The End of the Beginning: A Closer Look at the Impact of the New Health Reform Law and the Road Ahead to Implement It

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AFTER A LONG AND DIFFICULT PROCESS, A MAJOR ACHIEVEMENT

After fourteen months of summits, roundtables, committee hearings, white papers, calls to action, floor debate, raucous town hall meetings and closed-door negotiations, President Obama this week signed into law the most sweeping health care legislation since Medicare's creation in 1965. The path to passage of the Patient Protection and Affordable Care Act was far from easy. Not a single Republican voted for the final legislation, forcing Democratic leaders to find the requisite number of votes entirely from within their own caucus. Congress missed almost every self-imposed deadline, with the House barely passing a bill just before Thanksgiving last year and the Senate finally passing its version of the legislation in a rare Christmas Eve session.

Then, just weeks later, the President's top domestic priority looked all but dead. Republican Scott Brown won an improbable come-from-behind victory in a January 19 special election to fill the seat of the late Senator Edward Kennedy (D-MA). Brown's victory shook Washington, bringing an unmistakably strong anti-reform message to already-nervous lawmakers, depriving Democrats of the 60-vote Senate supermajority they were relying upon to pass health reform legislation and sending the White House and Congressional leaders scrambling for a "Plan B" rescue effort. But, eventually, Democratic leaders found a winning formula. On March 22, the House of Representatives passed the Senate version of the bill and sent it to President Obama for his signature. Then, both the House and Senate passed a subsequent bill under fast-track Budget Reconciliation procedures requiring only 51 Senate votes to modify the Senate bill.

There is no doubt that the passage of the $940 billion health reform bill represents a major accomplishment for the Obama Administration. It is also clear that the initiative will help shape the political landscape for years to come. Much has, and will be, written about the political obstacles and procedural pitfalls policy makers navigated on their way to passing this initiative. The plotline is fascinating with twists and turns worthy of a John Grisham thriller. This paper looks beyond the process and politics to examine more closely the content and likely impact of the new law.

A FRAMEWORK FOR EXAMINING THE IMPACT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

The sweep of health care reform is breathtaking. The nearly 1,000 page tome touches practically every sector of our nation's health care system. In some instances, the impact will be incremental. For example, the legislation largely preserves our nation's employer-sponsored health coverage model, makes modest improvements to Medicare and expands eligibility for Medicaid without making dramatic changes to those underlying entitlement programs. At the same time, health insurers will face sweeping new regulations. Some seniors may find reduced private health coverage options in the Medicare program. Medical device, insurance and pharmaceutical companies will face new excise taxes to help finance the reform. Many employers will be required to pay a penalty if they do not offer insurance to their employees. Most

Americans will have to pay higher taxes if they do not purchase health coverage, but will also have meaningful new protections such as limits on insurance coverage denials and lifetime financial coverage limits. States will have to expand their Medicaid programs fairly dramatically at a time when most face significant funding shortfalls. And although the prevention and wellness provisions did not take center stage, the law makes significant investments in public health initiatives aimed at improving maternal and child health, combating obesity, promoting immunizations, and coordinating care for individuals with chronic conditions.

From the outset of the debate, President Obama and Democratic Congressional leaders said that their goal in passing health reform legislation was to improve access to coverage, control costs and improve quality. Whether the legislation ultimately achieves these goals will depend on how effectively its legalistic text is translated to application in the real world and what modifications are made by future Congresses.

In fact, implementation of the new law could make the effort to pass it look like a cakewalk. First, there exist high expectations for the legislation's ability to make health coverage more affordable and accessible for millions of Americans. This will require the states and federal regulators to work closely together to set up health insurance purchasing exchanges and implement new insurance market regulatory measures, while making sure that Medicaid program expansions proceed smoothly and new subsidies find their way to consumers. Second, there also is hope that the law will help slow the rate of health care spending growth, which consumes an increasing portion of our nation's economy – in many cases, without any commensurate improvements in health or quality. Bending the cost curve, improving the balance sheet of Medicare and bringing health insurance premium increases more in line with general inflation will likely require efforts beyond what has been included in the new law. Third, health care reform exposed deep fissures within Congress, and in voters across the nation. Already, serious efforts are underway to modify key provisions of the legislation, to challenge their legality, or even repeal the entire law. Finally, even if all proceeds as planned, major elements of the complex and wide-ranging law will unfold over time (many of the most important features do not become effective until 2014), requiring Congress, the Obama Administration and outside supporters to manage the public's expectations and maintain their intense focus on health reform well into the future.

So, with the ink barely dry on the new health reform measure, this paper examines six key questions that undoubtedly are on the minds of policy makers and the public as we enter this next chapter of the health care reform debate:

1. How does the legislation address its intended goals of expanding coverage, controlling health costs and improving quality?
2. What impact will the legislation have on key health care sectors, including physicians, hospitals, health plans, pharmaceutical and biotechnology companies and medical device manufacturers?
3. What will the new law mean for both small and large employers, consumers and Medicare beneficiaries? (see attached document)
4. What impact will the legislation have on individual patients and consumers?
5. When will the reforms begin? What will it take to implement the new law?
6. What does the legislation mean for any future Congressional action on health care?

Each of these questions is examined in more detail here.

