? Or is it primarily a jobs program designed to keep well educated, well compensated people happy? Read on and decide for yourself.

## Success and failure defined and demonstrated

Let’s now define healthcare reform success and failure. Success in any business, economic, or public policy reform means better products at lower cost and with wider access. This applies to activities ranging from internet expansion to educational reforms, from air conditioning utilization to automobile safety and emission standards and from cell phone use to consumer product sales: better products at lower cost and

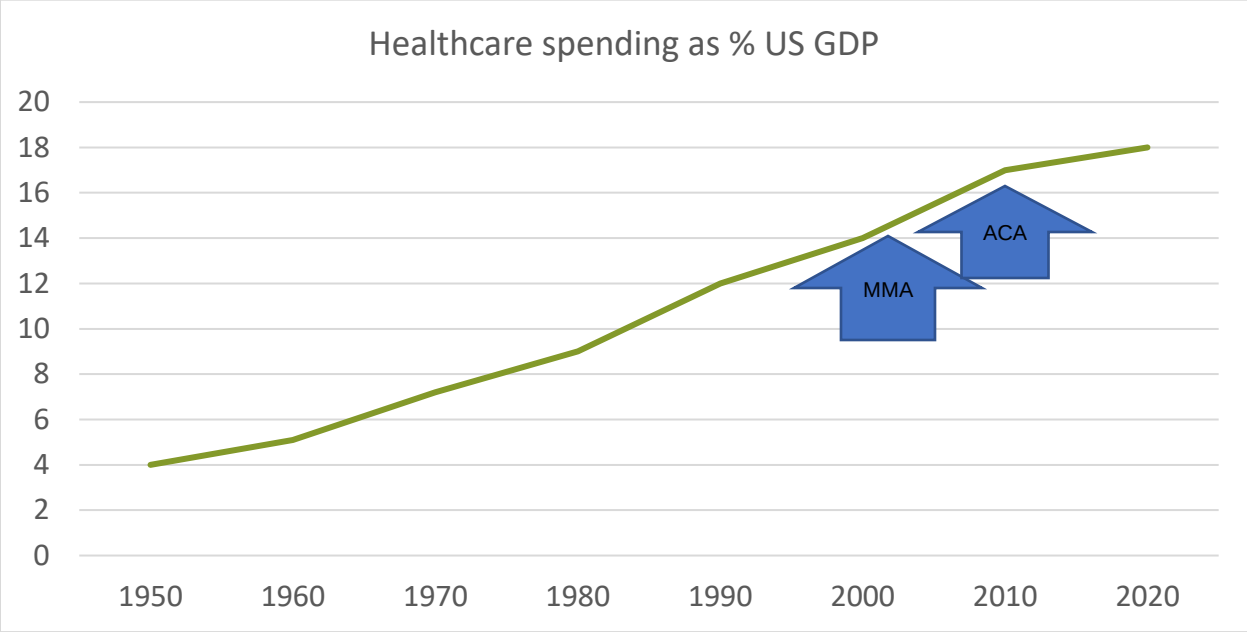
with wider access. By this definition, we can see internet success as an example – many more people have internet access today, at higher speeds, greater reliability and lower costs, than in 2003. Ditto cell phone use and automobile evolution and a host of other services and products.

> A quick note on car costs as an economic cost methodology example: we'll use the same approach to healthcare costs in a few pages.
>
> The average new car cost $24,770 in 2003, the average hourly wage then was $13 so the average person, working at the average wage, had to work 1905 hours to purchase a new car. (People generally financed new cars over time.)
>
> But in 2022, the average new car cost $47,150, the average hourly wage was $32 so the average person, working at the average wage, had to work only 1468 hours to purchase a new car. The 2022 new cars had a host of features that the 2003 cars lacked, including back up cameras, voice activated controls, onboard navigation, Wi-Fi and, increasingly, electric motors.
>
> Thus, despite the higher 2022 sticker price, the average 2022 new car, with all those additional safety and other features, cost less economically than the 2003 ones.

In healthcare, our reform definition means better health outcomes at lower costs for more people. Failure is the opposite: healthcare costs more, doesn't work any better than in the past and remains inaccessible to many.

How have we done on these metrics since 2003?

**Healthcare spending** as a percent of our total economy has risen since 1950 at about a constant rate. See the chart below. As healthcare spending grows, it consumes more and more of our economic resources. It inflates, in other words, more quickly than the economy as a whole. You can see that the Medicare Modernization Act had no impact on the rate of healthcare spending growth, while the Affordable Care Act has a minor impact. After both reforms, healthcare spending continues to grow faster than the overall economy and continues to consume more and more of our economic resources.




As a side note, ‘consume more and more of our economic resources’ means that we have fewer resources to invest in other parts of our economy as a percentage of our economy. Thus, as healthcare spending grows, other sectors – education, national defense, infrastructure development, etc. – have fewer resources available, again as a percentage of our total economy.

Phrased differently. this means that, as healthcare spending grows, we either spend less in these other sectors or borrow more to fund them fully.

**Healthcare outcome improvements**, though, do not demonstrate this same growth. See the chart below showing average life expectancy since 1950. I use life expectancy as the care quality metric since the fundamental function of a healthcare system is to keep people alive.

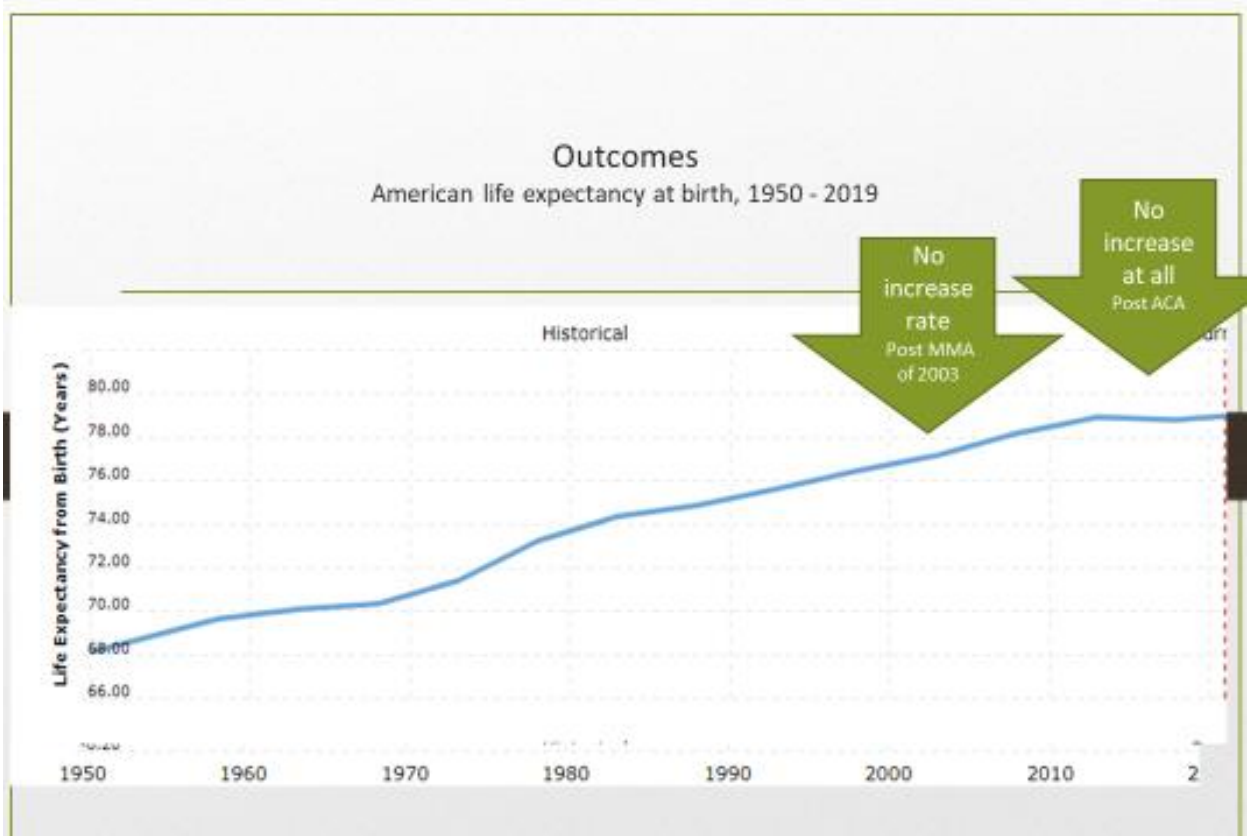
In economic / public policy terms, if our healthcare system keeps people alive longer, then it is arguably worth more funding; but if it does not, then I question whether the additional costs provide any value.

> Yes, I know that factors outside the healthcare system can impact longevity: wars, pollution, genetics, individual behaviors...a long list. But my point is that a healthcare system exists to keep people healthy and alive for longer. If a society identifies harms that limit longevity, then a good healthcare system will adapt and develop programs and treatments to ameliorate those harms. Take smoking, for example. Once identified as a cancer causing / life limiting agent, our healthcare system developed treatments – surgeries, early disease identification programs etc. – and preventive measures – patient education, smoking session programs,

medications to reduce smoker cravings, etc.- to combat smoking's negative effects. That's how a good healthcare system works.

A poor healthcare system limits the definition of 'healthcare' to functions it can perform well – knee surgeries and cataract removals for example - focuses on those, and claims that life extension is someone else's problem. A good healthcare system adapts and extends life. Is our healthcare system, post 2 reforms and by this definition, 'poor' or 'good'? See below.

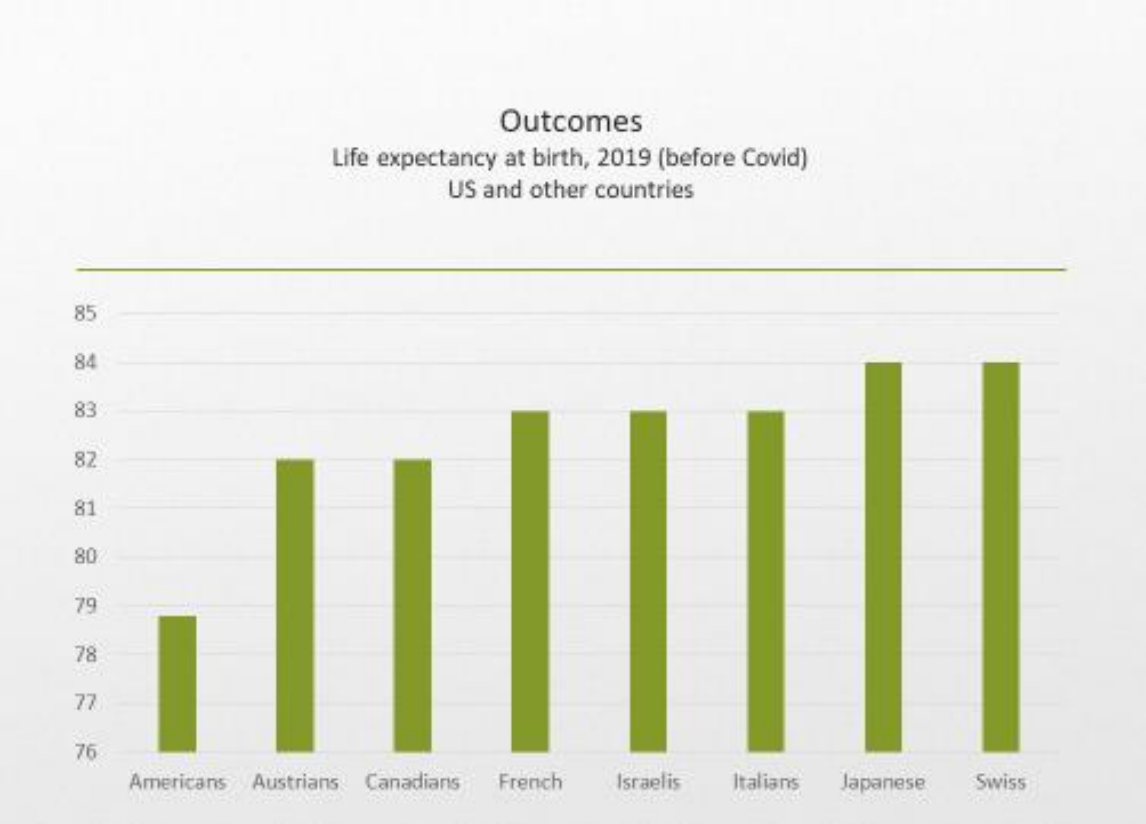
The chart below showing American average longevity at birth ends in 2019 on purpose: I did not want any Covid issues to interfere.




Four things to note here: first, the life expectancy annual increase is basically linear; we gained about as many life years in the 1950s as in the 1990s. Second, the biggest life expectancy gains occurred in the 1970s when we passed various public health measures like the Clean Water and Clean Air Acts. Third, the Medicare Modernization

Act had no impact on the rate of life expectancy growth; it was irrelevant. Fourth, interestingly and for some reason that I cannot explain, we saw no life expectancy growth post passage of the Affordable Care Act, again irrelevant.

In 2019, the last full year before Covid struck and all these metrics became murkier and more confusing, Americans lived less long than people in many (most?) other developed countries. See the chart below, generated **16 years** after passing the Medicare Modernization Act and **9** after passing the Affordable Care Act.




Neither the Medicare Modernization Act nor the Affordable Care Act impacted American's longevity. The underlying tends that existed when those healthcare reforms passed simply continued. The trillions of additional healthcare spending dollars encompassed in those legislations were irrelevant from a longevity perspective.

> Let's look at post-reform healthcare costs and outcomes as economists again, just like we looked at auto costs and quality a few pages ago. We'll use two different methodologies.
>
> First, the methodology we used in auto costs a few pages ago. In 2003, the US spent about $5,700 per capita on healthcare. The 2003 average hourly wage was about $13 so the average person, earning the average wage had to work 438 hours to pay for healthcare.

In 2019, the year before Covid hit, the US spent an average of about $11,500 per capita on healthcare. The 2019 the average hourly wage was about $15.35, so the average person, earning the average wage had to work 749 hours to pay for healthcare.

The analysis above shows that healthcare was much more expensive in 2022. It doesn't tell us if the more expensive healthcare system in 2019 worked better than the 2003 version like in the auto example above, where today's cars are better and safer than the 2003 versions.

So our second approach to thinking as economists will incorporate a productivity and quality indicator to measure healthcare system improvement (or lack thereof) over time. We'll divide average per capita healthcare spending per year by average longevity and compare that number in 2003 – the last year before passage of the Medicare Modernization Act - and 2019, the last year before Covid.

In 2003, again, the US spent about $5,700 per capita, we lived, on average, about 77 years, so our ratio of per capita spending to expected life years was 74. That doesn't mean anything in a vacuum but allows us to compare systemic quality and productivity over time.

In 2019, again, 16 years after passing the Medicare Modernization Act and 9 after passing the Affordable Care Act, we spent about $11,500 per capita and lived, on average, about 79 years. Our 2019 ratio of per capita spending to expected life years was 147, about 73 points higher than our 2003 indicator.

Could this increase be due to overall inflation? One online inflation calculator suggests that $1 in 2002 was equal to $1.42 in 2019.[1] Applying this factor, our healthcare efficiency metric of 74 in 2003 would reasonably be expected to rise to 105 in 2019 due to inflation, a rise of only 31. But it increased by 75. More than half the increase in our metric was something other than inflation.

What was it? My presumptive answer: healthcare system inefficiency, defined as outcomes per dollar spent. Leaving inflation out, we spent far more for each life year in 2019 than in 2003. I'll suggest 4 types of inefficiency or system value reductions.

- One type revolves around prices. Healthcare providers, pharmaceutical companies, medical device manufacturers etc. raised prices far more than at average overall inflation rates because they could – an indicator of market strength. We'll discuss market consolidation later in this chapter.

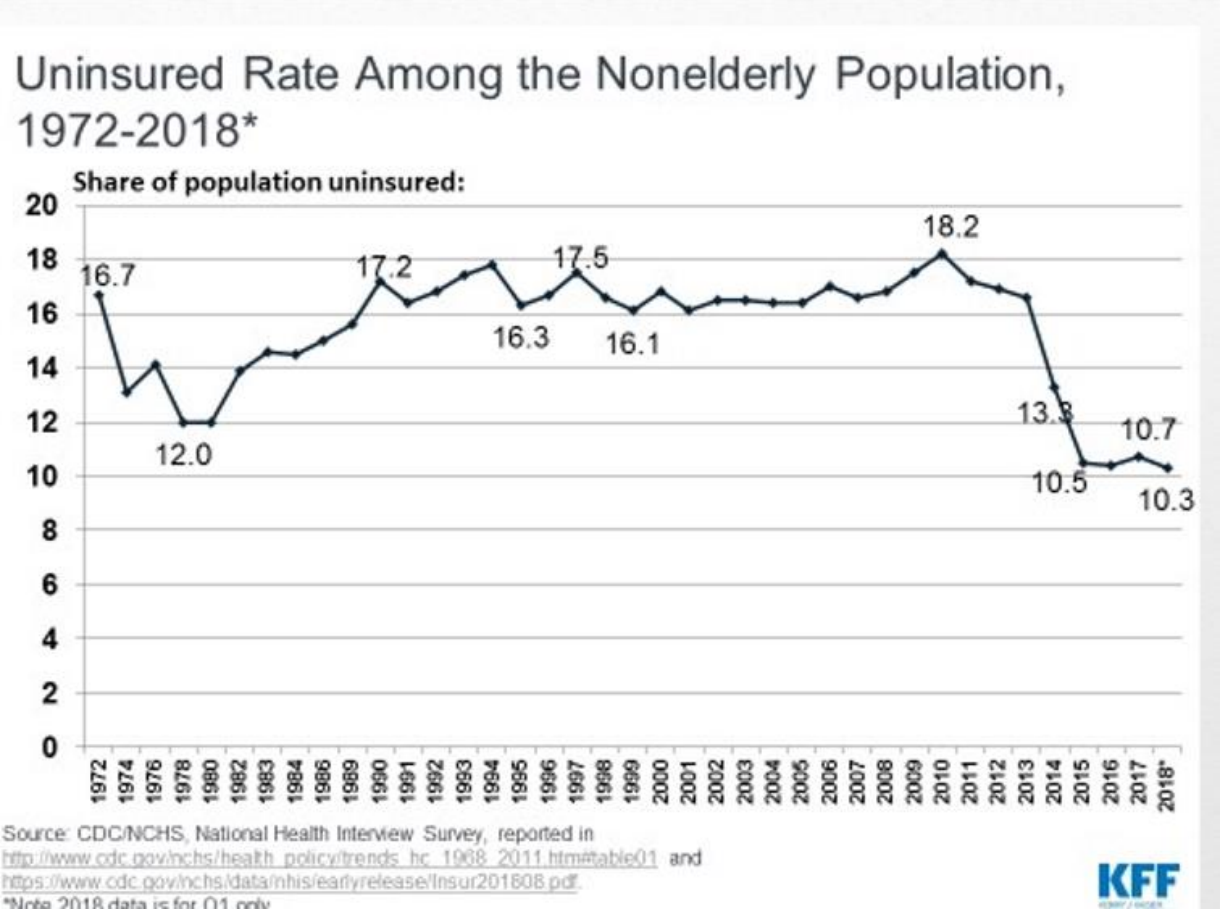
[1] CPI inflation calculator https://www.in2013dollars.com/us/inflation/2002?endYear=2019&amount=1

- A second type of inefficiency comes from patient coding. According to the HHS inspector general, “hospitals increasingly billed for inpatient stays at the most expensive level from FY2014 to FY2019…these stays are vulnerable to…upcoding.”[2] Upcoding means labelling a patient as sicker for financial and reimbursement purposes.
- A third type of inefficiency comes from the mix of medical services provided in 2019 vs. 2003. Providers in 2019 sometimes (often?) opted for more expensive treatments when less expensive ones existed, or new drugs that worked no better than older ones might dominate the marketplace, or new devices that worked no better than older ones.
- A fourth type of inefficiency might come from a changed patient population needing medical care. The 2019 folks might be older, sicker or more obese than the 2003 group.

There is good evidence that all 4 factors combined in 2019 to describe that increase in our healthcare efficiency metric. We’ll discuss some of this below. Regardless, though, of the exact cause, my underlying point here is that neither healthcare reform package – the 2003 Medicare Modernization Act nor the 2010 Affordable Care Act, nor both together – created a more efficient healthcare system that provided better outcomes at lower costs. Both reforms failed on that efficiency scale.

Let’s turn now to coverage expansion, one of the 3 goals of any economic reform program. Post-Medicare Modernization Act – the legislation that was supposed to reduce healthcare costs and thus stimulate higher coverage rates due to the lower costs of health insurance – our **national uninsured rate** did not decrease. But post-Affordable Care Act the national uninsured rate did decrease, from about 18 to 10% of our total non-elderly population, or from about 50 to 30 million people. See the chart below.

[2] HHS Inspector General Data Brief, **February 2021** OEI-01-18-00380



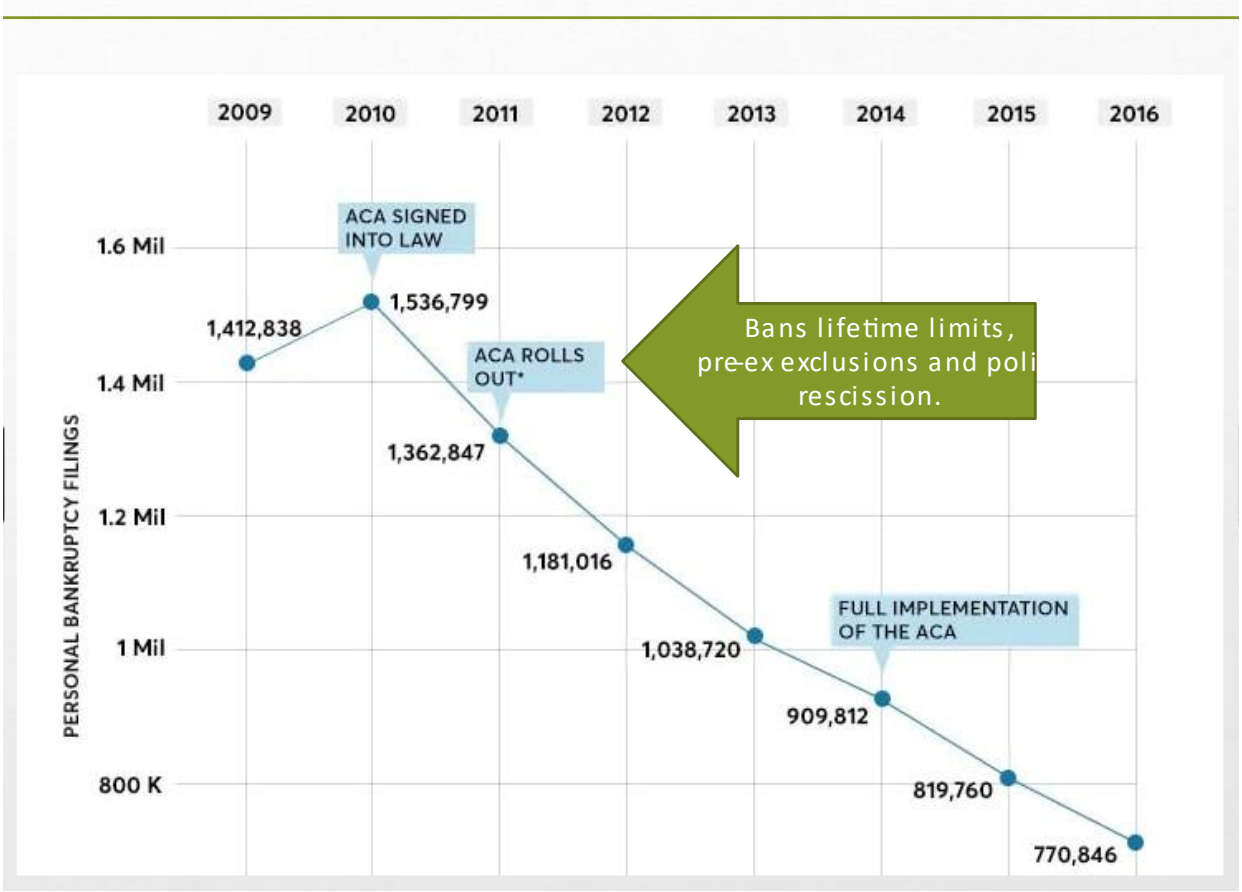

Wider health insurance coverage post-Affordable Care Act but no life expectancy gain. We'll discuss why below, but this initial analysis raises an interesting question: should we grade healthcare reforms *only* on coverage rates? After all, coverage rates are something we can control fairly easily (nothing in healthcare is easy but expanding coverage is mainly a political issue while extending longevity includes medical, economic, social, genetic, educational, behavioral and other issues.)

Some people say 'yes', that the government's role should only be to ensure coverage while the private sector – doctors, hospitals, pharmaceutical companies etc. - should focus on care quality and cost. The government's role is only to promote access; the private sector's is to promote quality. Thus 'good healthcare reform' by this definition, brings down the uninsured rate. Period.

> I find this a strange argument. Extending it to the logical conclusion, it makes the Canadian or British healthcare systems better than ours. After all, they cover everyone while we only mange to insure about 90% of Americans. Few brokers, in my experience, and fewer politicians I suspect, would embrace that conclusion.

All this supports my skeptical position about healthcare reform, that Americans have no clear national vision of what a good healthcare system actually is. Yet each of us, working in the healthcare arena, claims to using our own, parochial one: a good healthcare system is one that pays me well. Odd but, unfortunately I suspect, true.

There is, though, one unequivocal, clear winner from healthcare reforms since 2000 – people declaring bankruptcy from medical expenses. Our national bankruptcy rate has fallen by about half since passage of the Affordable Care Act, from about 1.5 million to 750,000 annually. See the chart below. Many, if not most bankruptcies in the US are caused by medical bills.




While reducing the number of personal bankruptcies is clearly a good thing, I wonder if there might be alternative strategies available to accomplish this goal – other, that is, than revamping the entire US healthcare system. Nonetheless, I take this as a healthcare reform win, the only one I see.

## Healthcare reform tools

Let's now consider the tools available to healthcare reformers.

Market based reforms, like the Medicare Modernization Act, focus on so-called 'bottom up' or consumer driven incentives. These market based folks like to deregulate so the market, i.e. the interactions between medical care suppliers and medical care purchasers, takes place as efficiently as possible. Market based reformers dislike mandates and requirements, seeing these are obstacles coming between clinicians and patients. They dislike, in other words, things like insurance coverage requirements or minimum benefit packages that, in their eyes, raise prices unnecessarily. The marketplace, they argue, would differentiate 'good' from 'bad' insurance policies more efficiently.

> Classical economic theory holds that an unencumbered buyer with access to all available information, will choose the highest quality / lowest cost products available. The market based reform team tries to apply this economic principle to healthcare.

Market based reformers like competition, figuring that more competition will force medical care suppliers (providers, clinicians, physicians, pharmaceutical companies and insurers) to find better / less expensive ways to treat sick patients. This becomes, they hope, a virtuous circle in which each product improvement / price reduction move stimulates others in the same direction.

Market based reformers like association health plans, seeing them as competition to large insurance companies. They like price lists and reference pricing figuring that patients will use price as a choice consideration, purchase lower priced care and therefore exert downward pressure on medical prices.