Expanding Coverage

Although there is some disagreement among policy makers about the precise number of uninsured Americans, with the federal government figure of 47 million most often cited, one thing is certain: the uninsured population in the United States is a diverse group. Some individuals are uninsured because they decline employer-offered coverage. Many individuals eligible for Medicaid do not apply for benefits. Some people can afford coverage, but cannot get it because of preexisting medical conditions. Small business owners face their own set of unique challenges in finding affordable health coverage for their employees.

So how well does the new health care law meet its objective of expanding health insurance coverage to the uninsured?

According to the Congressional Budget Office (CBO), the law will increase the rate of insurance from 83 percent to 94 percent over the next 10 years. In actual numbers, an estimated 32 million Americans currently without health insurance would have coverage by 2019. In expanding coverage, the legislation takes a multi-pronged strategy involving mandates, financial penalties, "exchanges," tax credits and cost-sharing reductions, but largely retains our nation's employer-sponsored model. In fact, the CBO estimates that by 2019, only about three million fewer Americans would receive employer-provided coverage relative to today. However, those Americans seeking coverage on their own and through small groups will face a new world. The bill also calls for the largest Medicaid eligibility expansion in the program's history.

Individual and Employer Mandates

Just like the long-abandoned public option, the law's requirement to obtain insurance coverage or face a financial penalty engendered tremendous opposition. Even before the bill became law, Attorneys General in 14 states announced their intent to challenge the constitutionality of the "requirement to maintain minimum essential coverage," which becomes effective January 2014. At that time, Americans who fail to maintain coverage for one month or more, with a series of exceptions including one for individuals with less than a three-month gap in coverage, would pay a 'shared responsibility penalty payment' set at the greater of a flat fee or a percentage of income up to a maximum of three times the flat fee.

Phase-In Schedule for Shared Responsibility Penalty Payment

Year	Flat Fee	Percent of Taxable Income
2014	$95	1
2015	$325	2
2016	$695	2.5
2017 and thereafter	Previous year updated by a cost-of living adjustment	Previous year updated by a cost-of living adjustment

Like individuals, employers with more than 50 full time employees will face some significant financial penalties beginning in 2014. These large employers will be required to pay a penalty

of $2,000 per full-time employee (excluding the first 30 full-time employees) if they:

1. do not offer coverage;
2. offer minimum essential coverage (described in greater detail below) that is "unaffordable;" or
3. offer coverage that covers less than 60 percent of the cost of benefits;

and

have an employee who enrolls in coverage through the exchange and receives the premium assistance tax credit (described below) or cost-sharing assistance.

Employers offering coverage can avoid penalties to some extent by providing "free choice vouchers" to employees with incomes less than 400 percent of poverty and for whom the premium for the employer-offered plan exceeds 8 percent, but is less than 9.8 percent of their income. The voucher would equal the amount that the employer would have paid to provide coverage under the employer plan and could be applied by the employee to enroll in a plan offered through the exchange.

In addition, employers would be prohibited from imposing a waiting period of more than 90 days, and those with 200 employees also must automatically enroll their employees into their health benefits programs, providing them with an option to opt-out.

Health Insurance Exchanges

As of 2014, "exchange" will no longer mean just a post-Christmas activity. Rather, it will be the mechanism through which millions of Americans – 29 million by 2019 – obtain health insurance. Modeled after the "Connector" established in Massachusetts, the state-level exchanges are intended to pool insurance risk with the goal of making coverage more affordable by applying specific requirements for rating, benefit design, marketing, provider networks and enrollment, policy makers also hope exchanges will allow easier comparisons among available coverage options. Individuals and employees of small businesses with less than 100 employees can elect coverage from a qualified plan offered through the exchange. In 2017, states have the option to permit exchanges to offer coverage to the large group market. Upon the Secretary's approval, an exchange could operate on a regional basis. With only one live exchange to look to as precedent (the one established under Massachusetts' state-level reform) policy makers have placed a huge bet on the exchanges to produce the expected results. Although the legislation provides $250 million in grants to assist states to plan and establish their exchanges, the funding remains available from 2010 and 2014, at which point, states must

Example:
Employer with 100 full-time workers some of whom receive premium or cost-sharing assistance

Fine: (100-30)*$2,000 = $140,000

Employers with more than 50 employees who do offer coverage, but have employees who receive the premium assistance tax credit must pay the lesser of $3,000 per employee receiving the credit or $2,000 per full-time employee.

Example:
Fine for Employer with 100 full-time workers with 10 workers receiving premium or cost-sharing assistance

Lesser of 10*$3,000 and (100-10)*$2,000
Fine: $30,000

Examples based on Joint Tax Committee, JCX-18-10

finance their exchanges through assessments and user fees.

Essential Health Benefits Package Requirements

To meet the requirement, the package must cover specific benefits with out-of-pocket limits, and in the individual and small group market, cover a specified percentage of costs.

Note: In general, the law **grandfathers** existing individual and group health plans with respect to the new benefit standards and dependent coverage up to age 26.

Required Benefits

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance use disorders
- Prescription drugs
- Rehabilitative and habilitative services and devices
- Laboratory services
- Prevention and wellness services and chronic disease management
- Pediatric services, including oral and vision care

Cost Sharing Limits

- For all markets: prohibits out-of-pocket limits greater than health savings accounts limits
- From the small group market: prohibits deductibles greater than $2,000 for individuals and $4,000 for families (indexed in future years to inflation)

Levels of Coverage

- **Bronze –** must provide coverage that is actuarially equivalent to 60 percent of the full actuarial value of the benefits provided under the plan.
- **Silver –** must provide coverage that is actuarially equivalent to 70 percent of the full actuarial value of the benefits provided under the plan.
- **Gold –** must provide coverage that is actuarially equivalent to 80 percent of the full actuarial value of the benefits provided under the plan.
- **Platinum –** must provide coverage that is actuarially equivalent to 90 percent of the full actuarial value of the benefits provided under the plan.

Tax Credits and Cost-Sharing Assistance

The cost of health care insurance, especially for small employers, has long caused concern among business owners and policy makers alike. After years of double-digit rate increases and numerous strategies to keep costs low, millions of small business owners have either scaled back or stopped offering health coverage. To help stem this trend, beginning January 1, 2010, the legislation provides a sliding scale tax credit to employers with no more than 25 full-time equivalent employees and average annual wages less than $50,000 that contribute at least 50 percent of the total premium cost. Employers with fewer than 10 employees and average annual wages would receive the full credit of 35 percent of their contribution available for 2010 through 2013. For taxable years thereafter, the credit increases to 50 percent. The Congressional Budget Office estimates that the tax breaks will lower the cost of insurance for the targeted employees by 8 to 10 percent.

In addition to the small business tax credit, individuals with incomes up to 400 percent of the federal poverty level (FPL) – or $88,000 for a family of four and $43,000 for an individual – will receive premium assistance in the form of a refundable tax credit to purchase coverage through the health insurance exchange. The law ties the sliding-scale credit, which begins January 2014, to the second lowest cost "silver" plan in the area. Individuals and families with incomes between 100 percent and 400 percent of FPL will receive additional cost-sharing assistance with reductions ranging from one-third to two-thirds based on income.

Medicaid

There is an old health policy adage that goes: "if you've seen one state's Medicaid program, you've seen one state's Medicaid program." Although all states must meet certain requirements to receive federal Medicaid funding, there are in fact many differences among the programs offered in the 50 states. Each state may choose to cover different optional health benefits, extend coverage to different groups of lower-income citizens and establish varying enrollment processes. This variation has long concerned Medicaid advocates, who in the reform bill achieved a trifecta of wins: (1) states must cover individuals with incomes at or below 133 percent of the federal poverty level (FPL), or $29,327 for a family of four; (2) the federal government will increase its share of spending; and (3) states must simplify enrollment processes. In addition, the law increases Medicaid payments for primary care services, putting them on par with Medicare reimbursement. No changes, however, were made to payments for specialty care services under Medicaid. With these changes, which go into effect in January 2014, an estimated 51 million Americans will receive health care coverage through Medicaid and the Children's Health Insurance Program (CHIP) in 2019. Adding the 60 million Americans who will receive Medicare means that nearly 110 million Americans – one-third of the population – will receive health insurance through a public program in 2019. To offset states' costs, the federal government will pay 100 percent of states' costs of covering newly Medicaid eligible individuals between 2014 and 2016; 95 percent in 2017; 94 percent in 2018; 93 percent in 2019; and 90 percent in 2020 and beyond.

Cost Control

For more than two decades, economists have warned that if left unchecked, the rate of growth in health care spending would devastate not only Main Street, but also the nation's competitiveness in the global marketplace. Last September, the highly-respected journal *"Health Affairs"* dedicated the entire issue to the topic. One study conducted by Harvard colleagues Michael Chernew and David Cutler, along with Richard Hirth from the University of Michigan, found that if health spending continued to outpace overall economic growth by two percentage points over the next 75 years, health care would absorb all – and then some – of the real increase in per capita income. Although policy makers made clear their desire to slow the rate of health care spending growth – coining the new phrase "bending the cost curve" along the way – the legislation's true cost-curbing effectiveness has many skeptics ranging from the Department of Health and Human Services' (HHS) independent actuary to leading economists.

So just what does the bill do to attempt to rein in costs?

The high-cost plan excise tax, often called the "Cadillac Plan tax," is the bill's centerpiece cost-containment measure and one of the few for

which there's some agreement on its ability to drive down costs. Along with the tax, the legislation includes an alphabet soup of new programs and policies – CER, HIT, ACOs and IPAB, among others. For most of these programs, however, the jury is still out among health policy experts on their effect in slowing cost growth.

Cadillac Plan Tax

General Motors (GM) had likely hoped to have its name out of the newspapers after the dust settled on the auto bailout. The company had no such luck, however, as one of its trademark brands – "Cadillac" – became the shorthand for what many policy makers considered the biggest health care cost driver. Key policy makers, most notably, Finance Committee Chairman Senator Max Baucus, maintained that employers' offering of broad health benefits packages or "Cadillac plans" cause unnecessary utilization and contribute to spending growth.

Faced with the real need to raise some real revenue – and with other options fraught with more political minefields – Baucus and Senate Democratic leaders early on embraced the concept of taxing those insurers who provide so-called high-cost plans. The final agreement calls for a 40 percent excise tax on the amount by which the value of employee health benefits exceeds in general, $27,500 for families and $10,200 for individuals beginning in 2018. Prior to 2020, the thresholds will be updated by CPI+1 percentage point, reduced to CPI in 2020 and beyond. Over the course of the debate, these thresholds crept steadily upward and the effective date pushed out to address concerns raised by a number of constituencies, including unions. To make up for the revenue lost by these changes, the bill increases Medicare taxes on individuals earning more than $200,000 and couples earning $250,000. In addition to primary health coverage, contributions to account based plans, such as flexible spending accounts (FSAs) and health savings accounts (HSAs) count toward the threshold for the tax. Certain Health Insurance Portability and Accountability Act (HIPAA)-excepted benefits along with stand-alone dental and vision plans do not count toward the threshold.