> Reference pricing means that an employer or insurance policy will pay a stipulated amount for a specific treatment, say $5000 for knee surgery for example. If the patient wants the $6000 treatment, or prefers the $6000 surgeon, then he or she pays the additional $1000. In theory, reference price lists reflect the lowest priced medical providers in an area, thus stimulating other providers to lower their own prices to compete.

Market based reformers like Health Savings Accounts and HRAs, both of which put money into patient hands, on the theory that patients will spend their money more wisely than a huge, bureaucratic, bulky insurance carrier.

Government based reforms, on the other hand, use more top-down tools. This team likes regulations that force medical providers and carriers to act in certain ways. They don't trust the market to work its magic in healthcare. These folks like mandates, for example, that require employers to provide health insurance to employees. They like

the individual mandate that requires everyone to have health insurance, this to avoid so-called ‘insurance death spirals’ in which only sick people purchase insurance.

> Insurance death spirals occur when healthier people don’t purchase health insurance, but sicker people do. This drives up premiums, so ‘slightly sicker’ people stop purchasing and only the sickest remain on the insurance books. This makes premiums too expensive for most people, uninsured rates skyrocket and the system collapses.
>
> Insurance operates on the law-of-large-numbers principle and needs lots of healthy people enrolled to counter the costs of sick people. That is why the Affordable Care Act instituted the individual mandate.

Government based reformers also like a required minimum set of benefits in any ACA compliant policies. They worry that carriers might lower their policy prices by leaving out important benefits. Policy holders, either unsophisticated purchasers or victims of unscrupulous sales tactics, might not learn of the benefit gaps until they get a bill, potentially a huge one. In other words, government based reformers see a minimum benefit requirement as consumer protection far less than inflationary. Our market based reform friends, discussed above, see the situation very differently.

The Affordable Care Act created health insurance exchanges, or online marketplaces where individuals could shop for health insurance. Exchanges list all available policy options from all available carriers in a region, encouraging consumers to compare prices and coverages before purchasing. By and large, exchange offered plans cover similar benefits but with different cost sharing.

> Cost sharing means that the policy holder and insurance company each pay a portion of the premium and medical costs. Some policies might cost less but force the insured to pay more at the point of service; others might cost more but have a lower annual deductible.

Which team of healthcare reformers is right - the market based or government based folks? Which approach will reduce healthcare spending, extend life expectancy and provide universal insurance coverage? The unsatisfactory answer is that no one knows for sure, but both teams are convinced of their own infallibility with almost religious zeal. The Medicare Modernization Act passed the Senate in 2003 with 45 Republican votes and only 9 Democrats; the Affordable Care Act passed with 60 Democrats and no Republicans. Given that neither reform reduced costs, extended life expectancy or provided universal insurance coverage, I suspect that the real purpose of healthcare reform is to fight the good fight, raise money from political supporters and stay in office rather than actually to solve any of our myriad healthcare system problems.

But that’s just my own point of view.

Why reforms always fail to reduce costs, extend longevity and provide universal access?

I would argue that all our healthcare reforms since 2003 have ignored the 3 elephants in the room: obesity, industry consolidation and so-called 'diseases of despair' a new term to describe suicide, alcoholism and drug abuse. Any one of these 3 elephants would have made true healthcare reform difficult; all three together make healthcare reform impossible and generate the dismal results we see today. Let's address each elephant in turn and do so in the classical economic terms of supply and demand. But in our case, we'll go in reverse order, demand and supply because this makes our story flow somewhat more logically.

Obesity on the demand side of our 'supply and demand' equation, suggests why Americans need so much medical care. High national obesity rates work in opposition to our 3 healthcare reform goals: obesity decreases life expectancy, increases healthcare costs and therefore exacerbates our uninsured problems.

As I researched the obesity data for this lecture, I found three examples of obesity costs that surprised even me, and I study this stuff for a living. First, as people become more obese, their need for knee surgery rises dramatically. For this analysis, remember that a normal or healthy Body Mass Index tops out at 25.

> Body Mass Index or BMI is our standard weight and obesity metric. It divides someone's weight in kilograms by their height in meters squared. You can find lots of online BMI calculators. A BMI between 18.5 and 24.9 is considered healthy. Below 18.5 is considered underweight, above 25 overweight. A BMI above 30 is labelled obese. The chart below shows BMI rates for a 6 foot tall person at different weights, simply as an example:
>
> - At 147.5 pounds, the 6 foot tall person has a BMI of 20
> - At 184 pounds, the 6 foot tall person has a BMI of 25
> - At 221 pounds, the 6 foot tall person has a BMI of 30
> - At 258 pounds, the 6 foot tall person has a BMI of 35
> - At 295 pounds, the 6 foot tall person has a BMI of 40

As the BMI increases, the need for knee surgery increases proportionally more. Here are estimates from the American Academy of Orthopedic Surgeons for the rate of total knee arthroscopy by BMI. Compared to a normal weight person,

- Someone with a BMI of 30 is 8.5 times more likely to need knee surgery;
- Someone with a BMI of 35 is 18.7 times more likely, and
- Someone with a BMI of 40 is 32.7 times more likely.

We'll label that example 'surprising cost impacts of obesity #1'.

Next, consider the need for bariatric surgery, or surgery to remove part of your stomach to reduce your weight. People generally opt for this procedure after diets and other

lifestyle changes have failed. The US annually spends about $180 billion on bariatric surgery and related medical procedures, that approximation in 2020 dollars.

Compare that to our annual cancer treatment expenditures of around 200 billion or so. Almost as much. But note that virtually everyone in American who gets diagnosed with cancer gets treated. By contrast only about 1% of the eligible obese population has so far had bariatric surgery. That's a huge population appropriate for and needing the procedure. We'll label this 'surprising cost impacts of obesity #2'.

And third, consider the additional Covid costs of obesity, including more severe symptoms, longer hospitalizations, more costly treatments and poorer outcomes. (This section was written in early 2022. Over time Covid treatments have evolved so some of this might be out-of-date when you read it.) According to Dr. Dariush Mozaffarian, dean of the Tufts Friedman School of Nutrition Science and Policy, as quoted in the Boston Globe on November 22, 2021 in an article The Obesity Pandemic Has Made Covid Much More Deadly, "64 percent of all the hospitalizations from COVID could have been prevented, if we had a metabolically healthy population, without the rates of obesity and diabetes and hypertension that we have now."

Let's try to calculate the obesity costs of Covid using Dr. Mozaffarian's estimate above. First, we'll assume the average hospital cost of treating a Covid patient at $100,000. Admittedly rough, this comes from the Becker's Hospital Review analysis by state.[3] To simplify, the average Massachusetts hospital costs of treating a complex Covid patient in 2020 – 2021 were $209,200; the average Massachusetts hospital cost of treating a non-complex patient were $62,900. Other states are basically in the same ballpark. $100,000 per patient is 'not obviously absurd' to quote one of my old grad school professor's mantra.

Meanwhile, the American Hospital Association estimates over 80 million Covid cases and 4.6 million hospitalizations.[4] Multiplying those 4.6 million hospitalizations times $100,000 per hospitalization comes to a whopping $460 billion. Dr. Mozaffarian's 64% of Covid hospitalizations attributable to obesity is almost $300 billion.

That's a huge cost! We'll label this 'surprising cost impact of obesity #3'.

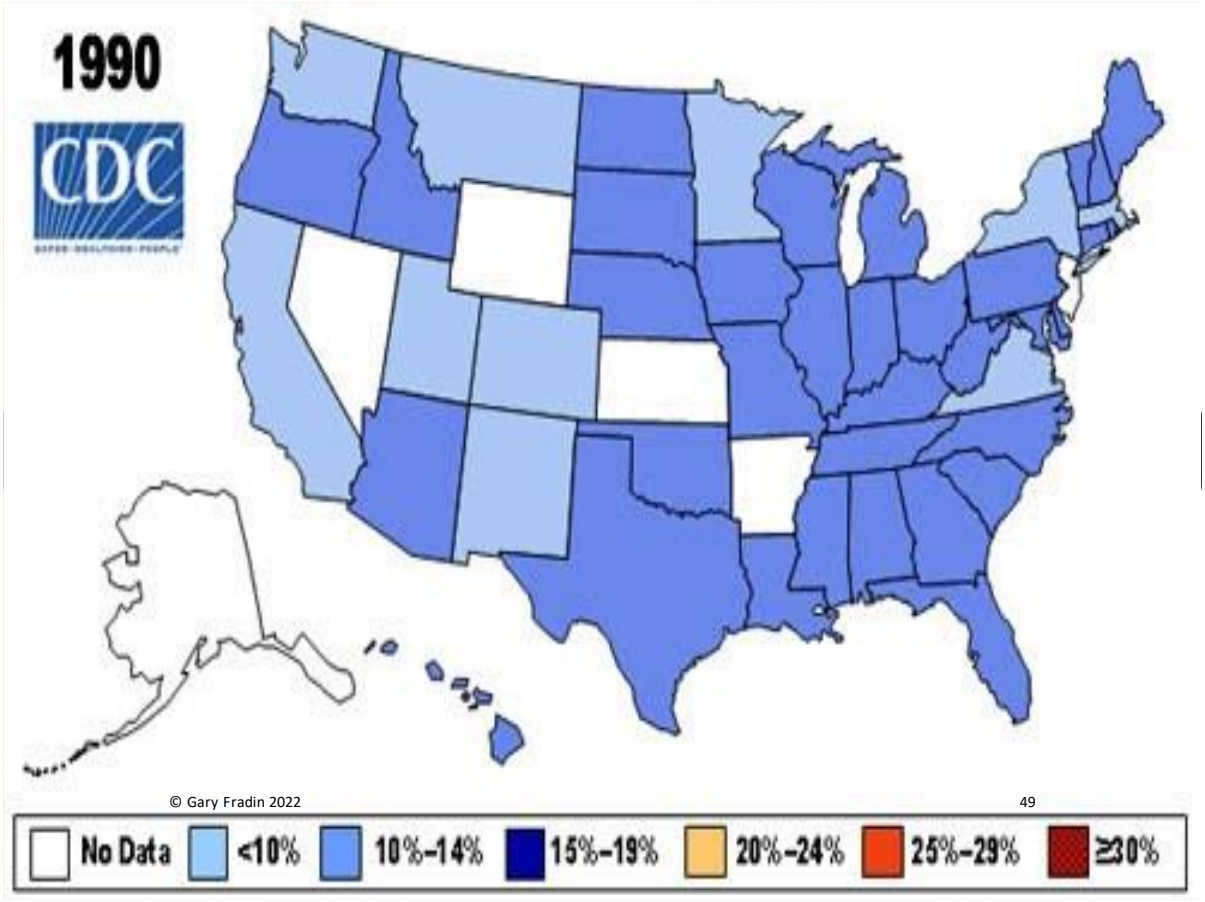
I hope I've made the basic point that obesity is a key driver of healthcare spending and adds a huge amount to our healthcare costs. Which raises the critical question of how well we have done on the obesity front since we reformed healthcare 2003. Presumably

[3] Average charge for Covid 19 hospitalization by state, Alia Paavola, Becker's Hospital Review, October 20, 2021

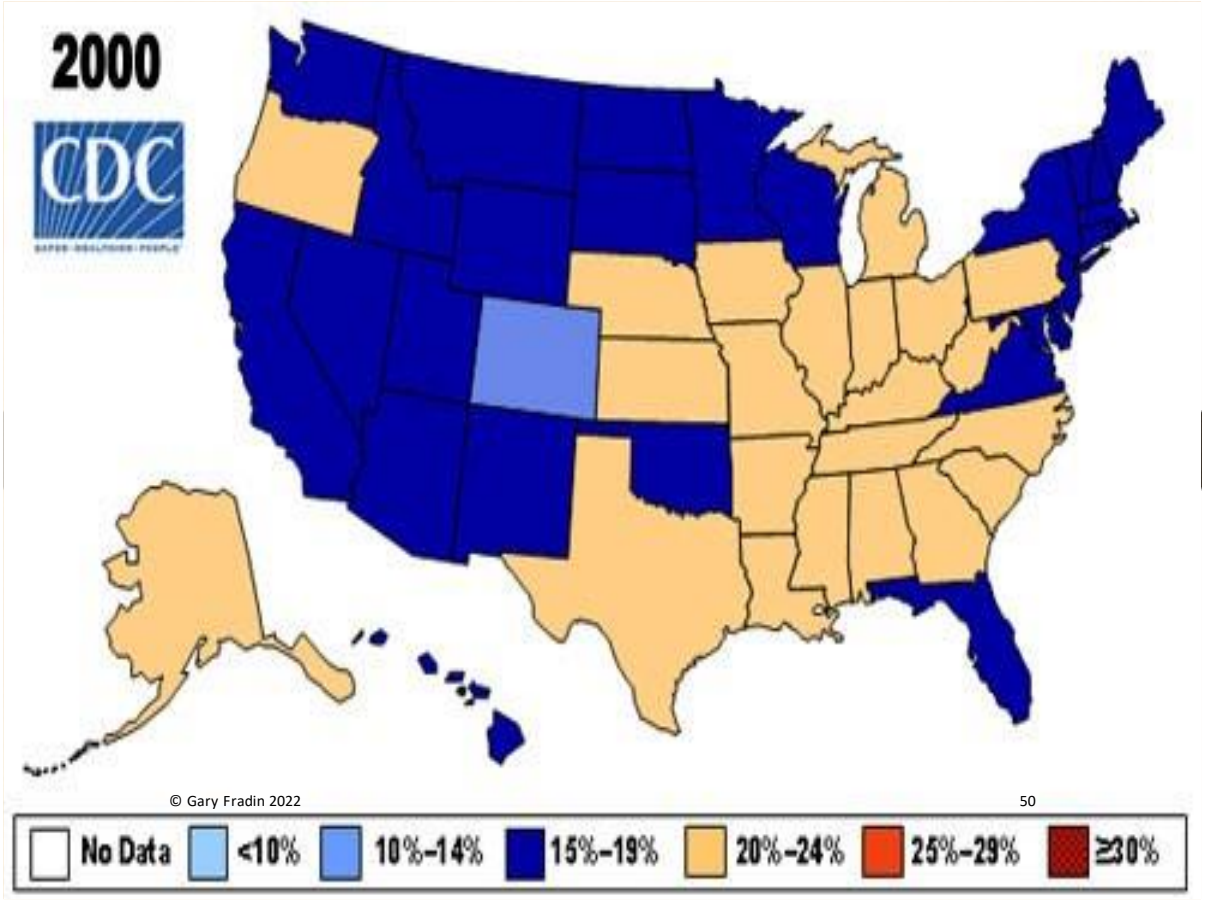
[4] Rising growth in expenses and rising inflation fuel financial challenges for America's hospitals and hospital systems, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial#:~:text=Medical%20supply%20expenses%20grew%2020.6,%2C%20from%20pre%2Dpandemic%20levels.

lower obesity would work toward our healthcare reform goals of better outcomes at lower costs for more people, which greater obesity would work in the opposite direction. In fact, I'll push this even further and suggest that healthcare reforms that fail to address or control obesity set themselves up for failure.

Let's see how we've done and use CDC charts as our guide. We'll start in 1990, before our healthcare reform packages, to set a baseline. The chart below shows obesity by state in 1990. The 4 white states mean 'no data', the 19 light colored states have less than 10% of their populations obese, and the remaining darker states have 10 – 14% of their populations obese. Note also that the CDC's grid at the bottom tops out at greater than 30% obese, a situation the CDC presumably figured unlikely to occur.

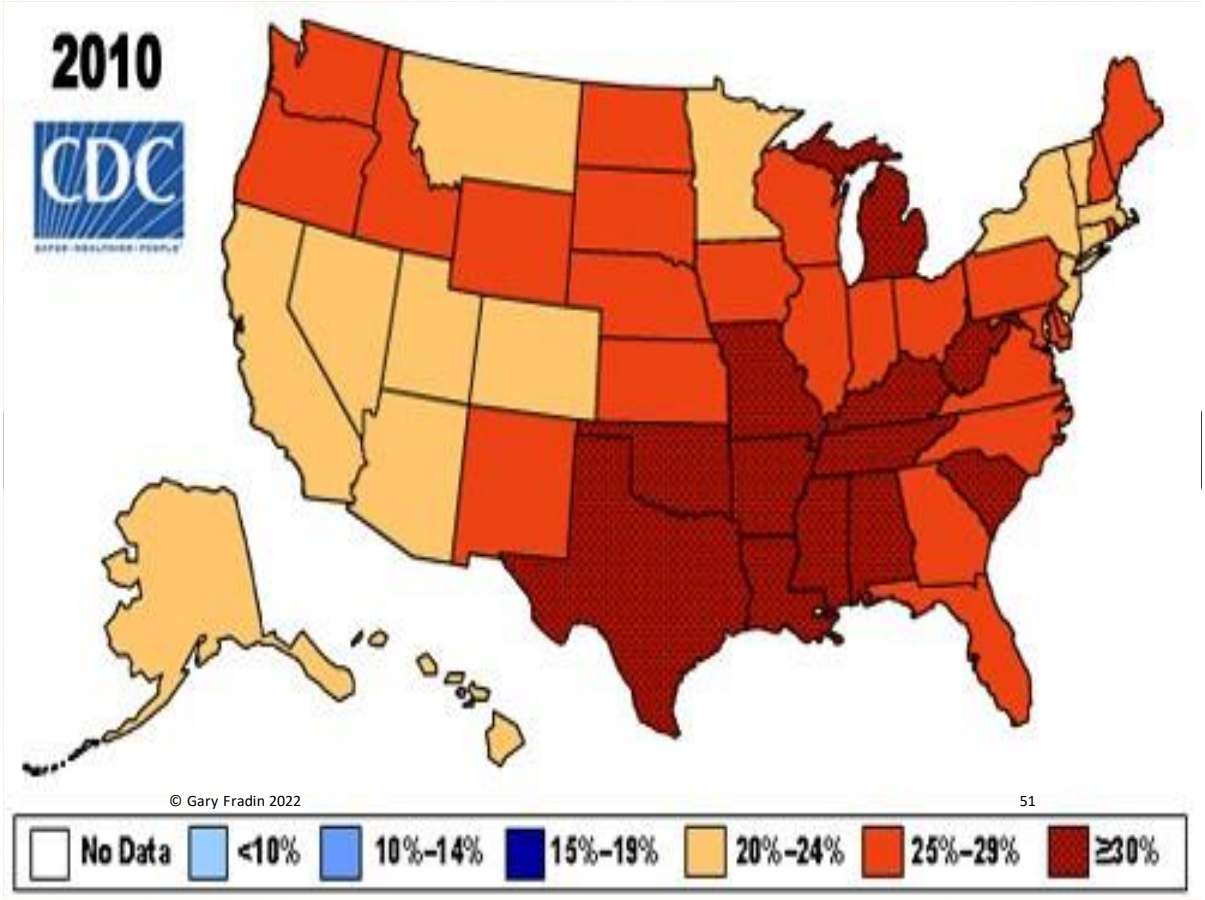



Then, 10 years later, our map changed. Same CDC methodology, same metrics, same format but a vastly different obesity map in only 10 years.



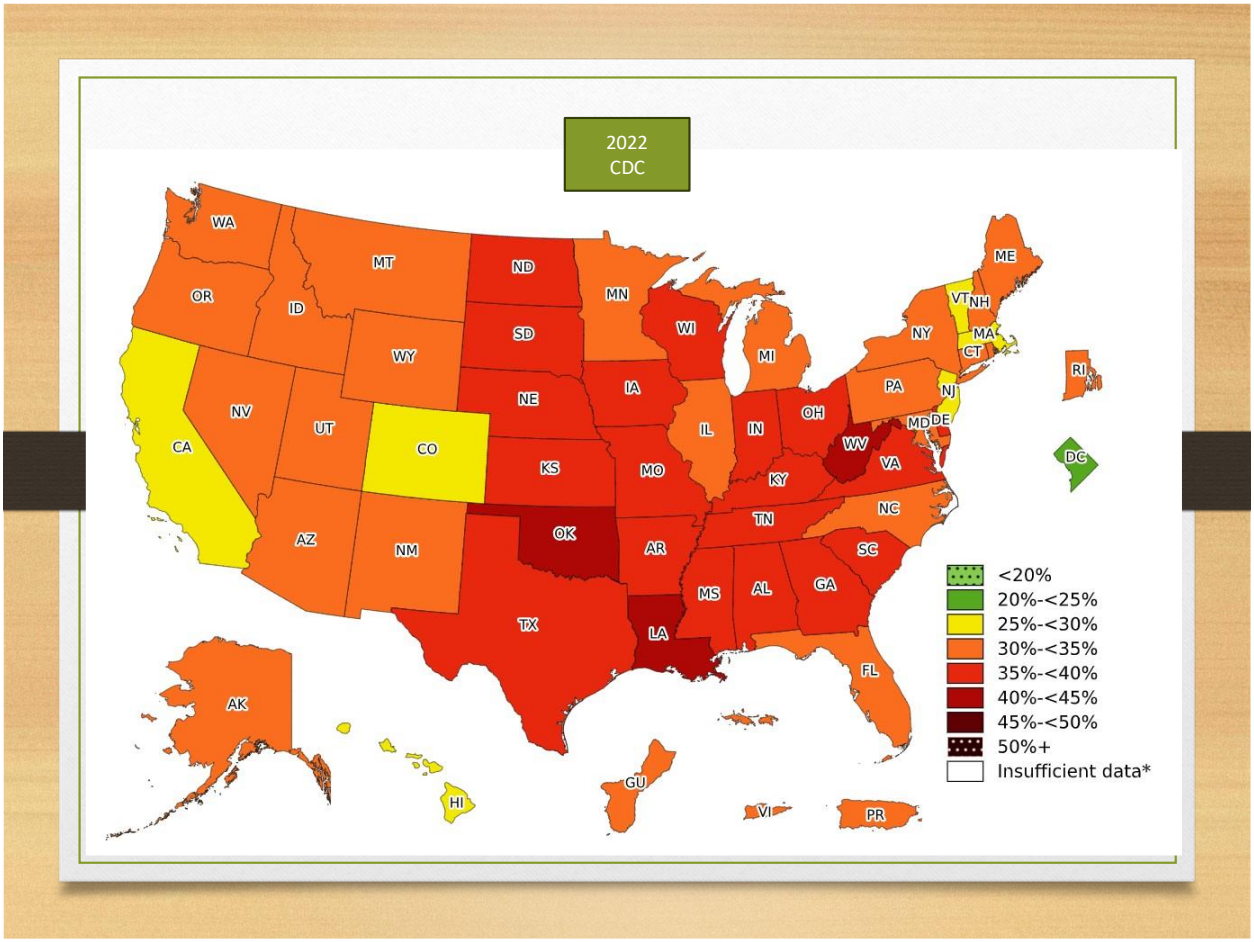

No state is less than 10% obese and only Colorado is less than 14% - the highest level of any state just 10 years before. Now, in 2000, over half the states are 20 – 24% obese, a level no one had reached in 1990.

We then passed the Medicare Modernization Act and the Affordable Care Act…and our map changed dramatically again.




Forget about being less than 20% obese, a level no state had approached just 20 years before. Now no state is less than 20% obese and 11 states had hit the CDC's top limit of 'greater than 30%' obese, a situation the CDC thought unlikely just 20 years previously.

This led the CDC to rethink their format and methodology. In 2022, the CDC had a completely different map.




Only 1 area – DC, not even a state - was less than 25% obese and only 5 less than 30% obese. All the others were greater than 30% obese and a handful exceeded 40%. That's exceptional growth since passage of the Medicare Modernization Act and Affordable Care Act, one that makes achievement of those reform goals overly difficult.

A different CDC study estimated that 42% of us were obese in 2018 and Dr. Mozaffarian, our old friend from the Tufts School of Nutrition, estimated at 1 in 4 teenagers were pre-diabetic.

How, I wonder, can we reduce healthcare spending, improve healthcare outcomes and insure more people with a national obesity rate of 42% and 25% of US teenagers suffering from pre-diabetes. My short answer: you can't.

Let's now move from obesity on the demand side of our 'supply and demand' analysis to the supply side and discuss industry consolidation in the healthcare arena. As a basic economic principle, if you have increasing demand for services – which we have from obesity – and fewer medical care suppliers, then you will see prices rise. Let's examine our post-reform history.

First, hospitals have merged to create large hospital systems. Though they had been merging fairly actively prior to passage of the Affordable Care Act – in Boston, for example, Brigham and Women's merged with Mass General in 1994 – mergermania continued in the hospital sector. Between 2011 and 2017, i.e. post passage of the Affordable Care Act, some 1587 hospitals or about 25% of the US total, merged. These merged hospital systems became the largest (or 2nd largest depending on Amazon) employer in most states. This middle class or wealthier employee population represented votes at the state level to promote the hospital system's interests. The hospital's coffers represented lobbying dollars to promote the hospital system's interests. The merged hospital system spoke with one voice in negotiations with health insurers. And the hospital's wealth funded high priced lawyers to defend the hospital system's interests against aggressive state attorneys general who wished to curb hospital dominance.

The net result was higher medical prices with, according to a 202 analysis in the New England Journal of Medicine, no significant change in 30 day readmission or mortality rates, i.e. no care quality improvement.[5] The Inspector General at the US Department of Health and Human Services phrased this differently in 2021 saying "hospitals increasingly billed for inpatient stays at the most expensive level from FY 2014 through FY 2019" because "these stays are vulnerable to … upcoding".[6] (Upcoding means labelling the patient as sicker to get a higher insurance or Medicare payments.)

The net result: fewer hospitals, caused by the huge number of hospital mergers, used their market power to raise prices.

Hospitals not only merged together but also purchase physician groups to act as 'patient feeders', directing patients to specific hospitals. Between 2016 – 2019, hospitals purchased some 9000 physician practices, again constraining the supply of medical care providers in a region.

Then private equity groups entered the picture, purchasing about 22 physician practices between 2018 and 2019. Private equity purchasers had specific goals: either make a good return on their purchase investment or build an asset for future sale, or both. This motivated physicians to perform more procedures at higher prices. According to a 2022 American Medical Association study 'prices rose 26% in private equity-backed practices, while prices at similar practices without private equity investment grew by 12.9%'.[7]

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[5] Beaulieu et al, Changes in Quality of Care After Hospital Mergers and Acquisitions, New England Journal of Medicine, 2020

[6] HHS Inspector General Data Brief, February 2021 OEI-01-18-00380

[7] Zhu, Private Equity Acquisitions of Physician Medical Groups, JAMA Network Research Letter, Feb 18, 2020

Merged hospitals, combined with acquired physician practices, reduced the number of independent, competitive, healthcare providers dramatically post-healthcare reform. (The actual number of physicians did not decrease, just the number of businesses competing.) Faced with less competition, these large, merged businesses did what any large business would do in similar circumstances: they raised prices. How, I wonder, do negotiations go between a hospital system that controls 75% of the beds in a region and most of the physicians, and an insurer who has a 15% market share?

So far, I've suggested that demand for healthcare services rose post-healthcare reform due to obesity (among other factors) and the supply of healthcare providers available to deal with that increased demand fell due to industry consolidation. Now let's switch focus and discuss the environment in which all this took place. We'll introduce a new term: 'diseases of despair' or alcoholism, drug abuse and suicide combined.