Independent Payment Advisory Board (IPAB)

Since Medicare's creation, Congress has held the reins on program changes, be they benefit expansions or provider cuts. And no other area, except for Social Security, comes close to the level of potential political dynamite inherent in those policy decisions. Remember the Medicare Catastrophic legislation? Almost one year to the day after its nearly unanimous adoption in the Senate and months of voter backlash, the Senate repealed the measure by the same nearly unanimous vote. Along with Social Security, Medicare has been referred to as the "third rail of politics." With Medicare spending projected to grow by 7 percent annually between 2011 and 2020 and end of decade total spending expected to exceed one trillion dollars, it's not likely to lose that characterization any time soon. The bottom line is that over the next decade, Congress will face tremendous pressure to slow that growth, and borrowing pages from the military base closure process, the bill creates an independent board – the IPAB – to give Congress political cover on those decisions.

The IPAB, whose fifteen members will be appointed by the President and confirmed by the Senate, will hold the grave responsibility of presenting the President and Congress with proposals to reduce excess growth should it exceed a target. Beginning in 2014, the IPAB must submit recommendations by January 15 if the Centers for Medicare and Medicaid Services (CMS) Actuary determines that per capita

Medicare spending growth exceeds a specified target growth rate or if medical CPI exceeds the CPI-U (the consumer price index in urban areas). In 2019 and beyond, the Board must submit recommendations if per capita growth in national health expenditures exceeds the Medicare per capita growth rate. But the legislation makes certain things strictly off-limits. The Board's proposals cannot: (1) ration health care; (2) raise revenues or Medicare beneficiary premiums; (3) increase beneficiary cost-sharing; (4) reduce cost-sharing assistance for low-income beneficiaries; or (5) otherwise restrict benefits or modify Medicare eligibility criteria. In the short term, Medicare reimbursements to hospitals are off limits, resulting in more payment pressure on Part B providers, Medicare Advantage and Medicare Prescription Drug Plans.

In years when growth outpaces the target, the IPAB's proposals would become effective unless Congress adopts an alternative strategy to achieve the same level of savings. Congress would consider the alternative under a "fast-track" process which specifies dates by which Committees of jurisdiction must complete action on the alternative package and sets rules for floor consideration and disposition (e.g., the motion to proceed is not debatable, germaneness rules and time agreements). Assuming the President does not veto the package, which is permissible, the proposal would be implemented in August of the given year. In years in which growth does not outpace the target, the IPAB must make non-binding recommending on topics including access, quality and utilization in various regions of the country, as well as across types of providers, services and payors.

Comparative Clinical Effectiveness Research (CER)

By establishing a private, non-profit research institute, the health care reform law continues Congress' foray into comparative effectiveness research (CER) that began with $1.1 billion in stimulus package dollars. To help fend off critics who claim that CER is merely a stalking horse for health care rationing, proponents borrowed a strategy employed by any good marketing agency: they rebranded it such that CER became PCOR or "Patient-Centered Outcomes Research" and reframed the Institute's purposes in more "patient-" and "clinician-" friendly language. In addition, a simple counting of pages shows that policy makers dedicated about the same space to setting forth the Institute's structure and activities as they did to spelling out requirements for transparency and limitations on the use of its research findings. In short, the bill prohibits the Institute from mandating coverage, reimbursement or other policies for any public or private payors.

The bill requires that the independent Government Accountability Office (GAO) appoint a public-private board to oversee the PCOR Institute, whose work – funded at $500 million annually – will entail evaluating and comparing the clinical effectiveness, risk and benefits of two or more medical treatments and services, defined broadly to include:

- health care interventions, care management, protocols for treatment, and delivery;
- procedures;
- medical devices;
- diagnostic tools;
- pharmaceuticals (including drugs and biologics);
- integrative health practices; and
- any other strategies or items being used in the treatment, management and diagnosis of, or prevention of illnesses or injury in, individuals.

The PCOR Institute board will identify national CER priorities with consideration to disease incidence, prevalence and burden. A standing committee will oversee the development and improvement of CER methodological standards.

New Delivery System and Payment Models

The growing incidence and prevalence of chronic diseases has renewed a strong interest in coordinated and integrated care as a means not only to improve care, but also to lower spending by keeping people healthier and avoiding duplication in services. But policy makers recognize that full-blown provider integration may be impossible in certain parts of the country and as an alternative opted for what could be called "virtual" integration models, known as accountable care organizations (ACOs) and medical homes, both of which are described briefly below.

- **Accountable Care Organizations (ACOs):** Health care providers, including physician groups, hospitals, nurse practitioners, physician assistants and others, would join together as a "virtually" integrated system. ACOs must agree to participate in Medicare for three years and at a minimum, report on measures related to clinical process and outcomes, patient and caregiver experience, and utilization. Those ACOs that meet quality of care targets and reduce patient costs relative to a specified benchmark receive a portion of the savings they achieve for the Medicare programs.

- **Medical Homes:** Eligible entities with federal grant support would establish health teams to support primary care providers (PCPs) and provide capitated payments to PCPs. The teams would support medical homes, defined to include personal physicians, coordinated and integrated care, expanded access, and payment that recognizes the added value from providing services to promote patient-centered care.

The legislation also creates a Center for Medicare and Medicaid Innovation within the Centers for Medicare and Medicaid Services to research, develop, test and expand innovative payment and delivery arrangement including models that require benefits not currently covered by Medicare.

Beginning January 2013, HHS will undertake a 5-year national, voluntary pilot "bundled" payment pilot program. Hospitals, physicians and post-acute care providers could participate in the program, which if found to improve quality and reduce costs, would be extended.

Health Information Technology

Over the past several years, policy makers have pointed to health information technology (HIT) as a means to improve efficiency and lower health care costs. The 2009 stimulus legislation incorporated the Health Information Technology for Economic and Clinical Health Act of 2009, which created financial incentives for physicians' and hospitals' adoption of HIT. A key to achieving the promise of HIT is interoperability, or more simply, making sure that various systems that support electronic medical records, for example, can "talk" to each other. As such, the health care reform bill requires the Secretary of Health and Human Services to develop interoperability standards and protocols for enrollment of individuals into federal and state health and human services programs. The Secretary also has discretion to require states and other entities to adopt the standards, which will support electronic data matching and

documentation, as a condition of receiving federal HIT funds.

Quality

According to leading experts, the saying "you get what you pay for" does not necessarily ring true for health care. Study after study confirms that increased spending often fails to produce commensurate improvements in quality and value. Although many quality improvement proponents view the bill as not going far or quickly enough, the bill does create a "national quality strategy" and builds on current Medicare quality reporting and programs that pay hospitals based on quality. In addition, the legislation seeks to promote new delivery mechanisms aimed at better coordinating care, particularly for patients with chronic illness.

National Quality Strategy

Beginning in 2011, the Secretary must develop a national strategy to improve the delivery of health care services, patient outcomes and population health. In selecting priorities, the Secretary will consider areas that have the greatest potential for rapid improvement in quality and efficiency of patient care, and through a number of mechanisms – including payment policy and dissemination of best practices – work to achieve those objectives. At a minimum, the strategy must include plans to coordinate inter-agency quality improvement activities, setting of agency-specific benchmarks and efforts to align public and private quality improvement and patient safety efforts.

The strategy also calls for using a consensus-based process to develop measures to assess numerous dimensions of health care quality including:

- health outcomes and functional status;
- care coordination across providers and transitions in care;
- meaningful use of health information technology;
- patient satisfaction; and
- safety, effectiveness and timeliness of care.

Payment for Quality

The Pacific Northwest and Southern Florida are separated by more than just geography. The difference in Medicare spending and quality between the two regions also sets them far apart. This variation has been a perennial issue – pitting Members from high-quality, low-cost states against their counterparts representing areas with higher-spending, but in most cases, lower quality and health outcomes. The health care reform bill takes a small step toward "value-based" reimbursement under the Medicare program by setting aside $800 million for payments to providers who serve beneficiaries in states that traditionally have had lower Medicare reimbursement, but have achieved high marks on quality and outcomes.

IMPACT ON MAJOR HEALTH CARE SECTORS

In addition to creating new purchasing options for many health care consumers, the legislation will bring significant changes for practically every major sector of our nation's health care system in the form of new payment methodologies, rules governing the offering of insurance, and excise taxes. The following briefly highlights what's in store for some of the key sectors.

Physicians

More than a decade ago, Congress created a Medicare physician payment system known as the sustainable growth rate (SGR) system that involves the annual setting of payment targets for

physician services with the goal of controlling aggregate Medicare expenditures. In the first years of operation, the SGR – a portion of which is tied to the growth in gross domestic product (GDP) – resulted in increases in physician payments. For the past several years, however, the SGR produced negative updates to physician payments. Under pressure from the physician community and concern about beneficiary access, Congress has consistently postponed the annual rate cuts by in essence, "borrowing" from future years' physician payments. This ritual of postponing the cut has led to an ever larger cumulative payment reduction that now exceeds 20 percent. Although not directly affected by the health care reform bill – Congress once again approved a separate measure to put off the pending cut until March 31 so it will need to take additional action soon – an understanding of the current system is helpful background to the bill's provisions.

In addition to volatility in payment rate increases or cuts, research indicates that the SGR disproportionately penalizes primary care physicians and has led many recent medical school graduates to enter a specialty. As the nation continues to age and spending on chronic conditions grows, policy makers have stepped up their efforts to rectify this situation. Better primary care presents an opportunity to keep Americans healthy, avoid complications, and in the long run, to save money. In keeping with the goal of promoting primary care, the bill provides a 10 percent payment bonus for five years to physicians in health professional shortage areas who devote more than 60 percent of their practices to primary care.

The bill also extends Medicare's physician quality reporting initiative – PQRI – which provides financial incentives for reporting quality data to Medicare – through 2014. To address concerns raised by the physician community, the legislation establishes an appeals and feedback process for PQRI-participating professionals. Come 2014, physicians who fail to submit PQRI measures will face payment reductions. In 2015, Medicare will begin applying a new "value-based" component to physician payments to adjust for the quality and cost of care delivered. Since the component will be "budget neutral," there will be "winners" and "losers" among the physician community.

In response to the physician community's distress about the cost and impact of medical liability, the legislation includes non-binding language encouraging states to develop and test alternative litigation models as a way of improving quality and reducing medical errors, while preserving individuals' rights to seek redress. It also opens the possibility for a federal demonstration program to evaluate state alternatives to existing litigation models.