People who die from alcoholism, drug abuse or suicide are said to die 'deaths of despair'. Some numbers to set the scene:

- Alcohol is linked to 95,000 annual deaths according to the CDC. This is about double gunshot deaths.[8]
- 500,000 Americans have died from drug abuse since 1999 including 107,000 in 2021.[9]
- 48,000 annual suicides.[10]

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

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AMA 2022 study, Robeznieks, 'Physicians warned of the pitfalls behind private equity promises, Aug 1, 2022 https://www.ama-assn.org/practice-management/private-practices/physicians-warned-pitfalls-behind-private-equity-promises

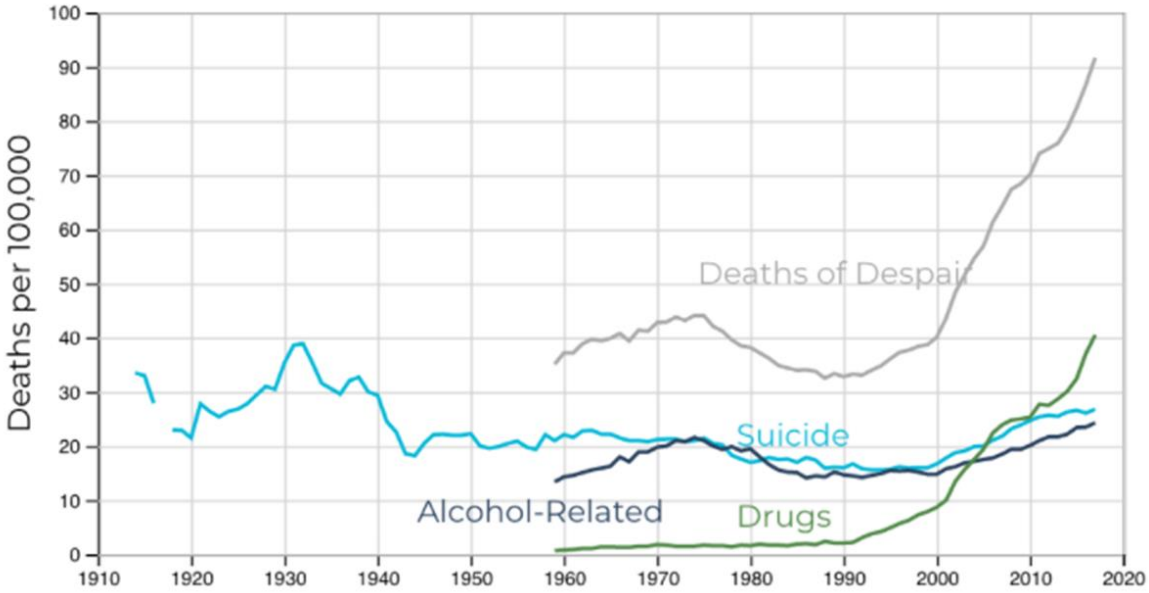
[8] Forbes https://www.forbes.com/sites/joshuacohen/2018/07/19/diseases-of-despair-contribute-to-declining-u-s-life-expectancy/#277e57f0656b, Gunshot deaths https://www.cdc.gov/nchs/fastats/injury.htm

[9] CDC estimate https://www.cdc.gov/media/releases/2020/p1218-overdose-deaths-covid-19.html

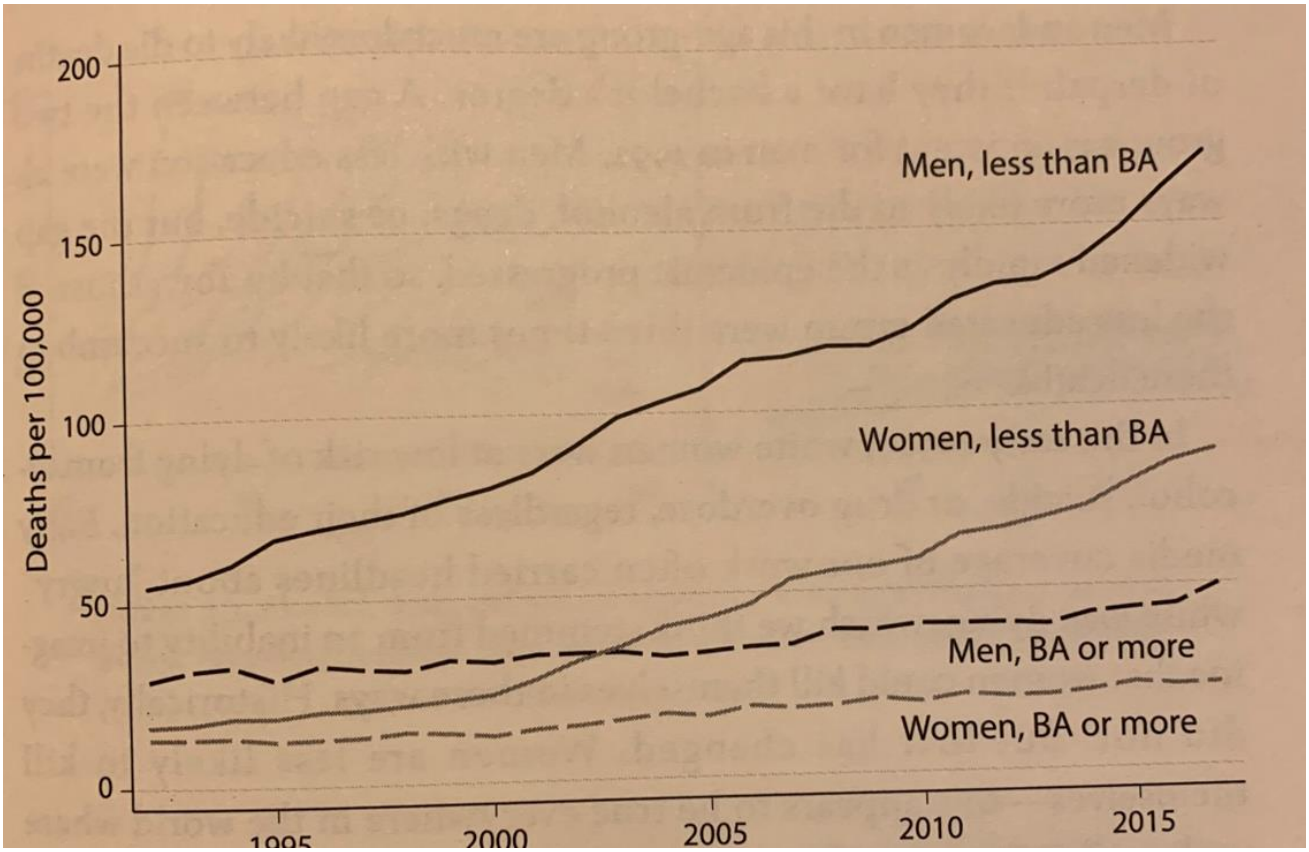
[10] Reference for Figure 3 chart **SEP 05** 2019 United States Congress Joint Economic Committee "Long term trends in deaths of despair"

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

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



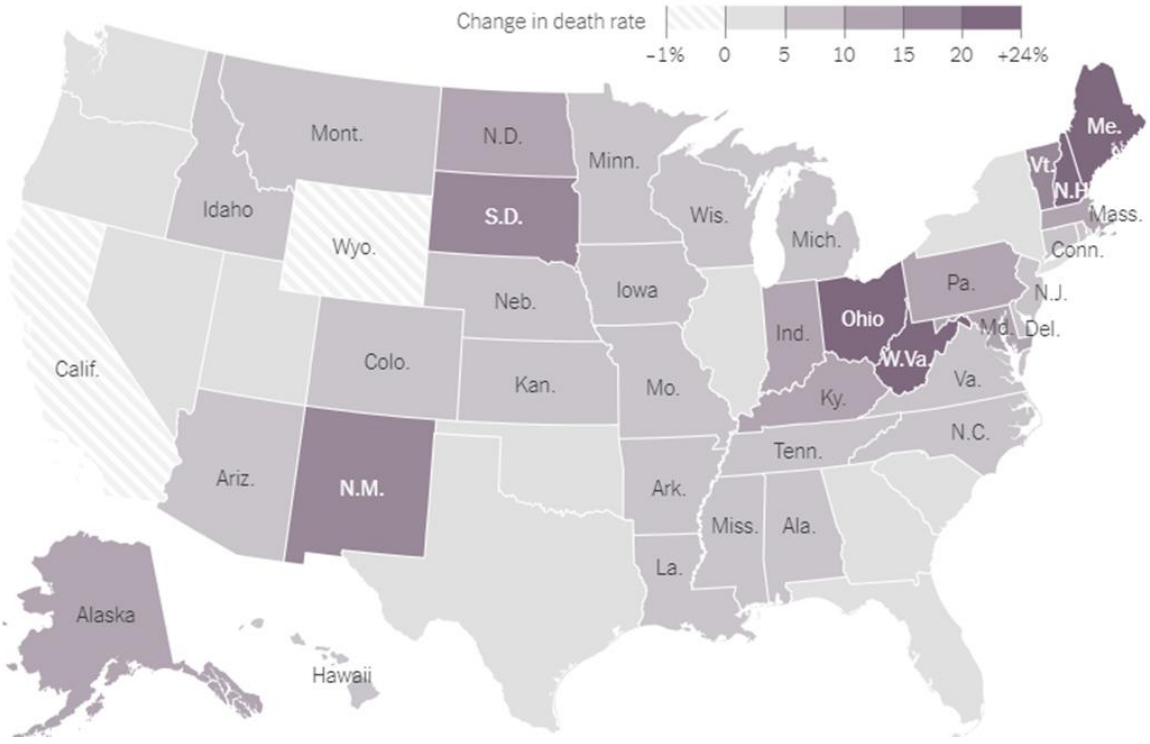

Deaths of despair fall disproportionately on middle aged, white, non-college educated men. The following chart, 'drug, alcohol and suicide mortality among white, non-Hispanics aged 45 – 54' shows this. It's from the 2020 book Deaths of Despair by Angus Deaton and Anne Case.




The next chart shows the net impacts of both healthcare reforms, the Medicare Modernization Act and Affordable Care Act. It shows the increase in mortality between 2010 and 2017 among people aged 25 – 64. These are the folks who should finish their education, begin and develop their careers, get married, have kids, build community and pay taxes. In all states except California and Wyoming, the death rate of this group has increased since passage of the ACA. In the darkest colored state, the death rate increase has been 20% or more.[11]

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

[11] NY Times, It's Not Just Poor White People Driving a Decline in Life Expectancy, Kolata and Tavernise, Feb 18, 2021 https://www.nytimes.com/2019/11/26/health/life-expectancy-rate-usa.html




I understand the components of healthcare reform and what they are supposed to do. Health insurance exchanges are designed to help people shop more easily for health insurance policies. Eliminating annual and lifetime caps allow patients to receive more medical care. Health Savings Accounts combined with annual deductibles and price lists can help people purchase lower cost commodities like MRIs, X rays and a few other relatively low cost products.

But I don't understand how expanding HSAs, increasing insurance options or publishing medical prices reduce obesity, because they don't.

I don't understand how any component of healthcare reform helps people navigate through our 'insane' (Harvard Business School's Regina Herzlinger's term) or 'uniquely dysfunctional' (Columbia School of Public Health's Jonathan Engle's term) healthcare system when 1 hospital system controls 70% of the physicians and beds in a region, because they don't.

And I don't understand how any component of healthcare reform addresses deaths of despair because they don't.

In other words, I don't see any financial, political, insurance or payment format solution to our healthcare system problems. We've seen in the combination of Medicare Modernization Act and Affordable Care Act that incremental reforms don't work. And we know that dramatic, radical healthcare system reforms are politically impossible. The situation looks hopeless.

What might save us?

To answer this question, I propose a quick review of America's history of change, an analysis of how we have solved unsolvable problems in the past. By studying how we solved these problems in the past, we can see how we will likely solve our healthcare system problems in the future.

I am guided in this analysis by two thoughtful comments. The first comes from Herbert Stein, a well-known economist in the last century – Chairman of the Council of Economic Advisors to Presidents Nixon and Ford, for example – who famously observed that 'trends that can't continue, won't'. Something, in other words, always intercedes to avoid utter catastrophe. I suspect Stein is right about this.

The second comes from Mark Twain who equally famously observed that 'history doesn't repeat itself but it rhymes.' Historical examples, in other words, don't tell us exactly what will happen in the future but they suggest a direction.

Let's explore a non-healthcare problem from the late 1800s that could have destroyed civilization as we know it. The problem is horse refuse in major cities. We'll focus on New York since I have some data about this courtesy of the New York Times.[12]

Building technologies changed in the 1870s or so, with Andrew Carnegie's commercialization of steel. Buildings were no longer limited to 4 or 5 stories but could now reach 40, 50 or more. This led to more people living and working per acre.

At the same time, immigrants flooded to New York, increasing the city's population from 950,000 in 1870 to 3.4 million in 1900. More people jammed into tighter spaces meant more need for goods and services on, for example, Manhattan Island.

All these goods and services were transported by horse and buggy. In fact, according to the New York Times, there were more than 150,000 horses in New York in 1880. Each horse, according to their estimate, generated 22 pounds of manure per day. That's 1,650 tons! Plus, again the Times' estimate, 10,000 gallons on urine each day. Plus, again the Times' estimate, about 15,000 horses died each year on the streets – not a bad estimate assuming that each of the 150,000 horses lived an average of 10 years.

All this – the manure, the urine and the horse carcasses – combined to pose a huge disease threat, potentially big enough to destroy cities as they then existed.

Let's now apply current healthcare reform thinking to the horse refuse problem. The market based approach to healthcare reform, a.k.a. the Medicare Modernization Act, would have proposed deregulating horse management, refuse collection and refuse dispersal. Market based thinkers like to deregulate. They probably also would have proposed tax breaks for companies that researched, implemented and demonstrated

[12] Lee, When Horses Posed a Public Health Hazard, NY Times, June 9, 2008

new and ‘better’ horse refuse control technologies and practices. Market based thinkers like tax breaks. They would have wanted to create an environment in which entrepreneurs and business builders would flourish, figuring that the market would solve the horse refuse problem more efficiently than any other approach.

By contrast, the government solution team, a.k.a. the Affordable Care Act thinkers, would have proposed a new government authority to oversee and manage horses. They likely would have wanted more regulations to control every aspect of horse management from feeding to housing to exercising and to refuse collection and dispersal. They would have wanted to license horse owners and users to ensure that the newest thinking and technologies applied to horse rearing. In short, the government solution team would have wanted to pass lots of rules to regulate as much about horses as possible.

I hope this brief historical example shows how both approaches – the market based and government solution – would have failed miserably to solve New York City’s horse problem…just as they have failed to solve our healthcare system problems.

We know what ultimately solved the horse problem in New York – someone invented a car. The horse problem disappeared shortly thereafter. A new technology, unrelated to horse refuse, completely changed the paradigm and eliminated the manure problem.

Our question has changed. It’s no longer ‘what form of healthcare reform can we best solve our healthcare system problems?’ Instead it has become ‘what is the healthcare equivalent of cars?’. I have 4 ideas.

First, the combination of plant based proteins and new medications to address obesity. Things like Impossible Meats, Beyond Meat burgers and the like. Burger King introduced the Impossible Whopper in 2019 to positive reviews. Indeed, as part of my research for this chapter, I visited my local Burger King and ate one; it was delicious. As good as premium burgers and, arguable, healthier. We regularly eat these at home though, truth be told, I prefer the Beyond Burger taste – an individual preference.

Plant based meats act and taste like premium beef and, with their increased scale and 2022 inflation, have become less expensive. This portends a positive trend.

Combine this movement from animal to plant based protein new obesity drugs like semaglutide, trade name Wegovy, manufactured by Nova Nordisk. A high quality study found that obese patients lost an average of 15% of their body weight over 68 weeks, making it twice as effective as older drugs. A similar new anti-obesity drug is Saxenda, also manufactured by Nova Nordisk.

This combination of plant based proteins and new anti-obesity medications could – emphasize ‘could’ – have a significant impact on our obesity rates. Stay tuned.

A second potential healthcare equivalent of cars is gene editing using CRISPR technologies. Full disclosure: as a non-scientist, I do not understand how DNA editing

works. But as an occasional medical news article reader, I have seen reports about sickle cell and leukemia patients being ***cured*** by DNA editing.[13] 'Cured' means there is no evidence that the disease exists in the patient, different from 'remission'. That's tremendously exciting. DNA editing research and trials are continuing in many directions. Again, stay tuned.

A third potential healthcare equivalent of cars is mRNA technology, or messenger RNA. Again as a non-scientist, I don't know how this works. But mRNA technologies are the basis of the Pfizer and Moderna anti-Covid vaccinations that apparently worked quite well. Messenger RNA instructs the body to make specific new proteins. Still early days but a promising and exciting technology.

And a fourth potential healthcare equivalent of cars is the movement to home based healthcare and away from hospital care. Wall Street is betting that this movement will success. Consider these purchase prices from home based healthcare companies in 2021:

- Kindred at Home purchased by Humana, 2021 with **$8.1 billion** market value
- LHC Group Inc, market cap **$5.5 billion** Sept 2021
- Encompass Health, market cap **$7.9 billion**, Sept 2021
- LHC Group, purchased by UHC, 3/22 for **$5.4 billion**

Compare those prices to publicly traded hospital company market values, also in 2021: Tenet Health, 65 hospitals, $8 billion market value; Universal Health, 211 hospitals, $12 billion.

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

[13] Sickle Cell success – BBC report Feb 20, 2022 'Sickle Cell: 'The Revolutionary Gene Editing….' https://www.bbc.com/news/health-60348497, Leukemia cure, Boston Globe, 2/3/22 'Doctors: Cancer Patients Cured a Decade After Gene Therapy', Laura Ungar

## The Medicare Modernization Act of 2003

Sometimes it's useful for brokers – and all professionals for that matter – to read a legislative summary of important laws. This chapter provides such a summary about the Medicare Modernization Act of 2003. Read this as one attempt to plug some of the obvious holes in our healthcare system; it created, among other things, Health Savings Accounts, Health Reimbursement Accounts, Medicare Part D (Prescription Drugs) and Medicare Part C a.k.a. Medicare Advantage.

The next chapter will present similar information about the Affordable Care Act.

**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 supppliers, to maintain an Internet website which provides answers in an easily accessible format to frequently asked questions, and includes other published materials of the contractractor, that relate to providers of services and suppliers under Medicare.

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

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

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

Directs the Secretary to provide through the toll free telephone number 1-800-MEDICARE for a means by which individuals seeking information about, or assistance

with, such programs who phone such toll-free numbers are transferred (without charge) to appropriate entities for the provision of such information or assistance.

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

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

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

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

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

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

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

(Sec. 932) Directs the Secretary to establish a process where a provider, supplier, or a beneficiary who has filed an appeal may obtain access to judicial review when a review entity determines, within 60 days of a complete written request, that the Departmental Appeals Board does not have the authority to decide the question of law or regulation

relevant to the matters in controversy and there is no material issue of fact in dispute. Provides that the determination by such review entity shall be considered a final decision and not be subject to review by the Secretary.

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

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

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

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

(Sec. 933) Revises the Medicare appeals process to: (1) require providers and suppliers to present all evidence for an appeal at the reconsideration level that is conducted by a qualified independent contractor (QTC) unless good cause precluded the introduction of the evidence; (2) provide for the use of beneficiaries' medical records in QIC reconsiderations; (3) require that notice of decisions or determinations, redeterminations, reconsiderations, and appeals be written in a manner calculated to be understood by a beneficiary and include reasons for the decision or determination or redetermination and the process for further appeal; (4) specify the eligibility requirements for QICs and their reviewer employees that relate to medical and legal expertise, independence, and prohibitions linked to decisions being rendered; and (5) reduce the required number of QICs from 12 to four.

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

(Sec. 935) Provides that in situations where repaying a Medicare overpayment within 30 days creates a hardship for a provider or supplier, the Secretary is required, upon the request of the provider or supplier, to enter into an extended repayment plan of at least six months duration, but not longer than three years (or five years in the case of

extreme hardship, as determined by the Secretary). Provides that if the Secretary has reason to suspect that the provider or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in Medicare or there is an indication of fraud or abuse, the Secretary is not obligated to enter into an extended repayment plan with the provider or supplier.

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

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

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

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

(Sec. 938) Amends SSA title XVIII to direct the Secretary to establish a prior determination process where physicians and beneficiaries can request through the Medicare administrative contractor whether Medicare covers certain physicians' services before such services are provided only if the physician requestor is a participating physician, but only with respect to physicians' services to be furnished to an individual who is entitled to benefits under Medicare and who has consented to the physician making the request for those physician services and the beneficiary is an individual entitled to benefits under Medicare, but only with respect to a physicians' service for which the individual receives an advance beneficiary notice from a physician who receives direct payment for that service.

Requires the Secretary to establish a process for the collection of information on the instances in which an advance beneficiary notice has been provided and on instances

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

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

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

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

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

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

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

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

Directs the Secretary to carry out a study of the following for a report to Congress: (1) the development of a simpler, alternative system of requirements for documentation

accompanying claims for evaluation and management physician services for which payment is made under Medicare; and (2) consideration of systems other than current coding and documentation requirements for payment for such physician services. Directs the MEDPAC to conduct an analysis of the results of the study included in the report for a report to Congress.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Provides for an appropriate DSH allotment adjustment for FY 2004 and 2005 for States with statewide "Section 1115" waivers which have been revoked or terminated before the end of either such fiscal year and for which there is no DSH allotment for the State. Requires the State whose waiver was revoked or terminated to submit an amendment to its State plan that would describe the methodology to be used by the State to identify and make payments to DSH hospitals, including children's hospitals and institutions for mental diseases or other mental health facilities (other than State-owned institutions or facilities), on the basis of the proportion of patients served by such hospitals that are low-income patients with special needs.

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

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

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

program). Provides for the application of specified auditing and recordkeeping requirements with respect to such high-volume DSH hospital safety net providers.

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

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

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

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

(Sec. 1014) Directs the Secretary to establish the Citizen's Health Care Working Group to hold hearings to examine: (1) the capacity of the public and private health care systems to expand coverage options; (2) the cost of health care and the effectiveness of care provided at all stages of the disease; (3) innovative State strategies used to expand health care coverage and lower health care costs; (4) local community solutions to accessing health care coverage; (5) efforts to enroll individuals currently eligible for public or private health care coverage; (6) the role of evidence-based medical practices that can be documented as restoring, maintaining, or improving a patient's health, and

the use of technology in supporting providers in improving quality of care and lowering costs; and (7) strategies to assist purchasers of health care to become more aware of the impact of costs and to lower the costs of health care. Requires the Working Group to prepare and make available to health care consumers through the Internet and other appropriate public channels a report entitled "The Health Report to the American People." Directs the Working Group to initiate health care community meetings throughout the United States to address certain topics and to prepare and make available to the public initial recommendations on health care coverage and ways to improve and strengthen the health care system. Requires the Working Group to submit to Congress for appropriate action the final set of recommendations put together after the period of public comment. Authorizes appropriations.

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

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

**Title XI: Access to Affordable Pharmaceuticals - Subtitle A: Access to Affordable Pharmaceuticals** - (Sec. 1101) - Amends the Federal Food, Drug, and Cosmetic Act to revise provisions (Hatch-Waxman Act) with respect to abbreviated new drug applications (ANDAs) to require the ANDA applicant to submit a more detailed statement when filing a paragraph IV certification than currently mandated.

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

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

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

Allows the paragraph IV ANDA applicant to request a declaratory judgment regarding the validity of the patent if an infringement suit is not filed within 45 days of the notification but provides however if sued that the patent holder and the brand name

company (if different) may file a counter claim to require that changes be made to correct the patient information submitted.

Disallows damages from being awarded in either case.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Allows contributions to remain in the HSA at the end of the year and to earn tax-exempt interest until they are withdrawn for uses other than for qualified medical expenses in which case they are to be included in the gross income of the account beneficiary and subjected to a ten percent penalty, except in cases of disability or death or where the contributions are distributed after the account beneficiary attains Medicare eligibility. Requires contributions to be in cash, except in the case of certain rollover contributions. Allows additional "catch up" contributions for eligible individuals age 55 or older.

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

Permits rollovers from Archer MSAs.

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

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

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

Allows HSAs to be offered under cafeteria plans.

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

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

## The Affordable Care Act

The Obama administration passed the Affordable Care Act (ACA), a.k.a. the Patient Protection and Affordable Care Act (PPACA), a.k.a. ObamaCare. All these terms – Affordable Care Act, PPACA and ObamaCare – mean exactly the same thing as all refer to exactly the same legislation.

**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 Ac**t - 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 l pre-existing condition coverage considerations, annual or lifetime maximum payouts and pol rescission;
2. Establishing individual and employer coverage mandates and exchanges and subsidies in the individ 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 Ac**t - 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.

**Impacts and Implications of Healthcare Reforms**
**An Historical Perspective**

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."

## A FALSE ALTERNATIVE

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.

## AN ARGUMENT WHICH WOULD DEFEND ANY CRIME

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.

## Some Current Health Insurance Risks

The US Surgeon General occasionally issues Advisories on key health issues affecting Americans. We will present two here; one on Loneliness and Isolation and a second on Social Media and Youth Mental Health. Both were issued in 2023. Consider these as examples of the research and information available from public sources; it is truly extensive.

Consider also as you read these, how licensed brokers and the larger insurance industry can respond.[14]

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## Our Epidemic of Loneliness and Isolation: The U.S. Surgeon General's Advisory on the Healing Effects of Social Connection and Community

Our relationships and interactions with family, friends, colleagues, and neighbors are just some of what create social connection. Our connection with others and our community is also informed by our neighborhoods, digital environments, schools, and workplaces. Social connection— the structure, function, and quality of our relationships with others—is a critical and underappreciated contributor to individual and population health, community safety, resilience, and prosperity. However, far too many Americans lack social connection in one or more ways, compromising these benefits and leading to poor health and other negative outcomes.

Introduction from Vivek H. Murthy, US Surgeon General, April 2023

When I first took office as Surgeon General in 2014, I didn't view loneliness as a public health concern. But that was before I embarked on a cross-country listening tour, where I heard stories from my fellow Americans that surprised me.

People began to tell me they felt isolated, invisible, and insignificant. Even when they couldn't put their finger on the word "lonely," time and time again, people of all ages and socioeconomic backgrounds, from every corner of the country, would tell me, "I have to shoulder all of life's burdens by myself," or "if I disappear tomorrow, no one will even notice."

In recent years, about one-in-two adults in America reported experiencing loneliness. And that was before the COVID-19 pandemic cut off so many of us from friends, loved ones, and support systems, exacerbating loneliness and isolation.

Loneliness is far more than just a bad feeling—it harms both individual and societal health. It is associated with a greater risk of cardiovascular disease, dementia, stroke, depression, anxiety, and premature death. The mortality impact of being socially

[14] Reference footnotes for this chapter are available on request. This material comes from the US Surgeon General and is reproduced under 17 U.S.C. § 105,

disconnected is similar to that caused by smoking up to 15 cigarettes a day, and even greater than that associated with obesity and physical inactivity. And the harmful consequences of a society that lacks social connection can be felt in our schools, workplaces, and civic organizations, where performance, productivity, and engagement are diminished.

Given the profound consequences of loneliness and isolation, we have an opportunity, and an obligation, to make the same investments in addressing social connection that we have made in addressing tobacco use, obesity, and the addiction crisis. This Surgeon General's Advisory shows us how to build more connected lives and a more connected society.