Finally, the work of the IPAB could have a direct affect on physicians.

Hospitals

The legislation affects hospitals primarily through two major Medicare changes: (1) the inclusion of a productivity adjuster in the hospital payment update formula and (2) a reduction in payments to Medicare disproportionate share hospitals (DSH). According to the CBO, the productivity adjuster, which in addition to hospitals, affects ambulance services, laboratory, medical equipment, among other providers, will reduce Medicare payments by $156.6 billion over the next decade. The hospital community maintains that failing to sunset the provision after the 10-year budget window will devastate the sector. In fact, a report issued by the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary states that "growth rate reductions and thus savings from productivity adjustments are

unlikely to be sustainable on a permanent annual basis." The Medicare DSH program, through which hospitals serving a large number of lower-income Medicare and Medicaid beneficiaries receive additional payments, will fall by $22.1 billion over the next decade. Arguably, with more Americans covered, and uncompensated care costs diminished, this loss of revenue could be offset to some degree.

In addition to these more straightforward payment changes, the legislation includes a series of quality-based payment provisions. Starting in fiscal year 2013, the bill establishes a hospital value-based purchasing program that ties a percentage of hospital payment to performance on quality measures related to cardiac, surgical and pneumonia care. Payment penalties would begin applying in 2015 to hospitals that rank in the top 25th quartile of rates for hospital-acquired infections related to common conditions. Hospitals also will face reductions in payments under the prospective payment system based on the dollar value of each hospital's potentially preventable readmissions during a fiscal year on or after 2012.

Finally, non-profit hospitals will also see some changes beginning in 2012 when they will have to submit a community needs assessment and meet requirements related to financial assistance, billing, and collection policies. To meet the needs assessment requirement, a non-profit hospital must consider input from a broad array of community stakeholders and must make the assessment publicly available. The financial assistance policy requirements call for a written statement that explains eligibility criteria, the formula for calculating sliding-scale charges, actions to be taken in the event of non-payment, and a means to widely publicize the policy within the community. Under their financial assistance programs, non-profits also will be prohibited beginning with taxable year 2011, from charging amounts in excess of the lowest charged to individuals with insurance. Non-profits that fail to meet the new requirements will be subject to a $50,000 per year excise tax. The Secretary of Health and Human Services also will audit a non-profit's community benefit activities at least once every three years.

Health Insurers

Of all sectors, health insurers face perhaps the most significant changes and challenges as a result of national health care reform. On the plus side, with the coverage expansions and mandates, health insurers will have a much larger potential enrollee base. In fact, CMS previously estimated that private insurers might see a gain of approximately 20 million potential new enrollees. Perhaps most significantly, the legislation does not fundamentally alter the role of private insurance in the U.S. or the primacy of the private insurance industry, rather it builds on the existing, mixed public and private systems including the employer-sponsored market.

On the downside, policy makers had insurers squarely in their line of sight as a means to finance health reform and put in place long-sought prohibitions on certain insurance practices. To that end, health plans participating in Medicare Advantage will face a dramatically altered payment methodology, expected to cut payments by more than $135 billion over 10 years. An additional $70 billion in reductions will result from changes to Medicare fee-for-service payments that flow through to the Medicare Advantage program. CBO has estimated that the cuts will cause Medicare Advantage enrollment to decline by nearly 5 million beneficiaries by 2019. In addition, the Medicare Advantage program is fair game for the IPAB.

The Cadillac plan tax could limit insurers' revenue and profitability as purchasers redesign benefit plans to avoid hitting the tax threshold. The legislation also directly taxes insurers' revenues with the aggregate tax set at $8 billion in 2014 rising to $14.3 billion in 2018. For 2019 and beyond, the amount will be updated by the rate of growth in premiums. The adoption, for the first time, of medical loss ratios may also have a serious impact on plans. This ratio formula would require insurers to pay a minimum of 85 percent in the large group market and 80 percent in the small and individual markets of their revenues for actual health care costs or rebate premium payments to their enrollees.

In addition to the law's impact on payments to plans under Medicare, it also makes significant changes to certain insurance practices. Specifically, within the first year of enactment, the law bars insurers from rescinding policies, prohibits life time limits; and regulates the use of annual limits. In 2014, insurers will no longer be able to charge higher rates based on health status, gender or other factors; refuse to sell or renew policies due to health status; or exclude coverage for pre-existing conditions.

Pharmaceutical and Biotechnology Companies

The pharmaceutical and biotechnology sectors entered the debate with perhaps the most to lose. With that stark understanding, and as has been widely reported, the industries took a proactive approach seeking early on to get a seat at the negotiating table with both Congressional leaders and the Administration. Although not unscathed by the law, the sectors achieved what some would claim to be significant victories.
On the downside, Medicaid, which already has among the lowest reimbursement rates for pharmaceutical products, will extract additional rebates for the federal and state governments when, beginning in January 2010, the flat Medicaid basic rebate increases from 15.1 percent to 23.1 percent for outpatient single source and innovator multiple source drugs and from 11 percent to 13 percent for non-innovator, multiple source drugs. The rebates will extend to beneficiaries who receive care through Medicaid managed care organizations and additional rebates apply to new drug formulations. In addition, the law extends 340B pricing discounts to certain children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral entities and sole community hospitals.

And just like many of their health care brethren, pharmaceutical and biotechnology companies will in 2011 begin making direct deposits to the "excise tax" bank based on market share with total deposits reaching $27 billion through 2019.