If we fail to do so, we will pay an ever-increasing price in the form of our individual and collective health and well-being. And we will continue to splinter and divide until we can no longer stand as a community or a country. Instead of coming together to take on the great challenges before us, we will further retreat to our corners—angry, sick, and alone.

We are called to build a movement to mend the social fabric of our nation. It will take all of us—individuals and families, schools and workplaces, health care and public health systems, technology companies, governments, faith organizations, and communities—working together to destigmatize loneliness and change our cultural and policy response to it. It will require reimagining the structures, policies, and programs that shape a community to best support the development of healthy relationships.

Each of us can start now, in our own lives, by strengthening our connections and relationships. Our individual relationships are an untapped resource—a source of healing hiding in plain sight. They can help us live healthier, more productive, and more fulfilled lives. Answer that phone call from a friend. Make time to share a meal. Listen without the distraction of your phone. Perform an act of service. Express yourself authentically. The keys to human connection are simple, but extraordinarily powerful.

Each of us can start now, in our own lives, by strengthening our connections and relationships.

Loneliness and isolation represent profound threats to our health and well-being. But we have the power to respond. By taking small steps every day to strengthen our relationships, and by supporting community efforts to rebuild social connection, we can rise to meet this moment together. We can build lives and communities that are healthier and happier. And we can ensure our country and the world are better poised than ever to take on the challenges that lay ahead.

Our future depends on what we do today.

Vivek H. Murthy, M.D., M.B.A.
19th and 21st Surgeon General of the United States
Vice Admiral, United States Public Health Service

## Introduction: Why Social Connection Matters

People may lack social connection in a variety of ways, though it is often illustrated in scientific research by measuring loneliness and social isolation. Social isolation and loneliness are related, but they are not the same. Social isolation is objectively having few social relationships, social roles, group memberships, and infrequent social interaction. On the other hand, loneliness is a subjective internal state. It's the distressing experience that results from perceived isolation or unmet need between an individual's preferred and actual experience.

The lack of social connection poses a significant risk for individual health and longevity. Loneliness and social isolation increase the risk for premature death by 26% and 29% respectively. More broadly, lacking social connection can increase the risk for premature death as much as smoking up to 15 cigarettes a day. In addition, poor or insufficient social connection is associated with increased risk of disease, including a 29% increased risk of heart disease and a 32% increased risk of stroke. Furthermore, it is associated with increased risk for anxiety, depression, and dementia. Additionally, the lack of social connection may increase susceptibility to viruses and respiratory illness and cost employers an estimated $154 billion annually. The impact of social connection not only affects individuals, but also the communities they live in. Social connection is an important social determinant of health, and more broadly, of community well-being, including (but not limited to) population health, community resilience when natural hazards strike, community safety, economic prosperity, and representative government.

What drives these profound health and well-being outcomes? Social connection is a fundamental human need, as essential to survival as food, water, and shelter. Throughout history, our ability to rely on one another has been crucial to survival. Now, even in modern times, we human beings are biologically wired for social connection. Our brains have adapted to expect proximity to others. Our distant ancestors relied on others to help them meet their basic needs. Living in isolation, or outside the group, means having to fulfill the many difficult demands of survival on one's own. This requires far more effort and reduces one's chances of survival. Despite current advancements that now allow us to live without engaging with others (e.g., food delivery, automation, remote entertainment), our biological need to connect remains.

The health and societal impacts of social isolation and loneliness are a critical public health concern in light of mounting evidence that millions of Americans lack adequate social connection in one or more ways. A 2022 study found that when people were asked how close they felt to others emotionally, only 39% of adults in the U.S. said that they felt very connected to others. An important indicator of this declining social connection is an increase in the proportion of Americans experiencing loneliness.

Recent surveys have found that approximately half of U.S. adults report experiencing loneliness, with some of the highest rates among young adults. These estimates and multiple other studies indicate that loneliness and isolation are more widespread than many of the other major health issues of our day, including smoking (12.5% of U.S. adults), diabetes (14.7%), and obesity (41.9%), and with comparable levels of risk to health and premature death. Despite such high prevalence, less than 20% of individuals who often or always feel lonely or isolated recognize it as a major problem.

Together, this represents an urgent public health concern. Every level of increase in social connection corresponds with a risk reduction across many health conditions. Further, social connection can be a proactive approach to living a fulfilled and happy life, enhancing life satisfaction, educational attainment, and performance in the workplace, as well as contributing to more-connected communities that are healthier, safer, and more prosperous.

Unsurprisingly, social connection is generally not something we can do alone and not something that is accessible equitably. That is partially because we need others to connect with, but also because our society —including our schools, workplaces, neighborhoods, public policies, and digital environments—plays a role in either facilitating or hindering social connection. Moreover, it is critical to carefully consider equity in any approach to addressing social connection, as access and barriers to social opportunities are often not the same for everyone and often reinforce longstanding and historical inequities.

This advisory calls attention to the critical role that social connection plays in individual and societal health and well-being and offers a framework for how we can all contribute to advancing social connection.

## What is Social Connection?

Social connection can encompass the interactions, relationships, roles, and sense of connection individuals, communities, or society may experience. An individual's level of social connection is not simply determined by the number of close relationships they have. There are many ways we can connect socially, and many ways we can lack social connection. These generally fall under one of three vital components of social connection: structure, function, and quality.

- **Structure**

The number of relationships, variety of relationships (e.g., co-worker, friend, family, neighbor), and the frequency of interactions with others.

- **Function**

The degree to which others can be relied upon for various needs.

- **Quality**

The degree to which relationships and interactions with others are positive, helpful, or satisfying (vs. negative, unhelpful, or unsatisfying).

These three vital components of social connection are each important for health, and may influence health in different ways.

It's also critical to understand other defining features of social connection.

First, it is a continuum. Too often, indicators of social connection or social disconnection are considered in dichotomous ways (e.g., someone is lonely or they're not), but the evidence points more to a gradient. Everyone falls somewhere on the continuum of social connection, with low social connection generally associated with poorer outcomes and higher social connection with better outcomes.

Second, social connection is dynamic. The amount and quality of social connection in our lives is not static. Social connectedness changes over time and can be improved or compromised for a myriad of reasons. Illness, moves, job transitions, and countless other life events, as well as changes in one's community and society, can all impact social connectedness in one direction or another. Further, how long we remain on one end of the continuum may matter. Transient feelings of loneliness may be less problematic, or even adaptive, because the distressing feeling motivates us to reconnect socially.[60] Similarly, temporary experiences of solitude may help us manage social demands.[61] However, chronic loneliness (even if someone is not isolated) and isolation (even if someone is not lonely) represent a significant health concern.

Third, much like the absence of disease does not equate to good health, the absence of social deficits (e.g., loneliness) does not necessarily equate to high levels of social connection. Although some measures of social connection represent the full continuum, others only focus on deficits, which do not capture the degree to which social assets may contribute to resilience, or even enable thriving. Consider two examples: first, an individual who is part of a large, highly-involved family, and second, an individual who has regular contact with colleagues through work but has little time for personal relationships outside of work. In each case, such an individual is not objectively isolated and may not feel subjectively lonely. However, in both cases key measures of isolation and loneliness may miss whether they are reaping the benefits of social connection in other ways, such as feeling adequately supported or having high-quality, close relationships.

## Current Trends: Is Social Connection Declining?

Across many measures, Americans appear to be becoming less socially connected over time. This is not a new problem—certain declines have been occurring for decades. While precise estimates of the rates of social connection nationally can be challenging because studies vary based on which indicator is measured, when the same measure is used at multiple time points, we can identify trends.

## Trends in Social Networks and Social Participation

Social networks are getting smaller, and levels of social participation are declining distinct from whether individuals report that they are lonely. For example, objective measures of social exposure obtained from 2003-2020 find that social isolation, measured by the average time spent alone, increased from 2003 (285-minutes/day, 142.5-hours/month) to 2019 (309-minutes/day, 154.5-hours/month) and continued to increase in 2020 (333-minutes/day, 166.5-hours/month). This represents an increase of 24 hours per month spent alone. At the same time, social participation across several types of relationships has steadily declined. For instance, the amount of time respondents engaged with friends socially in-person decreased from 2003 (60-minutes/day, 30-hours/month) to 2020 (20-minutes/day, 10-hours/month). This represents a decrease of 20 hours per month spent engaging with friends. This decline is starkest for young people ages 15 to 24. For this age group, time spent in-person with friends has reduced by nearly 70% over almost two decades, from roughly 150 minutes per day in 2003 to 40 minutes per day in 2020. The COVID-19 pandemic accelerated trends in declining social participation.

The number of close friendships has also declined over several decades. Among people not reporting loneliness or social isolation, nearly 90% have three or more confidants. Yet, almost half of Americans (49%) in 2021 reported having three or fewer close friends —only about a quarter (27%) reported the same in 1990. Social connection continued to decline during the COVID-19 pandemic, with one study finding a 16% decrease in network size from June 2019 to June 2020 among participants.

## Demographic Trends

Societal trends, including demographic changes such as age, marital/partnership status, and household size, also provide clues to current trends. For example, family size and marriage rates have been in steady decline for decades. The percentage of Americans living alone has also increased decade-to-decade. In 1960, single-person households accounted for only 13% of all U.S. households. In 2022, that number more than doubled, to 29% of all households.

The reasons people choose to remain single or unmarried, have smaller families, and live alone over time are complex and encompass many factors. Yet at the same time, it is important to acknowledge the contribution these demographic changes have on social disconnection because of the significant health impacts identified in the scientific evidence. Moreover, awareness can help individuals consider these impacts and cultivate ways to foster sufficient social connection outside of chosen traditional means and structures.

The research in this section points to overall declines in some of the critical structural elements of social connection (e.g., marital status, household size), which helps to explain increases in reported loneliness and social isolation and contributes to the

overall crisis of connection we are experiencing. Finally, this suggests we have fewer informal supports to draw upon in times of need—all while the number of older individuals and those living with chronic conditions continues to increase.

## Trends in Community Involvement

Although the concept of community has evolved over time, many traditional indicators of community involvement, including with religious groups, clubs, and labor unions, show declining trends in the United States since at least the 1970s. In 2018, only 16% of Americans reported that they felt very attached to their local community.

Membership in organizations that have been important pillars of community connection have declined significantly in this time. Take faith organizations, for example. Research produced by Gallup, Pew Research Center, and the National Opinion Research Center's General Social Survey demonstrates that since the 1970s, religious preference, affiliation, and participation among U.S. adults have declined. In 2020, only 47% of Americans said they belonged to a church, synagogue, or mosque. This is down from 70% in 1999 and represents a dip below 50% for the first time in the history of the survey question. Religious or faith-based groups can be a source for regular social contact, serve as a community of support, provide meaning and purpose, create a sense of belonging around shared values and beliefs, and are associated with reduced risk-taking behaviors. As a consequence of this decline in participation, individuals' health may be undermined in different ways.

## What Leads Us to Be More or Less Socially Connected?

A wide variety of factors can influence an individual or community's level of social connection. One organizing tool that helps us better understand these factors is the social-ecological model. This model organizes the interrelated factors that affect health on the individual level, in our relationships, in our communities, and in society. Each of these levels—from the smallest to the broadest—contribute to social connection and its associated risks and protection for health.

Social connection is most often viewed as driven by the individual —one's genetics, health, socioeconomic status, race, gender, age, household living situation, and personality, among other factors. These can influence motivation, ability, or access to connect socially. As we've seen, the level of one's connection is also dependent on the structure, function, and quality of relationships. However, connectedness is influenced by more than simply personal or interpersonal factors. It is also shaped by the social infrastructure of the community (or communities) in which one is born, grows up, learns, plays, works, and ages.

**Social infrastructure** includes the physical assets of a community (such as libraries and parks), programs (such as volunteer organizations and member associations), and local policies (such as public transportation and housing) that support the development of social connection.

The social infrastructure of these communities is in turn influenced by broader social policies, cultural norms, the technology environment, the political environment, and macroeconomic factors. Moreover, individuals are simultaneously influenced by societal-level conditions such as cooperation, discrimination, inequality, and the collective social connectedness or disconnectedness of the community. All of these shape the availability of opportunities for social connection.

In sum, social connection is more than a personal issue. The structural and social characteristics of the community produce the settings in which people build, maintain, and grow their social networks. Because many contributors to social connection go beyond an individual's control, in order to promote health, change is needed across the full scope of the social-ecological model. While every factor can be important contributors to social connection, it's important to look across these levels. That gives us clues to barriers to connection and the types of interventions which could successfully increase social connection. This broader view can also help identify what places groups at highest risk for social isolation and loneliness, as well as factors that reinforce cycles of risk or resilience.

Anyone of any age or background can experience loneliness and isolation, but some groups are at higher risk than others. Not all individuals or groups experience the factors that facilitate or become barriers to social connection equally. Some people or groups are exposed to greater barriers. It's critical to examine and highlight the disproportionate risk they face and to target interventions to address their needs.

Although risk may differ across indicators of social disconnection, currently, studies find the highest prevalence for loneliness and isolation among people with poor physical or mental health, disabilities, financial insecurity, those who live alone, single parents, as well as younger and older populations. For example, while the highest rates of social isolation are found among older adults, young adults are almost twice as likely to report feeling lonely than those over 65. The rate of loneliness among young adults increased every year between 1976 and 2019. In addition, lower-income adults are more likely to be lonely than those with higher incomes. Sixty-three percent of adults who earn less than $50,000 per year are considered lonely, which is 10 percentage points higher than those who earn more than $50,000 per year. These data do not suggest that individual or demographic factors inherently generate loneliness or isolation. Rather, the data enable us to understand the different socioeconomic, political, and cultural mechanisms that may indicate higher risk for certain groups and lead to loneliness and isolation.

Additional at-risk groups may include individuals from ethnic and racial minority groups, LGBTQ+ individuals, rural residents, victims of domestic violence, and those who experience discrimination or marginalization. Further research is needed to fully understand the disproportionate impacts of social disconnection.

## Impacts of Technology on Social Connection

There is more and more evidence pointing to the importance of our environments for health, and the same is true for digital environments and our social health. A variety of technologies have quickly and dramatically changed how we live, work, communicate, and socialize. These technologies include social media, smartphones, virtual reality, remote work, artificial intelligence, and assistive technologies, to name just a few.

These technologies are pervasive in our lives. Nearly all teens and adults under 65 (96-99%), and 75% of adults 65 and over, say that they use the internet. Americans spend an average of six hours per day on digital media. One-in-three U.S. adults 18 and over report that they are online “almost constantly,” and the percentage of teens ages 13 to 17 years who say they are online “almost constantly” has doubled since 2015. When looking at social media specifically, the percentage of U.S. adults 18 and over who reported using social media increased from 5% in 2005 to roughly 80% in 2019. Among teens ages 13 to 17 years, 95% report using social media as of 2022, with more than half reporting it would be hard to give up social media. Although tech adoption is relatively high among all groups, Americans with disabilities, adults with lower incomes, and Americans from rural areas[92] continue to experience a persistent, albeit shrinking, digital divide. They are relatively less likely to own a computer, smartphone, or tablet, or have broadband internet access.

Technology has evolved rapidly, and the evidence around its impact on our relationships has been complex. Each type of technology, the way in which it is used, and the characteristics of who is using it, needs to be considered when determining how it may contribute to greater or reduced risk for social disconnection. There are multiple meta-analyses and reviews examining this topic that identify both benefits and harms.

Several examples of benefits include technology that can foster connection by providing opportunities to stay in touch with friends and family, offering other routes for social participation for those with disabilities, and creating opportunities to find community, especially for those from marginalized groups. For example, online support groups allow individuals to share their personal experiences and to seek, receive, and provide social support—including information, advice, and emotional support.

Several examples of harms include technology that displaces in-person engagement, monopolizes our attention, reduces the quality of our interactions, and even diminishes our self-esteem. This can lead to greater loneliness, fear of missing out, conflict, and reduced social connection. For example, frequent phone use during face-to-face interactions between parents and children, and between family and friends, increased distraction, reduced conversation quality, and lowered self-reported enjoyment of time spent together in-person. In a U.S.-based study, participants who reported using social media for more than two hours a day had about double the odds of reporting increased perceptions of social isolation compared to those who used social media for less than 30 minutes per day. Additionally, targets of online harassment report feelings of increased loneliness, isolation, and relationship problems, as well as lower self-esteem

and trust in others. Evidence shows that even perpetrators of cyberbullying experience weakened emotional bonds with social contacts and deficits in perceived belongingness.

Understanding how technology can enhance or detract from social connection is complicated by ever-changing social media algorithms, complex differences in individual technology use, and balancing concerns over obtaining private user data. Advancing research in this area is essential. With that said, the existing evidence illustrates that we have reason to be concerned about the impact of some kinds of technology use on our relationships, our degree of social connection, and our health.

## Risk and Resilience Can Be Reinforcing

The factors that facilitate, or become barriers to, social connection can also reinforce either a virtuous or vicious cycle. Economic status, health, and service are just a few illustrative examples—better social connection can lead to better health, whereas less social connection can lead to poorer health. However, each of these can be reinforcing. Being in poorer health can become a barrier to engaging socially, reducing social opportunities and support, and reinforcing a vicious cycle of poorer health and less connection. A similar kind of pattern could occur among those struggling financially. For example, financial insecurity may require someone to work multiple jobs, resulting in less leisure time and limiting opportunities for social participation and connection—which, in turn, could provide fewer resources and financial opportunities. While these cycles can be reinforcing, they are not always negative. There is, for instance, a virtuous cycle between social connection and volunteerism or service. Those who are more connected to their communities are more likely to engage in service, and those who are engaged in service are more likely to feel connected to their communities and the individuals in it. Interestingly, there is also evidence showing that the well-being benefits associated with volunteering are even greater for those with higher social connectedness than those with less. Because these cycles can be reinforcing, prioritizing social connection can not only disrupt vicious cycles but also reinforce virtuous ones.

## Lessons from the COVID-19 Pandemic

While social connection had been declining for decades prior to the COVID-19 pandemic, the onset of the pandemic, with its lockdowns and stay-at-home orders, was a critical time during which the issue of connection came to the forefront of public consciousness, raising awareness about this critical and ongoing public health concern.

Many of us felt lonely or isolated in a way we had never experienced before. We postponed or canceled meaningful life moments and celebrations like birthdays, graduations, and marriages. Children’s education shifted online—and they missed out on the many benefits of interacting with their friends. Many people lost jobs and homes. We were unable to visit our children, siblings, parents, or grandparents. Many lost loved

ones. We experienced feelings of anxiety, stress, fear, sadness, grief, anger, and pain through the loss of these moments, rituals, celebrations, and relationships.

Although the COVID-19 pandemic was a collective experience, it impacted certain populations differently. Frontline workers had a different experience than those who could work from home. Parents managing their own work and their children's online school had a different experience than single young people unable to interact in-person with friends. And those at greater risk of severe COVID-19, including older individuals, those living in nursing homes, and people with underlying health conditions, faced unique challenges. Emerging data suggests that people with close and positive familial connections may have had a different experience than those without. A recent national survey showed that, by April 2021, 1 in 4 individuals reported feeling less close to family members compared to the beginning of the pandemic. Yet, at the same time, about 1 in 5 said they felt closer to family members,[122] perhaps indicating that the pandemic exacerbated existing family dynamics of connection or disconnection.

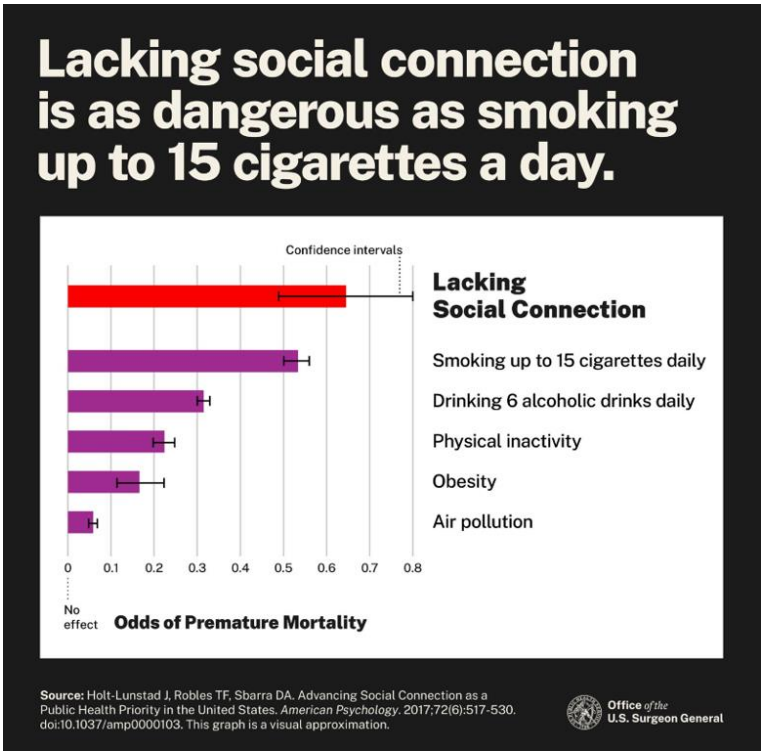
We also witnessed first responders, health care workers, community members, neighbors, and volunteers stepping up and offering their social support to one another. Service can be a powerful source of connection. From September 2020 to September 2021, the majority (51%) of U.S. individuals ages 16 and older reported informally helping others. This represents more than 120 million U.S. individuals helping informally, in addition to an estimated 60 million individuals formally volunteering through an organization during the same period. By engaging in service work, many were able to find and create pockets of connection for themselves and others during a public health crisis.

While profoundly disruptive in so many ways, the COVID-19 pandemic offers an opportunity to reflect more deeply on the state of social connection in our lives and in society. As we emerge from this era, rebuilding social connection and community offers us a promising and hopeful way forward.

## How Social Connection Impacts Individual Health and Well-Being

Extensive scientific findings from a variety of disciplines, including epidemiology, neuroscience, medicine, psychology, and sociology, converge on the same conclusion: social connection is a significant predictor of longevity and better physical, cognitive, and mental health, while social isolation and loneliness are significant predictors of premature death and poor health. In fact, the benefits of social connection extend beyond health-related outcomes. They influence an individual's educational attainment, workplace satisfaction, economic prosperity, and overall feelings of well-being and life fulfillment. This chapter summarizes the rapidly growing body of evidence on the relationship between various indicators of social connection and these outcomes for individuals.

Evidence across scientific disciplines converges on the conclusion that socially connected people live longer. Large population studies have documented that, among initially healthy people tracked over time, those who are more socially connected live longer, while those environmental factors (e.g., air pollution), and clinical interventions (e.g., flu vaccine, high blood pressure medication, rehabilitation).




Over the years, the number of studies, the rigor of their methods, and the size of the samples have all increased substantially, providing stronger confidence in this evidence. These replicate the finding that social connection decreases the risk of premature death.

Taken together, this research establishes that the lack of social connection is an independent risk factor for deaths from all causes, including deaths caused by diseases.

The evidence linking social connection to physical health is strongest in heart disease and stroke outcomes. Dozens of studies have found that social isolation and loneliness significantly increase the risk of morbidities from these conditions. Among this evidence, a synthesis of data across 16 independent longitudinal studies shows poor social relationships (social isolation, poor social support, loneliness) were associated with a 29% increase in the risk of heart disease and a 32% increase in the risk of stroke. Interestingly, these effects can begin early in life and stretch over a lifetime. Research has also found that childhood social isolation is associated with increased cardiovascular risk factors such as obesity, high blood pressure, and blood glucose

levels in adulthood. Further, in a 2022 statement, the American Heart Association concluded that “social isolation and loneliness are common, yet underrecognized, determinants of cardiovascular health and brain health.”

Heart failure patients who reported high levels of loneliness had a 68% increased risk of hospitalization, a 57% higher risk of emergency department visits, and a 26% increased risk of outpatient visits, compared with patients reporting low levels of loneliness. Combining data from 13 studies on heart failure patients, researchers found that poor social connection is associated with a 55% greater risk of hospital readmission. This was consistent across both objective and perceived social isolation, including living alone, lack of social support, and poor social network. Furthermore, evidence suggests that people who are less socially connected, particularly those living alone, may be less likely to make it to the hospital, increasing their risk of dying from a cardiac event. Conversely, a heart attack is less likely to be fatal for people living with others or who have more social contacts, perhaps because of the immediate response and availability of help during the event.

## Hypertension

High blood pressure (hypertension) is one of the leading causes of cardiovascular disease. Several studies demonstrate that the more social support one has, the greater the reduction in the possibility of developing high blood pressure, even in populations who are at higher risk for the condition, such as Black Americans. Greater social support in this group is associated with a 36% lower risk of high blood pressure in the long-term. Among older adults, the effect of social isolation on hypertension risk is even greater than that of other major clinical risk factors such as diabetes.

Since high blood pressure most often doesn’t have symptoms, it is possible for people to be unaware of even severe underlying cases. The disorder may remain undiagnosed for years, which can elevate the risk for a wide range of physiological complications. However, among older adults, people with higher perceived emotional support from family and friends, and with frequent exposure to health-related information within their social networks, are significantly less likely to have undiagnosed and uncontrolled hypertension.

The results of many research studies also reflect a strong correlation between social connection and high blood pressure control. Regular participation in two or more social or community-based groups; emotional and informational support from family, friends, professional contacts, community organizations, and peer groups; and frequent network interactions may improve hypertension management, including following treatment recommendations and long-term lifestyle adjustments. Findings from the National Social Life, Health, and Aging Project (NSHAP) suggest a “causal role of social connections in reducing hypertension,” particularly in adults over the age of 50.

## Diabetes

Evidence gathered over the last 25 years has demonstrated that social context is important to the development and management of diabetes. Population-based studies show the impact of social connection on the development of type 2 diabetes and diabetic complications. For example, social disconnection (poor structural social support and living alone in men, low emotional support in women, and not having a current partner in women older than 70) has been linked to an increased risk for the development of type 2 diabetes. Furthermore, living alone increased the risk of developing type 2 diabetes among women with impaired glucose tolerance.

By contrast, social connection has been associated with better self-rated health and disease management among individuals with diabetes. The involvement and support of family members has also been repeatedly shown to improve disease management and the health of people with type 1 diabetes and type 2 diabetes. Whereas, smaller social network size has been associated with newly diagnosed type 2 diabetes and complications from diabetes. These associations between social connection and broader diabetic outcomes including diagnosed pre-diabetes and type 2 diabetes, macrovascular complications (e.g., heart attack, stroke) and microvascular complications (e.g., diabetic retinopathy, impaired sensitivity in the feet, and signs of kidney disease) were independent of blood sugar (glucose) control, quality of life, and other cardiac risk factors.

What explains this phenomenon? Diabetic outcomes may be better among people who are more socially connected due to better diabetic management behaviors and patient self-care such as medication adherence, physical activity, diet, and foot care. For example, in a meta-analysis of 28 studies, social support from family and friends was significantly associated with better self-care, particularly blood sugar monitoring. Finally, evidence from the National Health and Nutrition Examination Survey found that among older adults with diabetes, those with a large social support network size (at least six close friends) had a reduced risk of all-cause mortality.

## Infectious Diseases

People who are less socially connected may have increased susceptibility and weaker immune responses when they are exposed to infectious diseases. In a series of studies examining factors that contribute to illness after exposure to viruses like the common cold and flu, loneliness and poor social support were found to significantly contribute to the development and severity of the illnesses. In one study where participants were exposed to a common cold virus, individuals with social ties to six or more diverse social roles (e.g., parent, spouse, friend, family, co-worker, group membership) had a four-fold lower risk of developing a cold when compared to people who had ties to fewer (1-3) diverse social roles. These effects cannot be explained by previous exposure, since those who are more socially connected have stronger immune responses independent of baseline antibody count—suggesting stronger immune responses even when exposed to new viruses. A study conducted on immune responses to the COVID-19

vaccine found that a lack of social connection with neighbors and resultant loneliness was associated with weaker antibody responses to the vaccine.

### Cognitive Function

Substantial evidence also links social isolation and loneliness with accelerated cognitive decline and an increased risk of dementia in older adults,[1] including Alzheimer's disease. Chronic loneliness and social isolation can increase the risk of developing dementia by approximately 50% in older adults, even after controlling for demographics and health status. A study that followed older adults over 12 years found that cognitive abilities declined 20% faster among those who reported loneliness.

When taken together, this evidence consistently shows that wider social networks and more frequent social engagements with friends and family are associated with better cognitive function and may protect against the risk of dementia. This suggests that investments in social connection may be an important public health response to cognitive decline.

### Depression and Anxiety

Depression and anxiety are often characterized by social withdrawal, which increases the risk for both social isolation and loneliness; however, social isolation and loneliness also predict increased risk for developing depression and anxiety and can worsen these conditions over time. A systematic review of multiple longitudinal studies found that the odds of developing depression in adults is more than double among people who report feeling lonely often, compared to those who rarely or never feel lonely. Furthermore, in older adults, both social isolation and loneliness have been shown to independently increase the likelihood of depression or anxiety. These findings are also consistent among younger people. A review of 63 studies concluded that loneliness and social isolation among children and adolescents increase the risk of depression and anxiety, and that this risk remained high even up to nine years later.

Importantly, social connection also seems to protect against depression even in people with a higher probability of developing the condition. For example, frequently confiding in others is associated with up to 15% reduced odds of developing depression among people who are already at higher risk due to their history of traumatic or otherwise adverse life experiences.

### Suicidality and Self-Harm

While many factors may contribute to suicide, more than a century of research has demonstrated significant links between a lack of social connection and death by suicide. This research suggests that social connection may protect against suicide as a cause of death, especially for men.

One study found that among men, deaths due to suicide are associated with loneliness and more strongly with indicators of objective isolation such as living alone.[170] In this

study of over 500,000 middle-aged adults, the probability of dying by suicide more than doubled among men who lived alone. The same study showed that for women loneliness was significantly associated with hospitalization for self-harm. Further, when examining suicidality among nursing home and other long-term care facility residents, cancer patients, older adults, and adolescents, systematic reviews of studies on loneliness, social isolation, and low social support were associated with suicidal ideation. These links may result from a low sense of belonging and perceiving oneself as a burden to others.

Loneliness and low social support are also associated with increased risk of self-harm. In a review of 40 studies of more than 60,000 older adults, an increase in loneliness was reported to be among the primary motivations for self-harm.

Given the totality of the evidence, social connection may be one of the strongest protective factors against self-harm and suicide among people with and without serious underlying mental health challenges.

## Social Connection Influences Health Through Multiple Pathways

While the effects of social connection on health are clear, research also helps explain how our level of social connection ultimately results in better or worse health. A key part of the explanation involves understanding how social connection influences behavioral, biological, and psychological processes, which in turn influence health outcomes. A large body of evidence has identified several plausible pathways.

## Social Connection Influences Biological Processes

The role of social connection on biology emerges early in life and continues across the life course, contributing to risk and protection from disease. Several reviews document that social connection can influence health through specific biological pathways, including cardiovascular and neuroendocrine dysregulation, immunity, and gut-microbiome interactions. Because regulation of these systems is critical for good health, the documented influence between social connection and these biological pathways likely explains the impact on the risk of the development of disease.

Biological systems often do not operate independently. This means that increases in blood pressure, circulating stress hormones, and inflammation may occur simultaneously, potentially compounding risk across several biological systems.

One biological pathway of great interest is inflammation, given that it has been implicated as a factor in many chronic illnesses. Evidence shows that being objectively isolated, or even the perception of isolation, can increase inflammation to the same degree as physical inactivity. Similarly, lower social support is associated with higher inflammation. Chronic inflammation throughout the body has been linked to various chronic illnesses across the lifespan, such as cardiovascular disease, cancer, diabetes, depression, and Alzheimer’s disease, as well as a variety of mental, cognitive, and

physical health outcomes that increase the risk of premature mortality. Thus, inflammation may be a common pathway that explains the many diverse health outcomes associated with isolation and loneliness.

The protective, or positive, effects of social connection may operate on biological systems in a similar way, meaning that social connection may reduce the risk of disease by reducing biological system dysregulation. For example, increased levels of social connection can improve various biomarkers of cardiovascular functioning, including blood pressure, cardiovascular reactivity, and oxidative stress. In addition, social support and social bonding are associated with better regulation of the neuroendocrine system, including the role of oxytocin in both early life and adult attachment.

### Social Connection Influences Behaviors

Social connection is also significantly associated with a number of health-related behaviors, including lifestyle behaviors (e.g., diet, exercise, sleep), and treatment adherence (e.g., taking medication as directed, engaging in recommended prevention measures) which ultimately influence our health and longevity. Social influence can be direct—loved ones encouraging one to get more sleep or reminding one to take their medication—or subtle, through social norms that communicate approval or disapproval of certain behaviors (like vaccination, smoking, exercise). In fact, evidence shows people are far more likely to be physically active if their peers and friends also exercise,[213,214] and they are more likely to stop smoking themselves if their social contacts do so as well. However, they are also less likely to stop smoking if they are in close connection to others who smoke, or even at risk for relapse if they had successfully quit smoking previously. Thus, it is clear that it is not just the presence of social connection and social support but the nature of the behaviors and norms in one's social network that influence health-related behaviors.

### Individual Educational and Economic Benefits

The benefits of social connection extend beyond the well-being of individuals' health to quality of life, education, employment, and economic outcomes. Just as with health, those who lack sufficient social connection, whether because they are isolated, lonely, or in poor-quality relationships, seem to be at higher risk for poorer outcomes in these aspects of life as well.

### Educational Benefits

Research shows that children and adolescents who enjoy positive relationships with their peers, parents, and teachers experience improved academic outcomes. For example, a review of youth mentoring programs found a positive association between mentoring programs intended to promote positive youth outcomes and improved school attendance, grades, and academic achievement test scores. Further, school and family connectedness during adolescent years may predict subsequent positive outcomes in

early adulthood, including a higher likelihood of graduating college and attaining a 4-year college degree.

In contrast, the lack of quality social connections inhibits student progression even in higher education settings. For example, among medical students, feeling socially isolated is associated with dropping out. The lack of social connection is cited as a prime reason for leaving a program.

## Economic Benefits

Supportive and inclusive relationships at work are associated with employee job satisfaction, creativity, competence, and better job performance. Quality social support, social integration, and regular communication among co-workers of all levels are key in preventing chronic work stress and workplace burnout. These resources may even be linked to shorter recovery times and less missed work after work-related injuries or illnesses. Workplace connectedness is also associated with enhanced individual innovation, engagement, and quality of work, all of which can influence career advancements, income, and overall economic stability.

Social connection outside the workplace also plays an important role in an individual's economic situation. Diverse social networks that facilitate interaction and relationship-building among people of differing socioeconomic status (SES) may provide opportunities for individuals from lower SES backgrounds to gain stronger footing in the labor market and obtain higher-paying jobs. Such bridging, cross-class ties are among the most important predictors of upward economic mobility.

Additionally, activities that better connect individuals to one another, including immersion in local community-based activities or volunteering, can also equip individuals with desirable skills that make them more employable, and significantly increase the likelihood of unemployed individuals becoming employed.

## How Social Connection Impacts Communities

Decades of research across disciplines such as political science, economics, sociology, behavioral science, and public health, among others, have examined the relationship between group social connection and population health and well-being. Though variation exists across studies and methodologies, the cumulative evidence generally points to the same conclusion: higher levels of social connectedness suggest better community outcomes, ranging from population health to community safety, resilience, prosperity, and representative government; while lower levels of social connectedness suggest worse outcomes in each of these areas. These studies establish that social connection is vital not only to our individual physical, mental, and emotional health, but also to the health and well-being of our communities.

This chapter explores what it means to be a socially connected community and examines the evidence that more connected communities benefit from higher levels of

well-being. The chapter also addresses the potential harms of negative social connection for community and societal well-being.

## Socially Connected Communities

The scientific literature on social connection has defined "community" in many ways. Broadly, the term refers to a group of people with a characteristic in common. For the purpose of this advisory, however, the terms "community" and "communities" refer to a shared geographic location—neighborhoods, towns, cities. This chapter summarizes research that pertains to in-person social connection and the benefits that exist within place-based communities.

This does not diminish other types of communities (including those online) that can also provide support and other important elements of social connection. However, in-depth review of these types of communities is beyond the scope of this advisory and requires additional research.

**Social capital** is a key concept that researchers have identified as an important characteristic for understanding the social connectedness of communities. The definition and measurement of social capital varies by discipline, but broadly, social capital may be understood as "the resources to which individuals and groups have access through their social networks." The term social capital is often used as an umbrella for both social support and social cohesion.

**Social support** refers to the perceived or actual availability of emotional, informational, or tangible resources from other individuals in one's social network. **Social cohesion** refers to the sense of solidarity within groups, marked by strong social connections and high levels of social participation, that generates trust, norms of reciprocity, and a sense of belonging.

**Trust** is a critical component of socially connected communities and a subjective indicator frequently used to measure social capital. Again, the scientific literature defines trust in many ways, but, broadly, it refers to an individual's expectation of positive intent and benevolence from the actions of others. Trust is an attitude that informs behavior towards unknown people (**generalized trust**), towards a known individual or group (**particularized trust**), or towards organizations and government (**institutional trust**).[29,234] It underlies communication and cooperation, both elements of social cohesion and social support. Higher levels of trust have been linked to improved population health, economic prosperity, and social functioning.

The **social infrastructure** of a community shapes its social capital. This refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that facilitate bringing people together. Social infrastructure may help a community by providing opportunities to foster social connections among residents,

local leaders, and community-serving organizations. As social networks grow in size, diversity, and strength, this produces greater levels of social support and social cohesion and builds social capital for a community.

Because belonging to a group is generally adaptive and improves survival, people have a natural tendency to build and maintain relationships with those who are most like themselves (e.g., those with similar educational backgrounds, incomes, professions, or family status). This type of social connection, defined as **bonding social capital**, is important and can provide the support and resources needed not only to prevent or reduce loneliness and social isolation but also to contribute to fulfillment and well-being.

Research suggests that diversifying social relationships to include connections with people who are outside of your group (**bridging social capital**), as well as connections between people of differing power status in the community (**linking social capital**) are also associated with improved community health and well-being. Examples of these types of relationships include cultivating intergenerational friendships (bridging) or developing programs like a mentorship exchange between youth and local employers (linking).

Larger and more diverse social networks, with a mixture of types of relationships, can provide access to more varied types of social support and generate greater levels of social capital. Furthermore, interacting with people from diverse backgrounds can help to stimulate creative thinking and encourage the consideration of different perspectives, leading to better problem-solving and decision-making. Finally, social interactions with neighbors and other community members —like small gestures such as smiling at a passerby or brief conversations at the bank, post office, grocery store, or local coffee shop—can foster a sense of interpersonal trust and create and maintain norms of reciprocity. This can also increase **empathy**, one of the best documented sources of altruism, by enhancing understanding with one another, supporting the development of shared identities and affiliations, and facilitating cooperation and beneficial interactions across individuals and groups. This helps to generate more social capital for the broader community.

These community interactions can be associated with a positive reinforcing cycle. As this chapter illustrates, individuals who immerse themselves in community-based activities are more likely to experience stronger feelings of social belonging and develop trusting relationships with fellow community members. This can lead people to more readily contribute their time and resources back to their communities. When community-based participation becomes the norm, social networks grow and produce high levels of trust among themselves, which facilitates the efficient exchange of information and sharing of resources within  a community.

## The Benefits of More Connected Communities

### Population Health

Communities with higher levels of social connection typically enjoy significantly better health outcomes than communities that have lower levels. Studies find that community-level social capital is positively associated with a reduced burden of disease and risk for all-cause mortality. A meta-analysis of several studies looking at the cumulative effects across multiple indicators of social capital on all-cause mortality and general health found that on average, a one-unit increase in social capital increases the likelihood of survival by 17% and of self-reporting good health by 29%. In a separate study using data from 39 states, the authors found a dose-response relationship between the extent of social capital within a community and age-adjusted mortality. A 10% increase (one standard deviation) in the proportion of residents in each state who felt that other people could be trusted was associated with an 8% decline in overall mortality. Another study found that those with very strong perceptions of community belonging—an indicator of social cohesion—reported very good or excellent health at a rate 2.6 times higher than those with very low perceptions of belongingness. This was true even after adjusting for demographic variables, health and health behaviors, and the built environment. Finally, communities with higher levels of social capital are also more likely to see decreased hospital readmission rates.

The positive effects of social capital on health are not only evident when added up across individuals. Synergistic effects among various aspects of social capital also exist and impact community-wide health outcomes. Connected individuals who leverage available social capital resources to improve their health-related behaviors or collectively reform their community culture can generate downstream improvements in overall population-level health.

For example, personal biases and fears about highly stigmatized diseases such as HIV create barriers to health care and social inclusion for individuals living with HIV. A review of multiple studies shows that high levels of social capital in high-risk populations can buffer against those harmful social barriers and significantly increase the likelihood of HIV prevention behaviors. In turn, members of highly connected communities are more likely to participate in health-protective efforts and seek care when needed, thereby decreasing the disease burden and risk of disease transmission among the whole population. Similarly, more connected communities have higher utilization of immunization services, and are more likely to adopt recommended health-protective behaviors— all of which benefit the broader community.

Evidence also shows that stronger social bonds and social capital in communities increase the likelihood that local community groups and health care institutions will build population health-focused partnerships. These partnerships rely on the existing mutual trust and reciprocity within community settings to increase engagement opportunities within the population and improve access to health care in low-resource populations.

On the other hand, several reports have found that lower community social connection is linked to poorer health outcomes. This was made clear when examining the spread of

the COVID-19 virus. One study in the United States compared changes in the county-level spread of COVID-19 against several measures of social capital. These included family structure and involvement, trust in community institutions, popularity of volunteerism, levels of participation in political discussions and voting efforts, and cohesion among community members. After controlling for potential alternative explanatory factors, the researchers found that lower levels of social capital were associated with a higher number of cases and deaths from COVID-19 infection. Further, counties with strong social ties experienced fewer deaths during the COVID-19 pandemic. Relatedly, an international study of COVID-19 infection and fatality rates across 177 countries also observed a statistically significant association between greater interpersonal and government trust and lower infection rates.

## Natural Hazard Preparation and Resilience

A community's resilience to natural hazard events such as earthquakes, tsunamis, hurricanes, large-scale flooding, and fires depends upon the collective ability of individuals, households, and institutions to prepare for anticipated events, adapt to and withstand changing conditions, and recover rapidly following disruption.

Studies show that neighbors are often the first to respond in disaster situations, even before trained emergency professionals, because they are physically nearby. Growing evidence suggests that in neighborhoods and communities where people know one another and are connected to community institutions (like service organizations, religious groups, or community-based organizations) people prepare for, respond to, and recover more quickly from natural hazards than those with lower levels of social connection.

In such connected communities, it is more likely that people will share their knowledge and informal resources with neighbors, prepare for natural hazards, comply with emergency procedures including evacuation, and engage in coordination of emergency response efforts after natural hazard events.

Further, high levels of social connection reduce the exodus of people immediately following a natural hazard, preserve valuable social capital like social support and interpersonal trust, enable neighbors to provide aid to one another, and allow communities to overcome collective action problems such as coordinating recovery and rebuilding. Despite these benefits of connection within and for neighborhood communities, only 3 in 10 Americans report knowing all or most of their neighbors.

## Community Safety

Not only do higher levels of social connection within a community correspond to better health and disaster outcomes, but they are also associated with lower levels of community violence.[271-274] One recent study on community violence showed that a one standard deviation increase in social connectedness was associated with a 21% reduction in murders and a 20% reduction in motor vehicle thefts. The Project on

Human Development in Chicago Neighborhoods longitudinal study that began in the late 1990s found that neighborhoods with higher perceptions of social cohesion and where residents felt a “willingness to act” on behalf of community members (**collective efficacy**) were more likely to have reduced levels of crime and residents were more likely to feel safer. Many subsequent analyses have confirmed the association between social connection, greater perceived collective efficacy, and community safety. Recent studies have found that greater perceived collective efficacy, trust, and social norms on violence as unacceptable behavior can be protective factors against community violence. Fostering social connection is not a singular solution to community violence; however, it does play an instrumental role in prevention and response.

## Economic Prosperity

Economic prosperity, including economic development, employment, the sharing of economic opportunities or information, and overall economic connectedness, is a key measure of the value that exists within a given society. Evidence illustrates that connected communities generally experience higher levels of economic prosperity. For example, an analysis of economic factors across the U.S. found that communities with higher social capital levels experienced greater resilience against unemployment between 2006 and 2010 and were able to weather the recession more successfully. In addition, a three-year study of 26 cities in the U.S. found that those with the highest levels of resident attachment experienced the greatest growth in GDP during the study period.

Further, members of these connected communities are more likely to recommend job and educational opportunities to one another, collaborate on ideas for innovation, build partnerships for local businesses, and directly advance economic progress in their communities. In addition, longitudinal evidence shows that civic engagement, another form of community participation, in adolescence and early adulthood positively predicts educational attainment and income potential in adulthood. In this way, local community participation may also influence socioeconomic mobility of individuals across their lifespan and also reduce large-scale socioeconomic disparities.

In contrast to the clear benefits of community connectedness, the consequences of disconnection on community prosperity can be detrimental. Long-standing systemic disinvestment, inequitable zoning laws, underdeveloped transportation systems, and residential segregation can perpetuate chronic poverty and isolate entire neighborhoods or towns from more prosperous local economies. On the other hand, cross-class exposure could have positive impacts on economic mobility across generations. For example, if children of low socioeconomic backgrounds had the share of high socioeconomic friends comparable to that of the average child with a high socioeconomic background, these children would increase their incomes in adulthood by an average of 20%. Pro-connection policies and practices can promote economic

prosperity in communities harmed by structural barriers and eliminate such obstacles toward prosperity.

### Civic Engagement and Representative Government

Higher levels of social connection are associated with increased levels of civic engagement (defined as “actions to address issues of public concern”) and more representative government. Emerging evidence has shown that civic engagement helps to develop “empathy, problem solving, [and] cooperation” among community members. One study showed that higher levels of family and community connection during adolescence predicted civic engagement outcomes in young adulthood including a greater likelihood of voting and involvement in social action and conversation groups. Further examples of civic engagement include registering to vote and voting, participating in advocacy groups or clubs, and connecting to information and current events. In addition, studies show that group membership and social networks strongly influence the decision to participate in the political process. Moreover, in a positive cycle, research suggests that greater civic engagement can lead to policies and programs that better reflect the will of a community’s residents, which in turn can promote continued and increased civic engagement.

### The Potential Negative Side of Social Connection

Our fundamental human need for belonging is so strong that we may seek it out even in ways that may be unhealthy to ourselves or to our broader community. This can include participation in gangs and joining extremist or other harmful groups. Our natural tendency to associate with those most like us can be manipulated, with potentially negative consequences for individual and community well-being. When there are scarce resources, this can also lead to competition among various groups, leading to an “us” versus “them” mentality.

We tend to view our own group as more favorable and deserving than members of other groups.[290] This can result in distrust and rejection of outsiders.[291] In addition, among highly cohesive groups, there are also strong pressures to conform to the group norms[292]—often with high costs like rejection or ostracization if one doesn’t comply. While high cohesion and conformity to group norms can be healthy and productive in many cases, among some groups, these social pressures may justify, rationalize, or encourage unhealthy, unsafe, or unfair behaviors such as binge drinking, violence, and discrimination.

### Societal Polarization

One consequence of the natural tendency for people to build and maintain relationships with those who are like themselves is the risk for exacerbating polarization in our discourse and in society—potentially leading to poorer outcomes for broader society.

“Core discussion networks,” are circles of people who have conversations on timely but difficult topics such as politics, finances, world events, religion, health, and more. The nature, size, and diversity of these discussion networks are important to how individuals form opinions, attitudes, and awareness of differing perspectives. They ultimately foster political tolerance. Generally, the size and diversity of core discussion networks have been shrinking substantially over the recent decades. One survey of 1,055 U.S. adults during the 2016 U.S. presidential election found that core discussion networks were smaller than in any other observed period and that the proportion of individuals with the same political preference within core discussion networks was higher than reported previously.

As discussion networks shrink and become more politically homogenous while society becomes more polarized, it is perhaps not surprising that almost 6 in 10 U.S. adults report that it is “stressful and frustrating” to talk about politics with people who hold different political opinions. A recent survey found that 64% of individuals believe that people are incapable of having constructive and civil debates about issues on which they disagree. Additionally, growing ideological divisions in the U.S. are fueling skepticism and even animosity between groups across the political divide —sentiments of enmity and disapproval between Democrats and Republicans more than doubled between 1994 and 2014. Polarization can lead to identity-based extremism and violence, pointing to the urgent need to foster social connection across group-based ideological differences through **bridging social capital**.

## A National Strategy to Advance Social Connection

The world is just beginning to recognize the vital importance of social connection. While the evidence of the severe consequences of social isolation, loneliness, and overall social disconnection has been building for decades, a global pandemic crystallized and accelerated the urgency for the United States to establish a National Strategy to Advance Social Connection. Such a strategy not only recognizes the critical importance of advancing social connection, but also serves as a commitment to invest in and take actions establishing that our connection with others is a core value of this nation.

As this advisory has shown, fulfilling connections are a critical and often underappreciated contributor to individual and population health and longevity, safety, prosperity, and well-being. On the other hand, social disconnection contributes to many poor health outcomes, and even to premature death. Sadly, around 50% of adults in the U.S. reported being lonely in recent years[1-3]— and that was even before COVID-19 separated so many of us from our friends, loved ones, and support systems. Our bonds with others and our community are also part of this equation. Research has shown that more connected communities enjoy higher levels of well-being. The converse is also true. How do we put this important information to practical use in our society? What actionable steps can we take to enhance social connection so that we can all enjoy its benefits?

A National Strategy to Advance Social Connection is the critical next step to catalyze action essential to our nation's health, safety, and prosperity. The strategy includes six foundational pillars and a series of key recommendations, organized according to stakeholder group, to support a whole-of-society approach to advancing social connection. Individuals and organizations can use this framework to propel the critical work of reversing these worrisome trends and strengthening social connection and community.

Doing so won't always be easy. Fostering greater connection requires widespread individual and institutional action. It demands our sustained investment, effort, and focus. But it will be worth it, because when we each take these critical steps, we are choosing better lives, and to create a better world for all.

Such a world, where we recognize that relationships are just as essential to our well-being as the air we breathe and the food we eat, is a world where everyone is healthier, physically and mentally. It is a world where we respect and value one another, where we look out for one another, and where we create opportunities to uplift one another. A world where our highs are higher because we celebrate them together; where our lows are more manageable because we respond to them together; and where our recovery is faster because we grieve and rebuild together.

It is a world where we are strong enough to hold our differences, where we are more comfortable and motivated to engage civically, and where our leaders and institutions are more representative of the people they serve. It is a world where we trust one another, where we feel safe to challenge one another and change our minds, and where prosperity and progress are not the privilege of the few but accessible to all.

We can choose, in short, to take the core values that make us strong—love, kindness, respect, service, and commitment to one another—and reflect them in the world we build for ourselves and our children. This strategy shows us how to create the connected lives and the connected world we need.

**Benefits of a National Strategy to Advance Social Connection**

- **Cultivating individual health and well-being** across physical and mental health and educational and economic outcomes. This enables individuals to be happier, more prosperous, and to contribute more fully to society.
- **Strengthening community health, safety, and prosperity** by cultivating social cohesion and social capital within and across communities. This enables communities to overcome adversity and thrive.
- **Building resilience for the next set of challenges** such as natural hazards, pandemics, and safety threats. This enables society to withstand unanticipated crises through stronger recovery and resilience.

- **Advancing civic engagement and representative government** by fostering a more engaged citizenry. This enables policies and programs to better reflect the will of a community and its individuals.

Many factors that influence social connection are environmental. Decisions about the layout of our cities, from the usability and reach of public transportation to the design of housing and green spaces, have a direct effect on social interaction in a community.[302,303] This is why strengthening social infrastructure that promotes social connection is critical to advancing key aspects of community health, resilience, safety, and prosperity. Social infrastructure refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that support the development of social connection.

Investing in local communities and in social infrastructure will fall short if access to the benefits is limited to only some groups. Equitable access to social infrastructure for all groups, including those most at-risk for social disconnection, is foundational to building a connected national and global community, and is essential to this pillar's success.

Moreover, community programs, such as those that connect us to our neighbors, those that help students establish social skills in schools, and those that generate opportunities for high-risk populations to create community, also have a powerful role in building relationships. For example, volunteering is a demonstrated and powerful way to advance connection to one's community and create diverse ties among community members. Finally, institutions that gather individuals for work, study, or prayer, such as workplaces, schools, and faith organizations, can function as sources of positive connection and thereby bolster the community's trust in those institutions and in fellow members. Investing in community connection will be important to repairing divisions and rebuilding trust in each other and our institutions, and is vital to achieving common societal goals.

National, state, local, and tribal governments play a critical role in strengthening social connection and community across all sectors. These institutions recognize the importance of social connection to the health of their communities. Policymakers understand that while the effects of social connection may be most evident for health, the drivers of connection and disconnection can be found in all types of policies, from transportation and zoning to nutrition and labor. A "Connection-in-All-Policies" approach recognizes that every sector of society is relevant to social connection, and that policy within each sector may potentially hinder or facilitate connection. Conversely, government has a responsibility to use its authority to monitor and mitigate the public health harm caused by policies, products, and services that drive social disconnection.

Prioritizing social connection in policy agendas and leveraging a "Connectionin-All-Policies" approach requires establishing cross-departmental leadership to develop and

oversee an overarching social connection strategy. Diversity, equity, inclusion, and accessibility are critical components of any such strategy. It must recognize that everyone is impacted by social connection, but that some groups may be more disproportionally impacted by some policies. Thus, policymakers must give focused attention to reducing disparities in risk and ensuring equal access to benefits.

Social connection is an independent protective factor, and social isolation and loneliness are independent risk factors for several major health conditions, including cardiovascular disease, dementia, depression, and premature mortality from all causes.[128] While all organizations have a role in addressing social connection, mobilizing the health sector—most notably health care delivery systems and the public health community—is a core pillar of the National Strategy.

It is critical that we invest in health care provider education on the physical and mental health benefits of social connection, as well as the risks associated with social disconnection. We must also create systems that enable and incentivize health care providers to educate patients as part of preventative care, assess for social disconnection, and respond to patients' health-relevant social needs. This can be accomplished both within the medical system and by linking individuals to community-based organizations that can provide necessary support and resources specifically designed to increase social connection.[10,285,304,305] Public health organizations can help track the community prevalence of social disconnection, promote individual best practices, and advance community solutions. By integrating social connection into primary-, secondary-, and tertiary-level prevention and care efforts, we can strive to prevent forms of social disconnection in healthy individuals, mitigate forms of social disconnection early on before they become severe, and provide adequate support for those who are experiencing severe forms of social disconnection.