On the upside, manufacturers will likely benefit from the insurance expansions and some of the new protections against excessive cost-sharing and other insurance limitations. They also avoided the application of Medicaid rebates to beneficiaries eligible for both Medicare and Medicaid (so-called, dual eligibles) enrolled in a Medicare prescription drug plan (Part D). However, as part of the industries' agreement with the Administration, manufacturers next year will begin providing a 50 percent discount on brand-name drugs to beneficiaries who enter the Medicare Part D coverage gap or "donut hole." But that provision, along with the law's reduced cost-sharing for both generic and brand-name drugs beneficiaries, effectively will close the donut hole, giving beneficiaries 75 percent discounts on drugs in the coverage gap by 2019.

The extent to which four other provisions – (1) the new follow-on biologics pathway; (2) greater transparency with respect to physician relationships; (3) comparative effectiveness research; and (4) the Independent Payment

Advisory Board (IPAB); and (5) 340B changes – affect the industries is less clear.

Biotech companies for the first time will face the prospect of competition from companies and products seeking to market "follow-on" products that rely in part on the safety and efficacy evidence submitted as part of the original "innovator" product approval. The law prohibits those data from being used for 12 years, but after that, companies can use them in developing their follow-on product. For a number of reasons, the immediate impact of this change may be limited. First, the Food and Drug Administration (FDA) must develop rules for approving follow-on products and determining if the follow-on is "interchangeable" with the innovator product. Second, product patents may continue to provide some degree of protection against competition. Third, some analysts suspect that follow-on prices will not be significantly lower than the original product price so that the impact of competition may be somewhat limited.

Beginning in March 2013, manufacturers have to report any payment or other transfer of value to a physician or teaching hospital. Often referred to as the "Sunshine Act," the provisions require the disclosure of the recipient's name, amount and nature of the payment. Given that a number of states have adopted – and many others were expected to follow – a uniform federal law avoids the administrative headaches of complying with separate state laws with shades of variation.

Another unknown is the extent of the impact that the PCOR Institute may have on future coverage and reimbursement decisions. The legislation imposes several limitations on the government's use of comparative effectiveness research in setting or reimbursement rules for both public and private payers. However, depending on who is appointed to serve on the board, how it sets its agenda, conducts its research and frames its findings, the Institute could have wide-ranging effects on the pharmaceutical and biotech industries. For example, if research sponsored by the Institute finds that a brand-name drug works no better than a generic, there is little to prevent physicians and patients from voluntarily seeking lower cost alternatives, or to prohibit private payers from restructuring coverage to encourage utilization of lower-cost alternatives. The impact of the Independent Payment Advisory Board (IPAB) is similarly difficult to predict, but the law makes clear that the Medicare Prescription Drug Program is fair game.

Medical Device Suppliers and Importers

In the spirit of leaving no revenue raiser on the table, the law applies a 2.3 percent tax on the sale of medical devices by manufacturers or importers beginning in 2013. The tax – estimated to raise $20 billion between 2013 and 2019 – went through several iterations over the course of the debate. Originally, set at a flat amount beginning in 2011 with companies with less than $5 million in sales and certain class II and all class I devices exempted, the law expands the tax's reach, covering all companies regardless of sales volume and with specific exceptions only for eyeglasses, contact lenses and hearing aids. The law does, however, grant the Secretary authority to expand that list to include additional devices sold in retail establishments to individuals for personal use.

This result is a mixed bag for the diverse medical device and importers sector. Although the law delays the effective date by two years, smaller medical device companies lost their protection from the tax, and it is very likely that some companies will owe more in taxes than they generate in profits. To give a sense of the impact, *MassDevice,* the Massachusetts Medical Device Journal, analyzed last year's sales data and found that 58 companies would generate

$1.87 billion. Obviously, larger companies will bear the brunt of the tax in terms of dollars, but – and not to diminish the effect of the tax – may be better positioned to absorb its shock. Case in point – the *MassDevice* analysis found that the tax would push three comparatively smaller companies into the red.

On top of the tax, the work of the PCOR Institute will apply to medical devices as well.

When do Provisions become effective? What will it take to Implement the New Law?

Federal agency officials will have little time to spend celebrating the law's passage before beginning the arduous task of implementing the new law. Experience shows that implementing a massive law – even a small one, for that matter – can be equally, if not more challenging than, the legislative process. Take the Medicare Prescription Drug Benefit, for example. Glitches in information sharing between CMS and prescription drug plans went on for months causing some beneficiaries to be erroneously disenrolled. The social security check withhold option was intended to provide beneficiaries a convenient way to pay Part D plan premiums, but thousands of beneficiaries were charged too much, too little or not at all. The bottom line is that even the best laid regulatory plans can go awry by the unexpected.

With that as a backdrop, let's consider what it will take to implement the health care reform bill.

First, it's going to take speed because a number of provisions – more than 20 – become effective upon enactment or within 90 days of enactment (see attached timeline). Although many of these provisions are straightforward or self-executing, the Administration will still likely need to issue guidance of some form.

The implementation effort also will require careful and consistent coordination not only within HHS, but also across agencies, such as Treasury, Labor, and the Social Security Administration (SSA), just to name a few. Within HHS, the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ), among others, all will play a role in crafting rules and guidance. The Internal Revenue Service will see a greatly expanded role in the health care arena ranging from the assessment of penalties on employers and individuals to determining whether or not a plan trips the high-cost plan tax threshold. States, too, will have a significant role in implementing various provisions of the law. Given that the law grants various Agencies discretion on a number of matters, there without a doubt will be skirmishes between Members of Congress, the Agencies and various stakeholders who believe that the Administration is either overstepping or understepping its bounds.