The exponential growth of technology crosses geographic borders, broadening communities and opening the world to those with limited access. It has had a tangible impact on how we live and work, from social connectivity, gaming, content sharing, and virality, to flexible work environments and communication.

But these benefits come at a cost. Technology can also distract us and occupy our mental bandwidth, make us feel worse about ourselves or our relationships, and diminish our ability to connect deeply with others. Some technology fans the flames of marginalization and discrimination, bullying, and other forms of severe social negativity.

We must decide how technology is designed and how we use it. There are many ways to minimize harms. We must learn more by requiring data transparency from technology companies. This will enable us to understand their current and long-term effects on social connection, and implement and enforce safety standards (such as age-related protections for young people) that ensure products do not worsen social disconnection. In a positive vein, we should support the development of pro-connection technology to promote healthy social connection, create safe environments for discourse, and

safeguard the well-being of users. This should be coupled with the public's greater ability to avoid or limit their own uses.

Finally, we need to recognize the unique aspects of digital technology that may differ from other modes of connecting socially. The modality of delivery matters, and should be strategically and explicitly acknowledged and evaluated.

This Surgeon General's Advisory outlines a summary of the evidence about how social connection and disconnection impact individual and community health and overall well-being. The totality of this evidence illustrates that urgent action is needed, including additional research to further advance our understanding of the causes and consequences of social connection, trends, populations at risk, and the effectiveness of interventions and other efforts to advance connection.

As a next step, relevant stakeholders, including government, policymakers, practitioners, and researchers, should work together to establish a research agenda focused on addressing identified gaps in the evidence base, fund research at levels commensurate with the seriousness of the problem, and create a plan to increase research coordination. Deepening our knowledge of social connection and disconnection also requires us to further refine and expand our capacity to measure these states via agreed upon standardized metrics. As individuals, communities, institutions, and governments implement the pillars of the National Strategy, consistent measurement will be critical to better understanding the driving forces of connection and disconnection, and how we can be more effective and efficient in addressing these states.

Public understanding of the essential role of social connection in health and well-being is critical to this pillar. Social connection should be included as a key driver of health in formal health education, from elementary to professional school curricula. It is also imperative that we share this knowledge beyond health professionals. Public awareness and education of the drivers and solutions of connection and disconnection will be a critical foundation to support sustained policy and cultural change.

A culture of connection is vital to creating the changes needed in society. While formal programs and policies can be impactful, the informal practices of everyday life—the norms and culture of how we engage one another—significantly influence social connection. These shared beliefs and values drive our individual and collective behaviors that then shape programs and policies. We cannot be successful in the other pillars without this underlying culture of connection.

Such a culture of connection rests on core values of kindness, respect, service, and commitment to one another. Everyone contributes to the collective culture of social connection by regularly practicing these values. Advancing this culture requires individuals and leaders to seek opportunities to do so in public and private dialogue, schools, workplaces, and in the forces that shape our society like media and

entertainment, among others. Behaviors are both learned from and reinforced by the groups we participate in and the communities we are a part of. Thus, the more we observe others practicing these values, the more they will be reinforced in us.

All types of leaders and influencers (national, local, political, cultural, corporate, etc.) can use their voices to underscore these core values and model healthy social connection and dialogue. Media and entertainment shape our beliefs through the depiction of stories. These narratives can help individuals see themselves in stories and help to reduce stigma, thus enabling more connection. Further, our institutions should invest time, attention, and resources in ways that demonstrate these values.

Office *of the* U.S. Surgeon General

# The Six Pillars to Advance Social Connection


## 1

### Strengthen Social Infrastructure in Local Communities

Design the built environment to promote social connection

Establish and scale community connection programs

Invest in local institutions that bring people together

## 2

### Enact Pro-Connection Public Policies

Adopt a "Connection-in-All-Policies" approach

Advance policies that minimize harm from disconnection

Establish cross-departmental leadership at all levels of government

## 3

### Mobilize the Health Sector

Train health care providers

Assess and support patients

Expand public health surveillance and interventions

## 4

### Reform Digital Environments

Require data transparency

Establish and implement safety standards

Support development of pro-connection technologies

## 5

### Deepen Our Knowledge

Develop and coordinate a national research agenda

Accelerate research funding

Increase public awareness

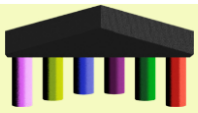
## 6

### Build a Culture of Connection

Cultivate values of kindness, respect, service, and commitment to one another

Model connection values in positions of leadership and influence

Expand conversation on social connection in schools, workplaces, and communities



The Six Pillars to Advance Social Connection

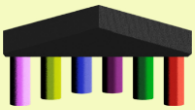
## Pillar 1 Strengthen Social Infrastructure in Local Communities

- Design the built environment to promote social connection
- Establish and scale community connection programs
- Invest in local institutions that bring people together

Many factors that influence social connection are environmental. Decisions about the layout of our cities, from the usability and reach of public transportation to the design of housing and green spaces, have a direct effect on social interaction in a community.[302,303] This is why strengthening social infrastructure that promotes social connection is critical to advancing key aspects of community health, resilience, safety, and prosperity. Social infrastructure refers to the programs (such as volunteer organizations, sports groups, religious groups, and member associations), policies (like public transportation, housing, and education), and physical elements of a community (such as libraries, parks, green spaces, and playgrounds) that support the development of social connection.

Investing in local communities and in social infrastructure will fall short if access to the benefits is limited to only some groups. Equitable access to social infrastructure for all groups, including those most at-risk for social disconnection, is foundational to building a connected national and global community, and is essential to this pillar's success.

Moreover, community programs, such as those that connect us to our neighbors, those that help students establish social skills in schools, and those that generate opportunities for high-risk populations to create community, also have a powerful role in building relationships. For example, volunteering is a demonstrated and powerful way to advance connection to one's community and create diverse ties among community members. Finally, institutions that gather individuals for work, study, or prayer, such as workplaces, schools, and faith organizations, can function as sources of positive connection and thereby bolster the community's trust in those institutions and in fellow members. Investing in community connection will be important to repairing divisions and rebuilding trust in each other and our institutions, and is vital to achieving common societal goals.



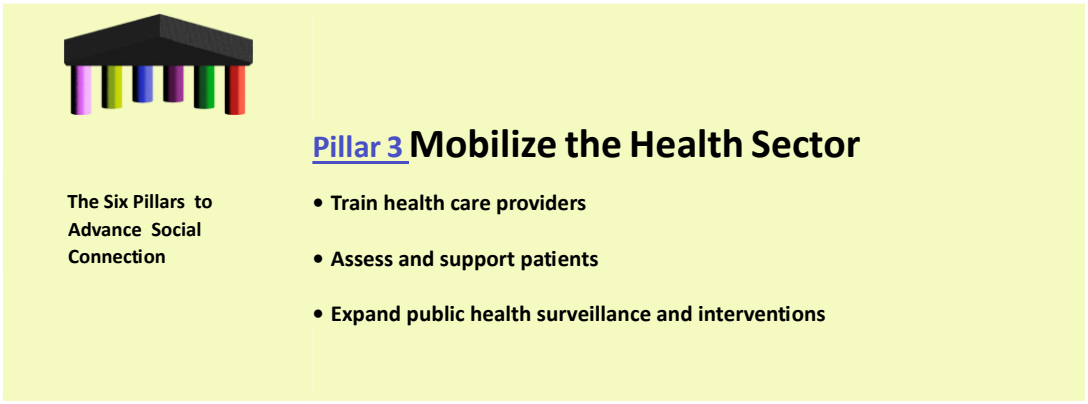
The Six Pillars to Advance Social Connection

## Pillar 2 Enact Pro-Connection Public Policies

- Adopt a "Connection-in-All-Policies" approach
- Advance policies that minimize harm from disconnection
- Establish cross-departmental leadership at all levels of government

National, state, local, and tribal governments play a critical role in strengthening social connection and community across all sectors. These institutions recognize the importance of social connection to the health of their communities. Policymakers understand that while the effects of social connection may be most evident for health, the drivers of connection and disconnection can be found in all types of policies, from transportation and zoning to nutrition and labor. A "Connection-in-All-Policies" approach recognizes that every sector of society is relevant to social connection, and that policy within each sector may potentially hinder or facilitate connection. Conversely, government has a responsibility to use its authority to monitor and mitigate the public health harm caused by policies, products, and services that drive social disconnection.

Prioritizing social connection in policy agendas and leveraging a "Connectionin-All-Policies" approach requires establishing cross-departmental leadership to develop and oversee an overarching social connection strategy. Diversity, equity, inclusion, and accessibility are critical components of any such strategy. It must recognize that everyone is impacted by social connection, but that some groups may be more disproportionally impacted by some policies. Thus, policymakers must give focused attention to reducing disparities in risk and ensuring equal access to benefits.




Social connection is an independent protective factor, and social isolation and loneliness are independent risk factors for several major health conditions, including cardiovascular disease, dementia, depression, and premature mortality from all causes.[128] While all organizations have a role in addressing social connection, mobilizing the health sector—most notably health care delivery systems and the public health community—is a core pillar of the National Strategy.

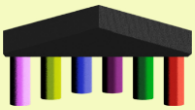
It is critical that we invest in health care provider education on the physical and mental health benefits of social connection, as well as the risks associated with social disconnection. We must also create systems that enable and incentivize health care providers to educate patients as part of preventative care, assess for social disconnection, and respond to patients' health-relevant social needs. This can be accomplished both within the medical system and by linking individuals to community-based organizations that can provide necessary support and resources specifically designed to increase social connection.[10,285,304,305] Public health organizations can help track the community prevalence of social disconnection, promote individual best practices, and advance community solutions. By integrating social connection into primary-, secondary-, and tertiary-level prevention and care efforts, we can strive to prevent forms of social disconnection in healthy individuals, mitigate forms of social disconnection early on before they become severe, and provide adequate support for those who are experiencing severe forms of social disconnection.


The exponential growth of technology crosses geographic borders, broadening communities and opening the world to those with limited access. It has had a tangible impact on how we live and work, from social connectivity, gaming, content sharing, and virality, to flexible work environments and communication.

But these benefits come at a cost. Technology can also distract us and occupy our mental bandwidth, make us feel worse about ourselves or our relationships, and diminish our ability to connect deeply with others. Some technology fans the flames of marginalization and discrimination, bullying, and other forms of severe social negativity.

We must decide how technology is designed and how we use it. There are many ways to minimize harms. We must learn more by requiring data transparency from technology companies. This will enable us to understand their current and long-term effects on social connection, and implement and enforce safety standards (such as age-related protections for young people) that ensure products do not worsen social disconnection. In a positive vein, we should support the development of pro-connection technology to promote healthy social connection, create safe environments for discourse, and safeguard the well-being of users. This should be coupled with the public's greater ability to avoid or limit their own uses.

Finally, we need to recognize the unique aspects of digital technology that may differ from other modes of connecting socially. The modality of delivery matters, and should be strategically and explicitly acknowledged and evaluated.



The Six Pillars to Advance Social Connection

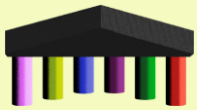
## Pillar 5 Deepen our Knowledge

- Develop and coordinate a national research agenda
- Accelerate research funding
- Increase public awareness

This Surgeon General's Advisory outlines a summary of the evidence about how social connection and disconnection impact individual and community health and overall well-being. The totality of this evidence illustrates that urgent action is needed, including additional research to further advance our understanding of the causes and consequences of social connection, trends, populations at risk, and the effectiveness of interventions and other efforts to advance connection.

As a next step, relevant stakeholders, including government, policymakers, practitioners, and researchers, should work together to establish a research agenda focused on addressing identified gaps in the evidence base, fund research at levels commensurate with the seriousness of the problem, and create a plan to increase research coordination. Deepening our knowledge of social connection and disconnection also requires us to further refine and expand our capacity to measure these states via agreed upon standardized metrics. As individuals, communities, institutions, and governments implement the pillars of the National Strategy, consistent measurement will be critical to better understanding the driving forces of connection and disconnection, and how we can be more effective and efficient in addressing these states.

Public understanding of the essential role of social connection in health and well-being is critical to this pillar. Social connection should be included as a key driver of health in formal health education, from elementary to professional school curricula. It is also imperative that we share this knowledge beyond health professionals. Public awareness and education of the drivers and solutions of connection and disconnection will be a critical foundation to support sustained policy and cultural change.



The Six Pillars to Advance Social Connection

## Pillar 6 Cultivate a Culture of Connection

- Cultivate values of kindness, respect, service, and commitment to one another
- Model connection values in positions of leadership and influence
- Expand conversations on social connection in schools, workplaces, and communities

A culture of connection is vital to creating the changes needed in society. While formal programs and policies can be impactful, the informal practices of everyday life—the norms and culture of how we engage one another—significantly influence social connection. These shared beliefs and values drive our individual and collective behaviors that then shape programs and policies. We cannot be successful in the other pillars without this underlying culture of connection.

Such a culture of connection rests on core values of kindness, respect, service, and commitment to one another. Everyone contributes to the collective culture of social connection by regularly practicing these values. Advancing this culture requires individuals and leaders to seek opportunities to do so in public and private dialogue, schools, workplaces, and in the forces that shape our society like media and entertainment, among others. Behaviors are both learned from and reinforced by the groups we participate in and the communities we are a part of. Thus, the more we observe others practicing these values, the more they will be reinforced in us.

All types of leaders and influencers (national, local, political, cultural, corporate, etc.) can use their voices to underscore these core values and model healthy social connection and dialogue. Media and entertainment shape our beliefs through the depiction of stories. These narratives can help individuals see themselves in stories and help to reduce stigma, thus enabling more connection. Further, our institutions should invest time, attention, and resources in ways that demonstrate these values.

### What National, Territory, State, Local, and Tribal Governments Can Do

- **Designate social connection a priority** by including it in public health and policy agendas, providing critical resources, and creating strategies to strengthen

social connection and community that include clear benchmarks, measurable outcomes, and periodic evaluation.

- **Establish a dedicated leadership position** to work across departments, convene stakeholders, and advance pro-connection policies.

- **Utilize a "Connection-in-All-Policies" Approach** that examines policies across sectors, including health, education, labor, housing, transportation, and the environment, and looks to identify and remedy policies that drive disconnection while advancing those that drive connection. Periodically, evaluate and revise existing policies and programs, and when appropriate, propose new policies to advance social connection. Examples of pro-connection policies include paid leave, which enables individuals to spend time with family during critical early life stages, and increased access to public transit, which allows individuals to physically connect more easily.

- **Monitor and regulate technology** by establishing transparency, accountability, safety, and consumer protections to ensure social health and safety (including for minors) and the ability for independent researchers to evaluate the impact of technology on our health and well-being.[306]

- **Create a standardized national measure or set of measures for social connection and standardized definitions for relevant terms**, in collaboration with the research community. Implement consistent, regular measurement of social connection metrics in current national health surveys, with the ability to capture the level of granularity needed to guide strategic decision-making, planning, and evaluation of strategies.

- **Prioritize research funding** such that research is supported at levels commensurate with the societal impact of loneliness, social isolation, and other forms of social disconnection, and enhance collaboration with researchers to improve research coordination.

- **Launch sustained and inclusive public education and awareness efforts**, including the development of national guidelines for social connection.[307]

- **Invest in social infrastructure at the local level**, including the programs, policies, and physical elements of a community that facilitate bringing people together.

- **Incentivize the assessment and integration of social connection** into health care delivery and public health, including through public insurance coverage and other government funding mechanisms.

- **Increase evaluation and oversight** of policy and programmatic outcomes from public institutions, programs, and services, and make the results available through public facing reports, databases, and other mechanisms. This will help improve existing policies and programs, demonstrate transparency, and increase public trust in institutions.

**What Health Workers, Health Care Systems, and Insurers Can Do**

- Explicitly **acknowledge social connection as a priority** for health.
- **Provide health professionals with formal training** and continuing education on the health and medical relevance of social connection and risks associated with social disconnection (e.g., isolation, loneliness, low social support, social negativity), as well as advanced training on prevention and interventions.

- Insurance companies should **provide adequate reimbursement** for time spent assessing and addressing concerns about social disconnection (e.g., isolation, loneliness, low social support, poor relationship quality), and incorporate these measurements into value-based payment models.
- **Facilitate inclusion of assessment results in electronic health records.**
- Providers and insurers can **educate and incentivize patients to understand the risks** of, and take action to address, inadequate social connection, with a particular focus on at-risk individuals, including but not limited to those with physical or mental health conditions or disabilities, financial insecurity, those who live alone, single parents, and both younger and aging populations.
- **Integrate social connection into patient care** in primary-, secondary-, and tertiary-level care settings by:

  ◦ Actively assessing patients' level of social connection to identify those who are at increased risk or already experiencing social disconnection and evaluate the level of necessary supports.[305]

  ◦ Educating patients about the benefits of social connection and the risk factors for social disconnection as part of primary prevention.

  ◦ Leveraging interventions that provide psychosocial support to patients, including involving family or other caregivers in treatment, group therapies, and other evidence-based options.[304]

- **Work with community organizations** to create partnerships that provide support for people who are at risk for, or are struggling with, loneliness, isolation, low social support, or poor-quality relationships.
- Create opportunities for clinicians to partner with researchers to **evaluate the application of evidence-based assessment tools and interventions within clinical settings,** including evaluating the efficacy of applications for specific populations.[10]

## What Public Health Professionals and Public Health Departments Can Do

- **Establish social connection as a priority health indicator and social determinant of health** with the goal of improving health and well-being through programs, education, research, and promotion of healthy lifestyles across the lifespan.

- **Develop, lead, and support public education programs, awareness campaigns, and health professional training programs** focused on the health impacts of social disconnection. Integrate social connection as a key component of health promotion and wellness programs focused on related health issues (e.g., suicide, workplace burnout, substance use).
- **Study and support research on the causes of social disconnection.**

- **Evaluate, develop, and implement sustainable interventions and strategies** (e.g., programs, campaigns, tools, partnerships) across the social-ecological model to promote greater connection and prevent social disconnection.

**Consistently and regularly track social connection** using validated metrics (such as the Berkman-Syme Social Network Index, UCLA Loneliness Scale), and validate new measures to capture the full complexity of social connection to guide strategic decision-making, planning, and evaluation of strategies.

### What Researchers and Research Institutions Can Do

- **Establish social connection as a research priority** and support researchers in this field with time, space, and funding.[32]

- **Develop a cross-disciplinary research agenda** including basic, translational, evaluation, and dissemination research that prioritizes systematically mapping outstanding evidence gaps to ensure adequate evidence across all levels of the social-ecological model, sectors of society, and the life course, with attention to inclusion, diversity, equity, access, and modality considerations. This research should include investigations into:

◦ The root causes of social disconnection, including how causal mechanisms vary across age, income, culture, race, ethnicity, gender identity, sexual orientation, and health status to advance equity in social well-being for all members of the community, and ensure research is inclusive of under-represented groups.[10,19]

◦ What social connection indicators may intersect or act independently, additively, or synergistically to influence risk and resilience for health and other societal outcomes.

◦ Fuller examinations of age, developmental, and cohort processes that may influence the onset and progression of disease and other adverse outcomes.

◦ Rigorous evaluation of technology's evolving impact on social connection.

◦ The effectiveness, efficiency, and acceptability of prevention, intervention, and dissemination approaches.

◦ Additional examinations of individual and societal effects of social connection within and beyond health outcomes, including indicators of well-being (e.g., wider community participation, quality of life), prosperity (e.g., educational attainment, employment, economic mobility), and public safety.

- **Develop and establish additional standardized national and local measures** that are regularly evaluated and can be used across basic research, clinical assessment, population surveillance, intervention evaluation, and other contexts.
- **Improve research coordination**, including the development of an accessible evidence database, a way to coordinate utilization of evidence among researchers, and a comprehensive way to track connection and community metrics over time.

**What Philanthropy Can Do**

- **Fund new programs and invest in existing successful programs** that advance social connection among individuals and within communities, including those that aim to prevent and treat social isolation and loneliness and those that reach populations at highest risk.
- Because social connection can be advanced through programs designed to support other outcomes (e.g., population health, community resilience, public safety, educational attainment, economic progress) funders should **evaluate cross-sector programs for their impact on social connection** by adding social connection and relationship-building as indicators of grantee success.
- **Provide support for adequate evaluation, reporting, and knowledge sharing** about the effectiveness of interventions designed to reduce loneliness and isolation and improve social connection.
- **Convene stakeholders** working to understand or strengthen social connection.
- **Invest in efforts to increase public awareness** and dissemination of findings.

**What Schools and Education Departments Can Do**

School administrators and leaders, boards of education, boards of trustees, teachers, parent teacher associations, state departments of education, and online learning platforms can all play a role.

- **Develop a strategic plan for school connectedness and social skills with benchmark tracking.** This could include providing regular opportunities and spaces for students to develop social skills and strengthen relationships, and the adoption of evidenced-based practices leveraging elements of the CDC Framework: Whole School, Whole Community, Whole Child.[310] Strategies to enhance connectedness may include promoting quality adult support from family and school staff, peer-led programs, and partnerships with key community groups.

- **Build social connection into health curricula,** including up-to-date, age-appropriate information on the consequences of social connection on physical and mental health, key risk and protective factors, and strategies for increasing social connection.

- **Implement socially based educational techniques** such as cooperative learning projects that can improve educational outcomes as well as peer relations.[311]

- **Create a supportive school environment** that fosters belonging through equitable classroom management, mentoring, and peer support groups that allow students to lean on one another and learn from each other's experiences.

**What Workplaces Can Do**

- **Make social connection a strategic priority in the workplace** at all levels (administration, management, and employees).[48]

- **Train, resource, and empower leaders and managers** to promote connection in the workplace and implement programs that foster connection. Assess program effectiveness, identify barriers to success, and facilitate continuous quality improvement.

- **Leverage existing leadership and employee training, orientation, and wellness resources** to educate the workforce about the importance of social connection for workplace well-being, health, productivity, performance, retention, and other markers of success.

- **Create practices and a workplace culture** that allow people to connect to one another as whole people, not just as skill sets, and that fosters inclusion and belonging.

- **Put in place policies that protect workers' ability to nurture their relationships outside work** including respecting boundaries between work and non-work time, supporting caregiving responsibilities, and creating a culture of norms and practices that support these policies.

- **Consider the opportunities and challenges posed by flexible work hours and arrangements** (including remote, hybrid, and in-person work), which may impact

workers' abilities to connect with others both within and outside of work. Evaluate how these policies can be applied equitably across the workforce.

**What Community-Based Organizations Can Do**

Community-based organizations include, but are not limited to, membership-based organizations, civic groups, arts and education groups, faith-based organizations, direct service providers, and youth-led organizations. Regardless of whether the mission of a community-based organization is focused on social connection, every organization can promote stronger social connection.

- **Create opportunities and spaces for inclusive social connection** and establish programs that foster positive and safe relationships, including among individuals of different ages, backgrounds, viewpoints, and life experiences.
- **Embed social connection** in internal policies, practices, programs, and evaluations.
- **Actively seek and build partnerships** with other community institutions (schools, health organizations, workplaces) to support those experiencing loneliness and social isolation, and to create a culture of connection in the broader community.
- **Advance public education and awareness efforts** to introduce and elevate the topic of social connection and disconnection among community members.
- **Create and provide education, resources, and support programs** for community members and key populations such as parents, youth, and at-risk populations. These could include community-wide social events, volunteering and community service activities, network-building professional development, and organizational opportunities for involvement by the community.
- **Foster a culture of connection in the broader community** by highlighting examples of healthy social connection and leading by example.

**What Technology Companies Can Do**

- **Be transparent with data** that illustrates both the positive and negative impacts of technology on social connection by sharing long-term and real-time data with independent researchers to enable a better understanding of technology's impact on individuals and communities, particularly those at higher risk of social disconnection.
- **Support the development and enforcement of industry-wide safety standards** with particular attention to social media, including age-appropriate protections and identity assurance mechanisms, to ensure safe digital environments that enable positive social connection, particularly for minors.

**Intentionally design technology that fosters healthy dialogue and relationships**, including across diverse communities and perspectives. The designs should prioritize

social health and safety as the first principle, from conception to launch to evaluation. This also means avoiding design features and algorithms that drive division, polarization, interpersonal conflict, and contribute to unhealthy perceptions of one's self and one's relationships.

**What Media and Entertainment Industries Can Do**

- **Create content that models and promotes positive social interactions**, healthy relationships, and reinforces the core values of connection: kindness, respect, service, and commitment to one another.
- **Utilize storylines and narratives** in film, television, and entertainment to provide messages that broaden public awareness of the health benefits of social connection and the risks of social disconnection.
- **Ensure that content related to social connection is scientifically accurate** in collaboration with the scientific community.
- **Avoid content and products that inadvertently increase disconnection or stigma around social disconnection**, recognizing the impact content can have on increasing societal distrust, polarization, and perpetuating harmful stereotypes.

**What Parents and Caregivers Can Do**

Parents and caregivers play an important role in shaping the experience of social connection. Although focused on parents of young children, many of these recommendations can apply more broadly to all types of caregivers.

- **Invest in your relationship with your child or loved one** by recognizing that strong, secure attachments are protective and a good foundation for other healthy relationships.
- **Model healthy social connection**, including constructive conflict resolution, spending time together, staying in regular contact with extended family, friends, and neighbors, setting time aside for socializing away from technology or social media, and participating in community events.
- **Help children and adolescents develop strong, safe, and stable relationships with supportive adults** like grandparents, teachers, coaches, counselors, and mentors.
- **Encourage healthy social connection with peers** by supporting individual friendships, as well as participation in structured activities such as volunteering, sports, community activities, and mentorship programs.
- **Be attentive to how young people spend their time online.** Delay the age at which children join social media platforms and monitor and decrease screen time in favor of positive, in-person, connection building activities.

- Identify and aim to **reduce behaviors and experiences that may increase the risk for social disconnection**, including bullying and excessive or harmful social media use.

- **Talk to your children about social connection regularly** to understand if they are struggling with loneliness or isolation, to destigmatize talking about these feelings, and to create space for children to share their perspective and needs.

◦ Look out for potential warning signs of loneliness and social isolation, such as increases in time spent alone, disproportionate online time, limited interactions with friends, or excessive attention-seeking behavior.[312,313]

◦ Connect youth to helpers like counselors, educators, and health care providers if they are struggling with loneliness, isolation, or unhealthy relationships.

**What Individuals Can Do**

- **Understand the power of social connection and the consequences of social disconnection** by learning how the vital components (structure, function, and quality) can impact your relationships, health, and well-being.

- **Invest time in nurturing your relationships** through consistent, frequent, and high-quality engagement with others. Take time each day to reach out to a friend or family member.

- **Minimize distraction during conversation** to increase the quality of the time you spend with others. For instance, don't check your phone during meals with friends, important conversations, and family time.

- **Seek out opportunities to serve and support others**, either by helping your family, co-workers, friends, or strangers in your community or by participating in community service.

- **Be responsive, supportive, and practice gratitude.**[314,315] As we practice these behaviors, others are more likely to reciprocate, strengthening our social bonds, improving relationship satisfaction, and building social capital.

- **Actively engage with people of different backgrounds and experiences** to expand your understanding of and relationships with others, given the benefits associated with diverse connections.

- **Participate in social and community groups** such as fitness, religious, hobby, professional, and community service organizations to foster a sense of belonging, meaning, and purpose.

- **Reduce practices that lead to feelings of disconnection from others.** These include harmful and excessive social media use, time spent in unhealthy relationships, and disproportionate time in front of screens instead of people.

- **Seek help during times of struggle** with loneliness or isolation by reaching out to a family member, friend, counselor, health care provider, or the 988 crisis line.[316]

- **Be open with your health care provider** about significant social changes in your life, as this may help them understand potential health impacts and guide them to provide recommendations to mitigate health risks.

- **Make time for civic engagement.** This could include being a positive and constructive participant in political discourse and gatherings (e.g., town halls, school board meetings, local government hearings).

- **Reflect the core values of connection** in how you approach others in conversation and through the actions you take. Key questions to ask yourself when considering your interactions with others include:
    How might kindness change this situation?
    What would it look like to treat others with respect?
    How can I be of service?
    How can I reflect my concern for and commitment to others?

**Strengths and Limitations of the Evidence**

Hundreds of independent studies across several scientific disciplines have examined the objective physical and mental health outcomes of social connection, social isolation, and loneliness for individuals. Despite the variability in conceptual and methodological approaches used in the research, these findings converge to demonstrate a robust and reliable association between social connection and health outcomes.

In addition to significant evidence of correlations between social connection and health, evidence supports a potential causal association. Using the Bradford Hill Guidelines, as well as some newer studies leveraging causal epidemiology and experimental evidence in animals, together suggests a likely causal association between social isolation and a variety of poor health outcomes, including death. In humans, experimental evidence and intervention-based studies using randomized controlled trials also supports the likelihood of a causal association between broader social connection and better health and longer life expectancy.

Importantly, there is evidence of a dose-response relationship between social connection and health. This means that incremental increases in social connection correspond to decreases in risk to health, and conversely, decreases in social connection correspond to increases in risk. Evidence demonstrates this dose-response relationship exists for developmental stages across the lifespan, suggesting that social connection is a continuum from risk (when low) to protection (when high). This suggests social connection is relevant to all humans regardless of our individual positions along the risk trajectory.

Despite the strength of the evidence linking social connection to various health outcomes, certain gaps and limitations in research still exist. For example, few studies examine more than one social connection component (structural, functional, and quality indicators) in the same sample to disentangle the independent, additive, and synergistic effects. This complicates the measurement of an individual's risk associated with lack of social connection (e.g., social isolation, loneliness, social negativity) and confounds the understanding of the unique and

complex pathways by which social connection influences health. Further, despite significant changes in the way in which we interact socially, many research studies do not distinguish remote or technology-mediated social connection from traditional means of connecting socially to determine equivalencies and to discern the influence on long-term health and mortality risk. Yet, despite these challenges, the extensive and replicated body of existing evidence offers a compelling basis for elevating the discourse on promoting social connection and addressing social disconnection with targeted public health policies, initiatives, and actions.

In regard to the study of community-level benefits, significant differences exist in how researchers approach community-level social connection across scientific studies. For instance, variations exist in the indicators researchers use to define and measure social connection. While social cohesion, social capital, belonging, and trust are all indicators of connected communities, many studies examine only one of these concepts and few examine all of these to disentangle their relative influence or relate them directly to loneliness and isolation. Complicating matters, some studies also use different terms to refer to the same concept or use the same term to refer to different concepts. Much of this research is correlative in nature and necessitates further study, including among often underrepresented groups,  in order to understand causative factors that produce community-level benefits.

Another layer of complexity is how different each community is along a multitude of dynamics and factors such as policies, customs, cultures, assets, challenges, demographics, and more. This variation means there is no “one-size-fits-all” approach to community connection, and it means that different communities will have different needs and desires. Despite all of these differences and complexities, there is strong evidence that points to social connection as an important factor in strengthening communities and community-level outcomes. While more research is needed, the evidence we do have suggests that enhancing community connection may help us address many important community and societal issues.

## Social Media and Youth Mental Health

## The U.S. Surgeon General’s Advisory

Office of the Surgeon General (OSG).

Washington (DC): US Department of Health and Human Services; 2023.

Social media use by youth is nearly universal. Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media “almost constantly.” Although age 13 is commonly the required minimum age used by social media platforms in the U.S., nearly 40% of children ages 8–12 use social media. Despite this widespread use among children and adolescents, robust independent

safety analyses on the impact of social media on youth have not yet been conducted. There are increasing concerns among researchers, parents and caregivers, young people, healthcare experts, and others about the impact of social media on youth mental health.

### About the Advisory

A Surgeon General's Advisory is a public statement that calls the American people's attention to an urgent public health issue and provides recommendations for how it should be addressed. Advisories are reserved for significant public health challenges that require the nation's immediate awareness and action.

This Advisory calls attention to the growing concerns about the effects of social media on youth mental health. It explores and describes the current evidence on the positive and negative impacts of social media on children and adolescents, some of the primary areas for mental health and well-being concerns, and opportunities for additional research to help understand the full scope and scale of social media's impact. This document is not an exhaustive review of the literature. Rather, it was developed through a substantial review of the available evidence, primarily found via electronic searches of research articles published in English and resources suggested by a wide range of subject matter experts, with priority given to, but not limited to, meta-analyses and systematic literature reviews. It also offers actionable recommendations for the institutions that can shape online environments—policymakers and technology companies—as well as for what parents and caregivers, young people, and researchers can do.

## Social Media and Youth Mental Health

Social media[1] use by youth is nearly universal. Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media "almost constantly."[2] Although age 13 is commonly the required minimum age used by social media platforms in the U.S.,[3] nearly 40% of children ages 8–12 use social media.[4] Despite this widespread use among children and adolescents, robust independent safety analyses on the impact of social media on youth have not yet been conducted. There are increasing concerns among researchers, parents and caregivers, young people, healthcare experts, and others about the impact of social media on youth mental health.[5, 6]

More research is needed to fully understand the impact of social media; however, the current body of evidence indicates that while social media may have benefits for some children and adolescents, there are ample indicators that social media can also have a profound risk of harm to the mental health and well-being of children and adolescents. At this time, we do not yet have enough evidence to determine if social media is sufficiently safe for children and adolescents. We must acknowledge the growing body

of research about potential harms, increase our collective understanding of the risks associated with social media use, and urgently take action to create safe and healthy digital environments that minimize harm and safeguard children's and adolescents' mental health and well-being during critical stages of development.

Up to 95% of youth ages 13–17 report using a social media platform, with more than a third saying they use social media "almost constantly."

## Social Media Has Both Positive and Negative Impacts on Children and Adolescents

The influence of social media on youth mental health is shaped by many complex factors, including, but not limited to, the amount of time children and adolescents spend on platforms, the type of content they consume or are otherwise exposed to, the activities and interactions social media affords, and the degree to which it disrupts activities that are essential for health like sleep and physical activity.[6] Importantly, different children and adolescents are affected by social media in different ways, based on their individual strengths and vulnerabilities, and based on cultural, historical, and socio-economic factors.[7, 8] There is broad agreement among the scientific community that social media has the potential to both benefit and harm children and adolescents.[6, 9]

Brain development is a critical factor to consider when assessing the risk for harm. Adolescents, ages 10 to 19, are undergoing a highly sensitive period of brain development.[10, 11] This is a period when risk-taking behaviors reach their peak, when well-being experiences the greatest fluctuations, and when mental health challenges such as depression typically emerge.[12, 13, 14] Furthermore, in early adolescence, when identities and sense of self-worth are forming, brain development is especially susceptible to social pressures, peer opinions, and peer comparison.[11, 13] Frequent social media use may be associated with distinct changes in the developing brain in the amygdala (important for emotional learning and behavior) and the prefrontal cortex (important for impulse control, emotional regulation, and moderating social behavior), and could increase sensitivity to social rewards and punishments.[15, 16] As such, adolescents may experience heightened emotional sensitivity to the communicative and interactive nature of social media.[16] Adolescent social media use is predictive of a subsequent decrease in life satisfaction for certain developmental stages including for girls 11–13 years old and boys 14–15 years old.[17] Because adolescence is a vulnerable period of brain development, social media exposure during this period warrants additional scrutiny.

## The Potential Benefits of Social Media Use Among Children and Adolescents

Social media can provide benefits for some youth by providing positive community and connection with others who share identities, abilities, and interests. It can provide

access to important information and create a space for self-expression.[9] The ability to form and maintain friendships online and develop social connections are among the positive effects of social media use for youth.[18, 19] These relationships can afford opportunities to have positive interactions with more diverse peer groups than are available to them offline and can provide important social support to youth.[18] The buffering effects against stress that online social support from peers may provide can be especially important for youth who are often marginalized, including racial, ethnic, and sexual and gender minorities.[20, 21, 22] For example, studies have shown that social media may support the mental health and well-being of lesbian, gay, bisexual, asexual, transgender, queer, intersex and other youths by enabling peer connection, identity development and management, and social support.[23] Seven out of ten adolescent girls of color report encountering positive or identity-affirming content related to race across social media platforms.[24] A majority of adolescents report that social media helps them feel more accepted (58%), like they have people who can support them through tough times (67%), like they have a place to show their creative side (71%), and more connected to what's going on in their friends' lives (80%).[25] In addition, research suggests that social media-based and other digitally-based mental health interventions may also be helpful for some children and adolescents by promoting help-seeking behaviors and serving as a gateway to initiating mental health care.[8, 26, 27, 28, 29]

**The Potential Harms of Social Media Use Among Children and Adolescents**

Over the last decade, evidence has emerged identifying reasons for concern about the potential negative impact of social media on children and adolescents.

A longitudinal cohort study of U.S. adolescents aged 12–15 (n=6,595) that adjusted for baseline mental health status found that adolescents who spent more than 3 hours per day on social media faced double the risk of experiencing poor mental health outcomes including symptoms of depression and anxiety.[30]

As of 2021, 8th and 10th graders now spend an average of 3.5 hours per day on social media.[31] In a unique natural experiment that leveraged the staggered introduction of a social media platform across U.S. colleges, the roll-out of the platform was associated with an increase in depression (9% over baseline) and anxiety (12% over baseline) among college-aged youth (n = 359,827 observations).[32] The study's co-author also noted that when applied across the entirety of the U.S. college population, the introduction of the social media platform may have contributed to more than 300,000 new cases of depression.[32, 33] If such sizable effects occurred in college-aged youth, these findings raise serious concerns about the risk of harm from social media exposure for children and adolescents who are at a more vulnerable stage of brain development.

Limits on the use of social media have resulted in mental health benefits for young adults and adults. A small, randomized controlled trial in college-aged youth found that limiting social media use to 30 minutes daily over three weeks led to significant improvements in depression severity.[34] This effect was particularly large for those with

high baseline levels of depression who saw an improvement in depression scores by more than 35%.[35] Another randomized controlled trial among young adults and adults found that deactivation of a social media platform for four weeks improved subjective well-being (i.e., self-reported happiness, life satisfaction, depression, and anxiety) by about 25–40% of the effect of psychological interventions like self-help therapy, group training, and individual therapy.[36]

In addition to these recent studies, correlational research on associations between social media use and mental health has indicated reason for concern and further investigation. These studies point to a higher relative concern of harm in adolescent girls and those already experiencing poor mental health,[37, 38, 39] as well as for particular health outcomes like cyberbullying-related depression,[40] body image and disordered eating behaviors,[41] and poor sleep quality linked to social media use.[42] For example, a study conducted among 14-year-olds (n = 10,904) found that greater social media use predicted poor sleep, online harassment, poor body image, low self-esteem, and higher depressive symptom scores with a larger association for girls than boys.[43] A majority of parents of adolescents say they are somewhat, very, or extremely worried that their child's use of social media could lead to problems with anxiety or depression (53%), lower self-esteem (54%), being harassed or bullied by others (54%), feeling pressured to act a certain way (59%), and exposure to explicit content (71%).[44]

## What Drives Mental Health and Well-Being Concerns: A Snapshot of the Scientific Evidence

Scientific evidence suggests that harmful content exposure as well as excessive and problematic social media use are primary areas for concern.

Go to:

### Potential Risk of Harm from Content Exposure

Extreme, inappropriate, and harmful content continues to be easily and widely accessible by children and adolescents. This can be spread through direct pushes, unwanted content exchanges, and algorithmic designs. In certain tragic cases, childhood deaths have been linked to suicide- and self-harm-related content and risk-taking challenges on social media platforms.[45, 46] This content may be especially risky for children and adolescents who are already experiencing mental health difficulties.[47] Despite social media providing a sense of community for some, a systematic review of more than two dozen studies found that some social media platforms show live depictions of self-harm acts like partial asphyxiation, leading to seizures, and cutting, leading to significant bleeding.[48] Further, these studies found that discussing or showing this content can normalize such behaviors, including through the formation of suicide pacts and posting of self-harm models for others to follow.

Social media may also perpetuate body dissatisfaction, disordered eating behaviors, social comparison, and low self-esteem, especially among adolescent girls.[49, 50, 51, 52] A synthesis of 20 studies demonstrated a significant relationship between social media use and body image concerns and eating disorders, with social comparison as a potential contributing factor.[41] Social comparison driven by social media is associated with body dissatisfaction, disordered eating, and depressive symptoms.[53, 54, 55, 56] When asked about the impact of social media on their body image, nearly half (46%) of adolescents aged 13–17 said social media makes them feel worse, 40% said it makes them feel neither better nor worse, and only 14% said it makes them feel better.[57]

Additionally, roughly two-thirds (64%) of adolescents are “often” or “sometimes” exposed to hate-based content.[58] Among adolescent girls of color, one-third or more report exposure to racist content or language on social media platforms at least monthly.[24] In a review of 36 studies, a consistent relationship was found between cyberbullying via social media and depression among children and adolescents,[40] with adolescent females and sexual minority youth more likely to report experiencing incidents of cyberbullying.[59, 60] Nearly 75% of adolescents say social media sites are only doing a fair to poor job of addressing online harassment and cyberbullying.[61]

In addition, social media platforms can be sites for predatory behaviors and interactions with malicious actors who target children and adolescents (e.g., adults seeking to sexually exploit children, to financially extort them through the threat or actual distribution of intimate images, or to sell illicitly manufactured fentanyl).[62, 63, 64] Adolescent girls and transgender youth are disproportionately impacted by online harassment and abuse, which is associated with negative emotional impacts (e.g., feeling sad, anxious or worried).[65, 66] Nearly 6-in-10 adolescent girls say they’ve been contacted by a stranger on certain social media platforms in ways that make them feel uncomfortable.[24]

Go to:

**Potential Risk of Harm from Excessive and Problematic Use**

Excessive and problematic use of social media can harm children and adolescents by disrupting important healthy behaviors. Social media platforms are often designed to maximize user engagement, which has the potential to encourage excessive use and behavioral dysregulation.[67, 68, 69, 70] Push notifications, autoplay, infinite scroll, quantifying and displaying popularity (i.e., ‘likes’), and algorithms that leverage user data to serve content recommendations are some examples of these features that maximize engagement. According to one recent model, nearly a third (31%) of social media use may be attributable to self-control challenges magnified by habit formation.[71] Further, some researchers believe that social media exposure can overstimulate the reward center in the brain and, when the stimulation becomes excessive, can trigger pathways comparable to addiction.[68, 72] Small studies have shown that people with frequent and problematic social media use can experience

changes in brain structure similar to changes seen in individuals with substance use or gambling addictions.[73, 74] In a nationally representative survey of girls aged 11–15, one-third or more say they feel “addicted” to a social media platform.[24] Over half of teenagers report that it would be hard to give up social media.[2] Nearly 3-in-4 teenagers believe that technology companies manipulate users to spend more time on their devices.[68] In addition, according to a survey of 8th and 10th graders, the average time spent on social media is 3.5 hours per day, 1-in-4 spend 5+ hours per day and 1-in-7 spend 7+ hours per day on social media.[31]

Excessive and problematic social media use, such as compulsive or uncontrollable use, has been linked to sleep problems, attention problems, and feelings of exclusion among adolescents.[43, 75, 76, 77] Sleep is essential for the healthy development of adolescents. A systematic review of 42 studies on the effects of excessive social media use found a consistent relationship between social media use and poor sleep quality, reduced sleep duration, sleep difficulties, and depression among youth.[42] Poor sleep has been linked to altered neurological development in adolescent brains, depressive symptoms, and suicidal thoughts and behaviors.[78, 79, 80] On a typical weekday, nearly 1-in-3 adolescents report using screen media until midnight or later.[58] While screen media use encompasses various digital activities, social media applications are the most commonly used applications by adolescents.[58]

In a recent narrative review of multiple studies, problematic social media use has also been linked to both self-reported and diagnosed attention-deficit/hyperactivity disorder (ADHD) in adolescents, although more research is necessary to understand whether one causes the other.[81] A longitudinal prospective study of adolescents without ADHD symptoms at the beginning of the study found that, over a 2-year follow-up, high-frequency use of digital media, with social media as one of the most common activities, was associated with a modest yet statistically significant increased odds of developing ADHD symptoms (OR 1.10; 95% CI, 1.05-1.15).[82] Additionally, social media-induced fear of missing out, or “the pervasive apprehension that others might be having rewarding experiences from which one is absent,”[83] has been associated with depression, anxiety, and neuroticism.[84]

### Critical Questions Remain Unanswered

Nearly every teenager in America uses social media, and yet we do not have enough evidence to conclude that it is sufficiently safe for them. Our children have become unknowing participants in a decades-long experiment. It is critical that independent researchers and technology companies work together to rapidly advance our understanding of the impact of social media on children and adolescents. This section describes the known gaps and proposes additional areas for research that warrant urgent consideration.

## Known Evidence Gaps

The relationship between social media and youth mental health is complex and potentially bidirectional.[19] There is broad concern among the scientific community that a lack of access to data and lack of transparency from technology companies have been barriers to understanding the full scope and scale of the impact of social media on mental health and well-being. Most prior research to date has been correlational, focused on young adults or adults, and generated a range of results.[85] Critical areas of research have been proposed to fill knowledge gaps and create evidence-based interventions, resources, and tools to support youth mental health.[86] Thus, there is an urgent need for additional research including on, but not limited to, the following questions:

- How do in-person vs. digital social interactions differ in terms of the impact on health, and what are the unique contributions of social media behavior to social connectedness, social isolation, and mental health symptoms?
- What are the potential pathways through which social media may cause harm to children's and adolescents' mental health and well-being? For example:

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How does social comparison affect one's sense of life satisfaction and in-person relationships?

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How does the use of social media, including specific designs and features, relate to dopamine pathways involved in motivation, reward, and addiction?

- What type of content, and at what frequency and intensity, generates the most harm? Through which modes of social media access (e.g., smartphone, computer) and design features? For which users and why?
- What are the beneficial effects of social media? For whom are the benefits greatest? In what ways, and under what circumstances?
- What individual-, community-, and societal-level factors may protect youth from the negative effects of social media?
- What types of strategies and approaches are effective in protecting the mental health and well-being of children and adolescents on social media (e.g., programs, policies, design features, interventions, norms)?
- How does social media use interact with a person's developmental stage for measuring risk of mental health impact?

It is critical that independent researchers and technology companies work together to rapidly advance our understanding of the impact of social media on children and adolescents.

### We Must Take Action: A Way Forward

Our children and adolescents don't have the luxury of waiting years until we know the full extent of social media's impact. Their childhoods and development are happening now. While social media use can have positive impacts for some children, the evidence noted throughout this Surgeon General's Advisory necessitates significant concern with the way it is currently designed, deployed, and utilized. Child and adolescent use of platforms designed for adults places them at high risk of "unsupervised, developmentally inappropriate, and potentially harmful" use according to the National Scientific Council on Adolescence.[87] At a moment when we are experiencing a national youth mental health crisis, now is the time to act swiftly and decisively to protect children and adolescents from risk of harm.

To date, the burden of protecting youth has fallen predominantly on children, adolescents, and their families. Parents face significant challenges in managing children and adolescents' use of social media applications, and youth are using social media at increasingly earlier ages.[4, 88] Nearly 70% of parents say parenting is now more difficult than it was 20 years ago, with technology and social media as the top two cited reasons.[89] While nearly all parents believe they have a responsibility to protect their children from inappropriate content online,[89] the entire burden of mitigating the risk of harm of social media cannot be placed on the shoulders of children and parents. Nearly 80% of parents believe technology companies have a responsibility to protect children from inappropriate content as well.[89]

We must provide children and their families with the information and tools to navigate the changing digital environment, but this burden to support our children must be further shared. There are actions technology companies can take to make their platforms safer for children and adolescents. There are actions researchers can take to develop the necessary research base to support further safeguards. And there is a role for local, state, and federal policy to implement protections for our children and adolescents.

The U.S. has a strong history of taking action in such circumstances. In the case of toys, transportation, and medications—among other sectors that have widespread adoption and impact on children—the U.S. has often adopted a safety-first approach to mitigate the risk of harm to consumers. According to this principle, a basic threshold for safety must be met, and until safety is demonstrated with rigorous evidence and independent evaluation, protections are put in place to minimize the risk of harm from products, services, or goods. For example, the Consumer Product Safety Commission requires toy manufacturers to undergo third-party testing and be certified through a

Children's Product Certificate as compliant with the federal toy safety standard for toys intended for use by children.[90] To reduce the risk of injury from motor vehicle accidents, the National Highway Traffic Safety Administration requires manufacturers to fit new motor vehicles with standard airbags and seat belts, among other safety features, and conduct crash tests to be compliant with the Federal Motor Vehicle Safety Standards.[91] Medications must demonstrate safety to the Food and Drug Administration before being made available and marketed for use.[92] Given the mounting evidence for the risk of harm to some children and adolescents from social media use, a safety-first approach should be applied in the context of social media products.

To better safeguard the mental health and well-being of children and adolescents, policymakers, technology companies, researchers, families, and young people must all engage in a proactive and multifaceted approach. Through the recommendations below, we can provide more resources and tools to children and families, we can gain a better understanding of the full impact of social media, and we can maximize the benefits and minimize the harms of social media platforms to create safer, healthier online environments for children.

We can maximize the benefits and minimize the harms of social media platforms to create safer, healthier online environments for children.

Go to:

**What Policymakers Can Do**

Policymakers play an important role in addressing the complex and multifaceted issues related to social media use and in protecting youth from harm.

- **Strengthen protections to ensure greater safety for children interacting with all social media platforms**, in collaboration with governments, academic organizations, public health experts, and technology companies.

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**Develop age-appropriate health and safety standards** for technology platforms. Such standards may include designing technology that is appropriate and safe for a child's developmental stage; protecting children and adolescents from accessing harmful content (e.g., content that encourages eating disorders, violence, substance abuse, sexual exploitation, and suicide or discusses suicide means); limiting the use of features that attempt to maximize time, attention, and engagement; developing tools that protect activities that are essential for healthy development like sleep; and regularly assessing and mitigating risks to children and adolescents.

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**Require a higher standard of data privacy for children** to protect them from potential harms like exploitation and abuse. Six-in-ten adolescents say they think they have little

or no control over the personal information that social media companies collect about them.[32]

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**Pursue policies that further limit access—in ways that minimize the risk of harm—to social media for all children**, including strengthening and enforcing age minimums.

- **Ensure technology companies share data relevant to the health impact of their platforms** with independent researchers and the public in a manner that is timely, sufficiently detailed, and protects privacy.
- **Support the development, implementation, and evaluation of digital and media literacy curricula in schools and within academic standards.** Digital and media literacy provides children and educators with digital skills to strengthen digital resilience, or the ability to recognize, manage, and recover from online risks (e.g., cyberbullying and other forms of online harassment and abuse, as well as excessive social media use).
- **Support increased funding for future research** on both the benefits and harms of social media use and other technology and digital media use for children, adolescents, and families.
- **Engage with international partners** working to protect children and adolescents against online harm to their health and safety.

Go to:

**What Technology Companies Can Do**

Technology companies play a central role and have a fundamental responsibility in designing safe online environments and in preventing, minimizing, and addressing the risks associated with social media.

- **Conduct and facilitate transparent and independent assessments of the impact of social media products and services on children and adolescents.** Assume responsibility for the impact of products on different subgroups and ages of children and adolescents, regardless of the intent behind them.

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**Be transparent and share assessment findings and underlying data** with independent researchers and the public in a privacy protecting manner.

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**Assess the potential risks of online interactions and take active steps to prevent potential misuse,** reducing exposure to harms. When proactive responses fail, take immediate action to mitigate unintended negative effects.

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**Establish scientific advisory committees to inform approaches and policies** aimed at creating safe online environments for children. Scientific advisory committees should be comprised of independent experts and members of user subgroups, including youth.

- **Prioritize user health and safety in the design and development of social media products and services.**[93, 94, 95, 96] Prioritize and leverage expertise in developmental psychology and user mental health and well-being in product teams to minimize risks of harm to children and adolescents.

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**Ensure default settings for children are set to highest safety and privacy standards**. Provide easy-to-read and highly visible information about policies regarding use by children.

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**Adhere to and enforce age minimums** in ways that respect the privacy of youth users.

- **Design, develop, and evaluate platforms, products, and tools that foster safe and healthy online environments for youth,** keeping in mind the needs of girls, racial, ethnic, and sexual and gender minorities. The platform design and algorithms should prioritize health and safety as the first principle, seek to maximize the potential benefits, and avoid design features that attempt to maximize time, attention, and engagement.
- **Share data relevant to the health impact of platforms and strategies employed to ensure safety and well-being** with independent researchers and the public in a manner that is timely and protects privacy.
- **Create effective and timely systems and processes to adjudicate requests and complaints from young people, families, educators, and others** to address online abuse, harmful content and interactions, and other threats to children's health and safety. Social media platforms should take these complaints seriously, thoroughly investigate and consider them, and respond in a timely and transparent manner.

Go to:

**What Parents and Caregivers Can Do**

The onus of mitigating the potential harms of social media should not be placed solely on the shoulders of parents and caregivers, but there are steps they can take to help protect and support children and adolescents against the risk of harm.

- **Create a family media plan.**[97] Agreed-upon expectations can help establish healthy technology boundaries at home – including social media use. A family media plan can promote open family discussion and rules about media use and include topics such as balancing screen/online time, content boundaries, and not disclosing personal information. For information on creating a family media plan, visit www.healthychildren.org/MediaUsePlan.
- **Create tech-free zones and encourage children to foster in-person friendships.**[98] Since electronics can be a potential distraction after bedtime and can interfere with sleep, consider restricting the use of phones, tablets, and computers for at least 1 hour before bedtime and through the night. Consider keeping family mealtimes and in-person gatherings device-free to build social bonds and engage in a two-way conversation. Help your child develop social skills and nurture his or her in-person relationships by encouraging unstructured and offline connections with others and making unplugged interactions a daily priority. See the American Academy of Pediatrics (AAP) guidelines for media use.
- **Model responsible social media behavior.** As children often learn behaviors and habits from what they see around them, try to model the behavior you want to see.[97, 99] Parents can set a good example of what responsible and healthy social media use looks like by limiting their own use, being mindful of social media habits (including when and how parents share information or content about their child), and modeling positive behavior on your social media accounts.
- **Teach kids about technology and empower them to be responsible online participants at the appropriate age.**[100] Discuss with children the benefits and risks of social media as well as the importance of respecting privacy and protecting personal information in age-appropriate ways. Have conversations with children about who they are connecting with, their privacy settings, their online experiences, and how they are spending their time online. Empower and encourage them to seek help should they need it. Learn more about the benefits and risks of social media use and get guidance from experts at AAP's Center of Excellence on Social Media and Youth Mental Health and from the American Psychological Association's Health Advisory on Social Media Use in Adolescence.
- **Report cyberbullying and online abuse and exploitation.** Talk to your child about their reporting options, and provide support, without judgment, if he or she tells or shows you that they (a) are being harassed through email, text message, online games, or social media or (b) have been contacted by an adult seeking

private images or asking them to perform intimate or sexual acts. You or your child can report cyberbullying to the school and/or the online platform, or your local law enforcement.[101] Visit CyberTipline, Take it Down, or contact your local law enforcement to report any instances of online exploitation.