The Future Legislative Agenda

If there's one word to sum up how policy makers feel about health care reform, it's fatigue. With the economy still lurching toward recovery, the President, Democratic leaders and rank and file Members of Congress want to move on to other topics, especially job creation, regulatory reform of the financial services industry and additional relief for the middle-class. President Obama's creation of a "debt reduction" commission headed up by President Clinton's former Chief of Staff Erskine Bowles and retired Republican Senator Alan Simpson of Wyoming has signaled to some that Social Security may be the next big thing the Administration wants to tackle. It is doubtful, however, that Congressional Democratic leaders share that desire as they recover from the brutal health care reform battle.

It is more than probable that the health care reform implementation process will raise some unforeseen issues. Despite best efforts to get things right, many aspects of the bill enter unchartered territory and what looked good on paper may turn out to be impractical or unworkable in the real world, necessitating legislative tweaks to get things back on track. In fact, on the same day that President Obama signed the bill into law, Congressional staff admitted that a drafting error has made a widely touted provision – the prohibition on denying new coverage to children due to a pre-existing condition – effective January 2014, not six months post-enactment. The Administration hopes to fix the issue through regulation.

Aside from a technical corrections bill or routine reauthorizations, Democratic leaders will likely try to keep health care legislation at a distance for as long as they can with one notable exception – the Medicare physician payment issue. Over the past few months, Congress has continued its long-standing trend of patching the Medicare physician reimbursement problem – once again, kicking the can down the road and making the cost of truly reforming the current sustainable growth rate (SGR) methodology even higher. Although a number of Members would like to see this fixed once and for all, the staggering billions it costs will likely prevent it from happening. Moreover, during the reform debate, Republicans pointed out that Democrats did not include a "doc fix" to help keep the bill's costs under one trillion dollars. Debating a permanent fix would give Republicans a platform to reiterate that point, and bring up health care reform again, which is something Democrats will likely want to avoid.

Republicans, however, may have a different plan in mind. Just minutes after President Obama signed the law, at least one Republican Senate candidate called for its repeal. During Senate debate on the Reconciliation package, Republicans filed more than 150 amendments, including those to strike or delay the excises taxes and the mandates. That list of amendments gives a glimpse into their thinking and possible approach to keep the law's unfavorability in view as the Administration begins its all out blitz to garner the public's support.

Even if Republicans win enough Congressional seats in November to take control of both the House and Senate, President Obama is almost certain to veto major changes to the new law. However, while outright repeal or even major modifications are unlikely in the short term, there could be several avenues of attack on fundamental aspects of the legislation in the years ahead. For example, critics might seek to repeal unpopular provisions such as the individual requirement to purchase insurance. They may reduce or eliminate penalties on employers who do not offer qualified coverage. They may seek ways to diminish the law's impact on smaller employers by, for example, changing definitions to exempt more small employers from the new mandates. They may give the states more flexibility in setting up Exchanges or in implementing the law's insurance reforms. Or, they may scale back any of the law's new taxes.

Democrats and proponents of the new law will be on the lookout for opportunities to build on the historic legislation. It is very possible that the public option will resurface along with attempts to further ratchet down payments to pharmaceutical manufacturers. But even despite best efforts to get out front on messages, Democrats will likely have to spend significant time playing defense and maintaining the public's support.

If history is a guide, both political parties will be responsive to efforts by an array of health care providers to reduce the impact of the new law's cuts to the Medicare program. Take the

Balanced Budget Act of 1997 (BBA) for example. Just two years after the BBA's enactment, Congress approved and President Clinton signed into law the Balanced Budget Refinement Act (BBRA), which according to HHS addressed, "flawed policy and excessive payment reductions." BBRA restored $6.8 billion in payments to hospitals, $2.7 billion to skilled nursing facilities and $1.3 billion to home health providers. At the end of 2000, Congress again passed legislation – the Benefits Improvement and Protection Act (BIPA) – which further modified payments to hospitals and Medicare health plans, among other providers.

As mentioned earlier, to the extent that cost containment and entitlement reform efforts gain momentum following the upcoming mid-term elections, several of the cost-cutting measures included already in the legislation could be expanded. Moreover, other policy changes excluded from the final 2010 health reform law could be on the table in future Congresses, such as applying Medicaid pricing to dual-eligibles enrolled in Part D and prescription drug reimportation.

Conclusion

While President Obama's health care reform plan is now the law of the land, the debate over the political impact of health care reform, in many ways, is only just beginning. The true political impact will not be known until after the 2010 midterm elections and beyond. Passing health care reform was an historic achievement. But it left Republicans and Democrats in Congress, as well as the general public, deeply divided in their views of the new law.

The focus on health care reform will now shift from the creation of the policy to its implementation. Out of the white hot political spotlight, the difficult work of implementing the complex new law will begin in earnest at the Department of Health and Human Services, the Department of Treasury, the Department of Labor, other federal agencies, as well as in all 50 states.

This paper highlights many of the implementation issues that lie ahead as well as a series of potential legislative changes that may be considered even before the new law is fully implemented. There is much work ahead and we stand ready to work with you as you face new challenges and opportunities in the aftermath of the passage of comprehensive health reform.