- **Work with other parents to help establish shared norms and practices and to support programs and policies around healthy social media use.** Such norms and practices among parents facilitate collective action and can make it easier to set and implement boundaries on social media use for children.

Go to:

### What Children and Adolescents Can Do

The burden of mitigating the potential harms of social media does not rest solely on the shoulders of children and adolescents, but there are measures they can take to navigate social media in a safe and healthy way.

- **Reach out for help.** If you or someone you know is being negatively affected by social media, reach out to a trusted friend or adult for help. For information from experts, visit AAP's Center of Excellence on Social Media and Youth Mental Health. If you or someone you know is experiencing a mental health crisis, contact the 988 Suicide and Crisis Lifeline by calling or texting 988 for immediate help.
- **Create boundaries to help balance online and offline activities.** Limit the use of phones, tablets, and computers for at least 1 hour before bedtime and through the night to enable sufficient and quality sleep. Keep mealtimes and in-person gatherings device-free to help build social bonds and engage in two-way conversations with others. Nurture your in-person relationships by connecting with others and making unplugged interactions a daily priority.
- **Develop protective strategies and healthy practices** such as tracking the amount of time you spend online, blocking unwanted contacts and content, learning about and using available privacy and safety settings, learning and utilizing digital media literacy skills to help tell the difference between fact and opinion, and ensuring you are connecting with peers in-person. See this Tip Sheet on Social Media Use and Mental Health for healthy social media use created for and by young people.
- **Be cautious about what you share.** Personal information about you has value. Be selective with what you post and share online and with whom, as it is often public and can be stored permanently. If you aren't sure if you should post something, it's usually best if you don't. Talk to a family member or trusted adult to see if you should.

- **Protect yourself and others.** Harassment that happens in email, text messaging, direct messaging, online games, or on social media is harmful and can be cyberbullying. It might involve trolling, rumors, or photos passed around for others to see – and it can leave people feeling angry, sad, ashamed, or hurt. If you or someone you know is the victim of cyberbullying or other forms of online harassment and abuse:

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**Don't keep online harassment or abuse a secret.** Reach out to at least one person you trust, such as a close friend, family member, counselor, or teacher, who can give you the help and support you deserve. Visit stopbullying.gov for helpful tips on how to report cyberbullying. If you have experienced online harassment and abuse by a dating partner, contact an expert at Love is Respect for support or if your private images have been taken and shared online without your permission, visit Take it Down to help get them removed.

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**Don't take part in online harassment or abuse.** Avoid forwarding or sharing messages or images and tell others to stop. Another way is to report offensive content to the site or network where you saw it.

Go to:

**What Researchers Can Do**

Researchers play a critical role in helping to gain a better understanding of the full impact of social media on mental health and well-being and informing policy, best practices, and effective interventions.

- **Establish the impact of social media on youth mental health as a research priority and develop a shared research agenda.**[102] Research should include but not be limited to:

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**Rigorous evaluation of social media's impact** on youth mental health and well-being, including longitudinal and experimental studies. This could also include research on specific outcomes and clinical diagnoses (e.g., sleep duration and quality, attention, depression, anxiety, and body image), among specific populations (e.g., racial, ethnic, and sexual and gender minorities), and based on specific aspects of social media (e.g., designs, features, and algorithms).

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**Role of age, developmental stage, cohort processes, and the in-person environment** in influencing the onset and progression of poor mental health outcomes among social media users.

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**Benefits and risks associated** with specific social media designs, features, and content.

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**Long-term effects on adults** of social media use during childhood and adolescence.

- **Develop and establish standardized definitions and measures** for social media and mental health outcomes that are regularly evaluated and can be applied across basic research, population surveillance, intervention evaluation, and other contexts.
- **Evaluate best practices for healthy social media use** in collaboration with experts including healthcare providers, parents, and youth.[94, 103, 104]
- **Enhance research coordination and collaboration.** Example opportunities include developing an accessible evidence database and forming a consortium of researchers focused on examining the positive and negative effects of social media on mental health and well-being. Researchers should work with community partners to make research findings publicly accessible and digestible.

All notes and references available under Endnotes at https://www.ncbi.nlm.nih.gov/books/NBK594762/

## Consumer Engagement, Education and Broker Services

In the conclusion to this text, we'll attempt to combine many of the themes and issues we have discussed. We'll do this around the notion of consumer engagement.

Brokers and other insurance professionals use terms like 'consumer engagement' and 'informed consumer' in two very different – and sometimes opposing – ways. This can create confusion among subscribers and patients, and even among brokers themselves.

To *risk management professionals* – and the medical community - 'informed consumer' means someone who understands treatment options, risks, benefits and trade-offs. An informed consumer - to risk management folks, for example - might prefer a treatment that *differs* from the one recommended by his/her physician.

A case-in-point: an oncologist might recommend a mastectomy for a woman with early stage breast cancer, based on *his* analysis of the risk-reward tradeoffs. Meanwhile the patient might prefer to watch-and-wait before operating based on *her* analysis. Both analyses may be factually correct, but the doctor and patient value the risks and rewards differently.

An informed consumer, from the risk management or medical point-of-view, thus takes an active role his/her own *medical decision making* and is able to make wise medical care decisions.

To *compliance oriented insurance professionals,* 'informed consumer' means a subscriber who understands the component parts of the health insurance policy and the associated regulations about how to use it.

An informed insurance consumer - to the compliance professional, for example - might prefer to compliment a Health Savings Account with a Flexible Spending Account rather than a Health Reimbursement Account, based on some set of specific medical spending habits and needs. Or the informed insurance consumer might prefer a lower-cost policy that pays for medical services on a reference-based model rather than a higher-cost plan that pays everything over the deductible.

This type of informed consumer is one able to make wise *coverage choices* and use the insurance policy most effectively.

This interview highlights these two different definitions of 'informed consumer'. It occurred in 2012 but remains relevant in our current health insurance environment. One specific note though: the 33% waste factor discussed here in 2012 was an overall, somewhat gross estimate. Some commentators continue to think that waste amount remains approximately valid today. Others, using different definitions of 'unnecessary care', have lower estimates. My own take-away: whatever the exact number, it's a lot of care, a lot of money and a lot of unnecessary patient risk.

The unnamed interviewer – a health insurance broker - articulates the *compliance definition*. He wants to help insurance customers understand policy provisions and tax implications so they can use their policies most effectively.

The interviewer initially wants to leave the consumer alone to decide which medical care is necessary and which providers appropriate; he doesn't, initially, adopt the risk manager perspective. He suggests that the traditional broker advisory responsibility ends when the consumer understands policy provisions.

Meanwhile the responder Gary Fradin – a.k.a. me - uses the *risk manager's - or medical – definition* of informed and engaged consumer. I suggest that consumers who are well informed about medical care options will make better choices for themselves, meaning better outcomes at lower costs.

I also suggest that the process of becoming a 'well informed medical consumer' is one that can be taught and learned, though admittedly, it rarely is today. My comments focus on the types of education one needs to become well informed about medical purchasing and suggest that choosing care based on medical quality metrics generally results is lower total care costs, and probably lower insurance costs too.

The savings available from making informed *medical* choices, I suggest, likely exceed the savings available from making informed *insurance* choices.

I wonder who in our medical care system can teach consumers to become well informed about medical care. Doctors? Hospitals? Carriers? Brokers? Or some other entity.

As you read this interview, ask yourself if either definition of 'well informed' is *sufficient* in our evolving healthcare system and market…or if we need to combine *both*.

The interviewer ultimately suggests that wise and innovative brokers will need to combine both definitions of informed and engaged consumers in order to maintain their advisory role. You can sense his discomfort – and also his excitement – about exactly how to do this.

Do you agree? Do you think he's being too aggressive, defining the broker's future roll too expansively? Or do you think he's being too conservative by not defining the broker's role expansively enough?

**Transcript**

**Interviewer:** This morning we're going to spend some time talking about consumer engagement. What does it mean? What is it? So welcome Gary.

As I take a look back in time and think about the notion of Consumer Engagement and Consumer Driven Health Plans, I keep wonder 'what is it'? Ten years ago we saw the introduction of annual deductibles, high deductible health plans sometimes called CDHC or Consumer Driven Healthcare, I think that was the introduction of consumerism

in healthcare. The challenge was the lack of data, the lack of information and so forth. So Gary, in your mind, what is consumer engagement?

**Gary Fradin:** Great question. You started off with a hard one.

I think consumer engagement means helping healthcare consumers – patients – make medical decisions the same way they would make car-buying decisions, or refrigerator-buying decisions. Use the same types of criteria, ask the same types of questions and bring all the skills that we have developed as a society that make us great consumers to medical care. I think we'll have tremendous benefits, both for the patients and for healthcare costs.

So I'd say consumerism in medical care means the same thing as consumerism in automobiles and other products.

**Interviewer:** And in automobiles, for those of us buying a new car, you can go online, you can research, you can find out what a dealer paid for the car, the mark-up and all of that.

I think the challenge that we've had in healthcare historically is the lack of information, the costs and quality. So let's talk a little bit about that. What you say seems to be straight-forward, seems to make sense to me in the role that I play as a benefits advisor to companies.

Why is there such a challenge to make it happen? What are the barriers to entry to consumer engagement when it comes to this type of consumerism?

**GF:** Barriers to entry. Tough question.

There are probably lots of barriers to entry. The one that strikes me as most significant is the fact that we have relatively lousy outcome data about medical care. We simply don't know what works well, what works badly, and exactly *how well* it works.

It's like buying a car if you don't know the miles per gallon. Maybe we can get some pricing information. But if a car dealer tells you a car gets good gas mileage, does this mean 16 miles per gallon or 41?

In medical care, we hear things like 'that's a risk factor for having a heart attack' or 'that's a risk factor for cancer' and this is a good treatment. Well…*how much* of a risk factor, *how good* of a treatment and how will it affect *me*? Those are questions that we're increasingly starting to focus on and we're developing some data to help us get those answers.

**Int:** What's interesting in the role that I play with clients is that consumer engagement really plays out around product design. The various health insurance carriers have created over the past several years, new products designed to engage the consumer. Deductibles, co-insurance and things of that nature. We have products today designed

to get consumers to make decisions, to learn where providers fall within certain tiers for example, limited networks.

So from a product standpoint there's this notion of consumer engagement, working with employers and employees to understand product.

From your perspective and the topic that we really want to get into today, beyond insurance products, beyond 'where do I go, what hospital is in-network', you're talking about consumer engagement at the physician level, at the choice level, is there an overabundance of prescriptions, of unnecessary medical care. Let's talk a little bit about that from your perspective.

**GF:** Let me make a couple points because you're raising critical issues here.

One is that researchers estimate, based on lots and lots of medical studies, that we waste up to about 1/3 of all medical spending on unnecessary medical care. That's care that can't help you – because it's unnecessary – but costs you money and could potentially actually harm you.

*That estimate hasn't changed much despite plan design changes.* We still waste up to about a third.

My comment about plan design changes is that carriers and regulators have tried to organize our healthcare delivery system to become more efficient and cut down on unnecessary care through iteration after iteration after iteration over the past over the past 20 or 30 years, and we have always seen healthcare inflation running about double CPI (the Consumer Price Index inflation rate) or about double the GDP growth rate. We haven't seen that fall significantly despite plan design changes.

I don't think this is a regulatory issue – reducing unnecessary care – and I don't think it's a plan design issue, although high deductibles seem to have some impact. I think the way to reduce unnecessary spending is to educate consumers, educate patients and show why it's in their interest not to get unnecessary care. It doesn't benefit them – it might hurt them.

**Int:** Let's talk about that a little bit. My firm provides advice and guidance to clients. We do it at the employer level and at the employee level. We have benefit communication meetings and so forth. From your perspective, what are the tools and resources available? What tools exist to engage consumers outside of products, outside of plan designs?

**GF:** I think that those tools are being developed. We're starting to get the relevant data about quality so people can make medical decisions based on care quality, not necessarily price.

Nobody wants to get bad quality care. Forget price for a moment. I have yet to hear a parent say 'times are tough, we're cutting back on medical care quality for our kids'. I've

never heard that. I always hear parents say ‘I don’t care what it costs, I want my kid to get the best care he or she can get.’

One tool that we’ve been working on a lot is called the Number Needed to Treat. Teaching consumers to ask their doctor ‘what’s the Number Needed to Treat with this medication, this medicine or this screening test?’ NNT simply tells you how many people have to have a medical procedure or take a medication in order for 1 person to benefit.

**Int:** Can you give an example.

**GF:** Sure, I can tell you about cholesterol lowering medications. Lots of people think that high cholesterol leads to heart attacks.

Studies have suggested that people with high cholesterol – using all kinds of different definitions of ‘high’ cholesterol, these are generally industry funded studies with, presumably, highly selected data so the numbers may well be skewed – suggest that about 3 people out of 100 with high cholesterol will have a heart attack in the next 5 or so years.[15] Roughly, approximately 3 out of 100. Some studies show somewhat higher rates. These are folks who don’t have heart disease.

If you reduce your cholesterol with a statin, you bring that number from about 3 having a heart attack out of 100 to about 2 having a heart attack out of 100. Again, industry funded studies.

In other words, you have to give 100 people a statin for about 5 years to prevent 1 heart attack. The Number Needed to Treat is about 100.

Let me make 2 points going in 2 different directions here. Some commentators have suggested that insurance not pay for interventions that have a Number Needed to Treat greater than 20. An NNT of 20 means that only 5% of people benefit. So if you learn the Number Needed to Treat, you can learn how efficient or how effective this medical intervention is, so you can choose.

The sister, or cousin if you will, of Number Needed to Treat is Number Needed to Harm.

**Int:** NNH?

**GF:** Yes, NNH. Obviously that tells you how many people have to take the medication for 1 person to be harmed.

Let me tie all this together and suggest that knowing the Number Needed to Treat and Number Needed to Harm is basic medical literacy. If you don’t know these numbers and you can’t discuss them, then you’re medically illiterate. It’s sort of like an accountant

[15] This specific estimate comes from number in an ad that ran in several newspapers in the 2004 – 2007 time frame.

saying ‘you made money, but I don’t know what your earnings per share were, or exactly how much you made’.

**Int:** So is your expectation that individual consumers should know their own NNT and NNH information and should know these facts and be able to go into a physician and discuss them?

I guess I’ll use myself as an example. I happen to have had, 2 days ago, my annual physical. I went in and had my 12 minutes with my doctor and part of the discussion was, ironically, around cholesterol. There have been a lot of articles about cholesterol and statins and the danger of them.

I thought I was being a good consumer, I thought I was engaging by simply asking my doctor and challenging the notion of whether or not I should remain on a statin. And my doctor’s comment to me was that the belief still is that the rewards of being on a statin outweigh the risks.

My doctor went on to say ‘if it’s of any help, I too am on a statin and have been, so I would not be prescribing something to you that I myself am actually not engaged in taking.’

From my standpoint as someone who is in this industry and do what I do, I felt that I had become a better consumer, that I engaged in the process more by asking questions and actually challenging the notion of remaining on this, asking about the risks and rewards. I’m not sure that many people take the step that I took.

But I get the sense from our discussion certainly that there’s more to do, more questions to ask and that I should be armed with NNTs and NNHs and so forth. Is that true?

**GF:** I think so.

First, let me make one point very strongly: if you’re comfortable with your doctor, do what your doctor says. I in no way want to make people uncomfortable. That is dysfunctional all the way through.

But I hesitate to rely very much on your doctor’s story about himself. Your doctor may have different risk tolerances from you. He may have different orientations. Different family background and genetics. He may or may not exercise the same as you. He may have all kinds of different risk factors. And his decision criteria may not be the same as yours.

To some extent, and I don’t want to belittle doctors, I’m not trying to do that, but to some extent this is like when you buy a used car and you go to a dealer with lots and lots of high quality used cars. You look at a Ford Taurus. The salesman says ‘well, I drive a Ford Taurus’ suggesting a personal endorsement for how good this car is. OK, but I don’t know how he made his decision. Does he drive young kids around? Does he schlep hockey equipment? Is his wife a baker and he makes deliveries for her? Did he

get a particularly good deal on a used Taurus, when, perhaps, he would have preferred a Honda Civic? I don't know how he made his decision.

And I don't know how your doctor made his statin decision. Lots of studies suggest that when patients are well informed about their treatment options, they often choose differently from their doctors. That's why I think you have to know what the outcome numbers are.

Remember, doctors learn how to calculate the Number Needed to Treat and Number Needed to Harm in medical school. But they don't talk to patients about it because they figure that in 12 minutes, they don't have time to teach this to a patient.

But if you go in and ask the question, and say 'I will take a medication that you prescribe, but I want to know the NNT, I want to know the Number Needed to Treat so I know how well it works. In fact, I want to know the Number Needed to Treat for 2 or 3 different options, and then I want to choose the best. And I don't want to take a medication if you don't know how well it's going to work for me.' That's how I would like to see consumers engage with their doctors.

**Int:** And I like it. I truly do. The question is how to get consumers to be able to take that step, to have the comfort and the confidence to be able to challenge their physician, question their physician – and I don't mean that in a negative or derogatory sense – but to give them the comfort and the confidence.

**GF:** Yes. Let me turn this into a question for you. We're in a high deductible world where people try to spend their money 'more wisely'. To do this, somebody has to educate people about *how* to spend their money more wisely.

Where in our healthcare distribution system does that entity lie?

- Is it physicians – you have 12 minutes per year. Is that the right entity?
- Is it the hospital – are they going to teach you which questions to ask about your medical care?
- Is it the insurance carrier? The problem with the carrier is we all know why a carrier would tell you about unnecessary care. They want to save money. Or, at least, that's the cynical public perception.
- Is it the employer, who's probably pretty busy making widgets. They don't have a lot of extra resources to teach about medical care.

Where in our healthcare distribution system – our medical distribution system – is there an entity that can take on the responsibility of doing this teaching so we can reduce the waste factor, besides the broker?

**Int:** I don't think there is, and I think that of all the stakeholders, the various people involved in the process, none others of them have the ability, the bandwidth, the time to do that, and I think you make a very valid point.

It's just an interesting dynamic that for 20 years I've been in the business. We provide advice and guidance and council to employers, more and more to employees, now the notion of wellness which engages a whole different element to all this.

Now all of a sudden, in the role that we play, thinking about education and engagement at a completely different level. To talk about NNTs and NNHs, what questions to ask your provider. It's a completely different way to proceeding, a completely different approach. And at the same time, critically important.

**GF:** Let me ask you a question.

**Int:** Please.

**GF:** You said that at your physical a couple days ago was the first time you pushed back and challenged your doctor. Why? You've had a physical presumably every year for many years. Why now? What happened this year?

**Int:** A little more knowledge, a little more understanding. Certainly the likes of folks like you. News and information is becoming greater. I don't simply want to take the status quo as many of us have done, when the doctor gives a prescription we take it without asking.

I think the notion of statins and harms and long term effects have really resonated with me and have caused me to push back on that particular item.

I think in general, we can all agree that our healthcare system is flawed, at many levels.

You mentioned waste before, 33% waste. Above and beyond all of that, for me to go in once a year for my personal health, and literally have about 12 minutes to ask questions, review data, update personal information and all that to me is challenging and troubling. I need to become my biggest and my own advocate for my own healthcare.

And I think getting back to your original question 'why this year?' I think because more information is available. We are changing and I think there's a dynamic going on in our industry where we need to challenge where we need to be, in the role that we play providing advice and guidance beyond product, beyond solution, beyond all of that to provide advice and guidance at the employee level.

**GF:** I think it's really interesting when you make the point about more information becoming available. That resonates with me. More and more information is becoming available to consumers. I think we run the risk of having information overload. The question is 'what information is really useful?' What information is bogus or biased or not terribly useful? How does a consumer figure that out?

**Int:** That's a complete struggle for me and I'm sure for just about every consumer. What is the right information? If I read the Harvard Business Journal, that's one piece of information. If I read another article, another book…it's very challenging to know what information is accurate. From which stakeholders does this information come and is there any bias or connection back to a provider or manufacturer?

Maybe I can turn this back to a question for you. As a consumer, how do I navigate my way through the various information channels to arrive at what I think is good, solid accurate information so that I can make good, solid, accurate personal choices?

**GF:** I think that's the question that highlights the broker's role.

A broker clearly can't give medical advice. They're not licensed for this. And a broker can't say 'here is a procedure that works and here is a procedure that doesn't work' according to some study. That's not the broker's role.

It seems to me that the broker's future role and the growth of this part of the business is teaching people the questions to ask. If you ask the right question, you have a pretty good chance of getting a good answer. But if you don't ask the right questions, then you may get all kinds of misinformation or confusing information or biased information.

I think we, the industry, needs to simplify the questioning process by teaching people to ask questions about the Number Needed to Treat and Number Needed to Harm.

I guess my feeling is that if brokers can put on consumer engagement programs and courses for their subscribers that help people ask the right questions of their doctors, then we've gone a big step. We've made progress. And Step 2 I can't tell you about yet. I don't know what it is!

**Int:** Going back to your question - when you have all these stakeholders and providers being part of the equation, who is best served to do it – for someone who spent 20 years in this business, I have an initial challenge, internally, to think that I am the one, and my firm is the one, to provide consumer engagement at a level that gets so specific to medical care and so forth.

At the same time, I can see the validity to this and that many of us can't hide behind the notion that consumer engagement is teaching and educating about product and all of the elements that go along with that. It's a challenge. It's a shift in thinking for me.

**GF:** Do you think, as a business owner, you can avoid getting involved in this kind of consumer education?

**Int:** I don't. I truly don't.

The question is when? How quickly? How broad of a spectrum? How deeply? It's a challenge. I say this openly, it's really a shift. It's a mental shift to think of the role that we play and how we will engage the consumer at a completely different level.

At the same time, it's tremendously exciting.

And then beyond all of that, the complexities to everybody. As we sit in the roles that we play as advisors to employers and employees, you have new products – with all sorts of functionality and limitations, with tiers and networks, and the account based elements of HSAs, HRAs and all that. It has become so complicated. My point being that complexities at the product level and at the distribution level are just immense and enormous, and then you fold in another component and layer.

I guess trying to understand it and articulate it, and taking it back to the role that we play, I have to wonder and ask 'how do we do this?' What is the first, best step for us to do it? I guess I'll put that to you. There was a question, or at least a thought of a question in all that.

**GF:** I think it's very thought provoking. I don't have an answer. As you were talking, I was thinking about that famous Chinese curse or blessing 'May you live in interesting times.' Yes, it is tough to navigate the future.

Look, it's always tough to navigate. It's always tough to run a small business. I guess the first step I would say to brokers who want to get into this brave new world is to become familiar with some of these consumer aids, these medical decision making aids, to become familiar with this part of the business, and on a case-by-case basis work it in. I wish I had a better and more complete answer.

**Int:** But I think that your answer is representative of the stage we're at in the development of all this. I truly do.

One of the things that comes to my mind, and I certainly want to garner your perspective on, is this notion of cost and quality. It's at times such a nebulous thing, where many carriers, going back to the product designs, and consumer engagement at the product level, is about cost and quality.

Your thoughts on cost vs. quality, the importance of it. Is cost a real driver and issue or do you believe quality prevails, that someone is going to request and require quality without much notion of cost?

**GF:** I think transparency is clearly both. You have to know price. You don't want to get the same quality for $2000 that you can buy for $600.

But I think that the first step, the driving force, is quality. Everyone wants the best medical care they can get for themselves and their family. One of the reasons that so many people use expensive hospitals is that we equate higher costs with better quality care. Or high credentials with better quality. Or medical school affiliation with better quality. I think people want quality. Then, if you find 2 procedures that have the same NNT and the same outcomes, then sure, go for the least expensive one.

I would warn people against assuming that you can learn something about the care quality from the price, because you can't. A broker once said to me 'this quality information is too complicated. If you assume the quality is all the same, then you can shop based on price'. My response was 'besides that Mrs. Kennedy, how was your trip to Dallas? I heard you had a nice breakfast.'

The ballgame is quality. And price is a secondary consideration. I have yet to meet a person who wants poor medical care, and I have yet to meet someone who wants the cheapest *un*necessary medical care. I only meet people who want good, necessary care.

**Int:** I think you bring up a great point, and the challenge that we see every day is also the waste in care. People don't want bad care, but I think it still goes back to waste. It goes back to that 33% waste factor, it goes back to how the system is currently structured, and I think that is a tremendous challenge. The complexities of the system. Waste continues to be an issue.

But getting back to your NNT, unnecessary care ideas, are these regional? National? International? Is this about how our healthcare is structured here or is it relevant beyond state and even national boundaries?

**GF:** I think all healthcare consumers in all countries have the same questions. I think all parents want good care for their kids, all sick people want good care for themselves, and if you're in a government funded system, a privately funded system, or a mixed system, you as the consumer still have the responsibility for asking the right questions and getting the best care for yourself. So I don't think the structure of the system matters for consumer responsibility and engagement. I think people are all the same – they all want good medical care. No one wants to have unnecessary care that won't help them but might harm them.

Research is currently being done on all these different kinds of metrics all over the world, with researchers having the same fundamental question: how can we identify good, high quality, necessary care as opposed to poor, unnecessary, low quality, wasteful care. Everyone is interested in the same thing.

My guess would be that there will be an explosion of knowledge in this whole quality arena in the next decade or so. The early adopter brokers who start to educate their clients now, start to learn the programs now, start to learn what this is all about now will put themselves in an awfully strong position as all of this evolves to capitalize on it and grow their businesses in the future.

**Int:** I think that's a great point. I think that's something that brokers like me need to be mindful of. We have been, and continue to be moving away from product based sales, product based advice and guidance to become a true benefits consultant. I think it's a tremendous opportunity personally for those willing to engage.

**GF:** It's exciting.

**Int:** It's tremendously exciting. I think we as brokers have a role to play and I think a unique one. The other stakeholders that we don't believe are equipped to participate in this consumer engagement process, my hope is that that changes at least in some capacity. We really need them to be part of the equation in some way, shape or form, so this becomes a collaboration.

**GF:** I would agree with that.

**Int:** This has been a tremendous dialogue.

**GF:** Yes, it's been interesting. You asked good questions.

**Int:** Thanks. Hopefully this has been useful for people who want to learn more about the consumer engagement process.

We've discussed a tremendous spectrum of what it means and what it is. Historically, engagement has been around product – how can we engage consumers around products, so they best utilize the plan that they have chosen.

But today we've discussed taking this to a different level and really getting to the medical aspect of consumerism and consumer engagement…asking questions, understanding outcomes, a completely different aspect to the world of healthcare as it stands today. Gary, thank you for your time, your comments, your insights…