health reform matters

ROPES & GRAY

FEBRUARY 2009

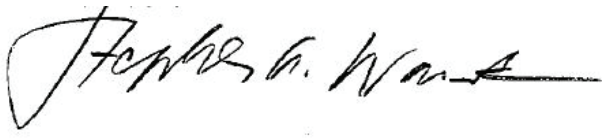
Welcome to the inaugural issue of Ropes & Gray's quarterly ***Health Reform Matters.***

Over the last year, the drumbeat for major national health care reform has built to a crescendo, culminating in the election of a new president and majorities in both houses of Congress that are pledged to enacting major fixes to the country's crisis-ridden health care system. Already the 111th Congress has signaled its resolve by renewing and expanding the state Children's Health Insurance Program (CHIP) and by committing massive amounts to health information technology, comparative effectiveness research, and further coverage expansions as part of this month's $787 billion stimulus package.

Inconceivable or stymied only a year ago, these measures promise to be only the first installment of an historic effort to bring about universal coverage in the United States—the first since the Clinton-era Health Security Act died in committee almost a generation ago. To inform our clients on all dimensions of this effort as it plays out across Congress, federal regulatory agencies and the states, Ropes & Gray is launching a quarterly newsletter addressing the full spectrum of issues, from efforts to guarantee universal coverage and payment and delivery reform, to the tax deductibility of employer-sponsored health benefits and the regulation of provider-industry conflicts of interest, among others.

In this debut issue, we include articles about the very first pieces of "reform" legislation, enacted over the last few weeks—the American Recovery and Reinvestment Act, a.k.a. the economic stimulus bill, and the Children's Health Insurance Program Reauthorization Act. Be sure to follow the link in the stimulus article to a detailed side-by-side chart comparing the key health provisions in the House, Senate and final versions of this bill. Other articles introduce you to the key reform protagonists in the Obama Administration and in Congress, and provide an outlook of what to expect as the health reform debate gets into full swing in the months ahead. Finally, this edition concludes with an interview of Larry Gage, a partner in our Washington, DC office who, as founder and president of the National Association of Public Hospitals, a member of the Carter administration health care team and on Capitol Hill, has participated in reform efforts dating back to the 1970s. Larry offers political and practical insight into the obstacles that the Administration and Congress face as they wrestle yet again with the Gordian knot of health care reform.

To keep you abreast of breaking health reform developments, Ropes & Gray will complement this newsletter with focused and timely Health Reform Alerts. We have also launched a Health Reform Resource Center, containing the latest versions of health-related legislation, committee reports, analyses and other key documents, as well as copies of past Health Reform Newsletters and Alerts. We hope you will find these resources valuable as you and your organizations prepare to navigate the extraordinary challenges and opportunities of this extraordinary year. As always, don't hesitate to call on me, on any of our subject area professionals or on your regular Ropes and Gray attorneys for additional information or analysis to ensure that you are prepared for whatever reform Washington serves up in the months ahead.



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A Down-payment on Health Reform: The American Recovery and Reinvestment Act of 2009

On February 17, 2009, less than a month after his inauguration, President Obama signed into law a $787 billion economic recovery package that includes over $100 billion in new health care investments. Although the law, the American Recovery and Reinvestment Act (Public Law No. 111-5), failed to gain the bipartisan support that the administration had sought, three Republican Senators played a significant role in shaping the legislation, cutting $100 billion from the package on the Senate floor (including several health care measures) and influencing the final compromise with the House.

The law's health care provisions not only respond to the current recession, but also comprise an early down-payment on health reform by Congress and the Obama Administration. The law includes a $19.2 billion investment in health information technology, $86.6 billion in Medicaid relief for states, insurance options for the newly uninsured, financing support for health-related capital projects, and funding for biomedical research. A detailed chart outlining the law's key health care provisions can be found here.

- **Health Information Technology (HIT)**. Expanding the use of HIT is viewed as a long-term yet essential building block of health care reform, one that is designed both to help rein in spiraling health care costs and to improve the quality of care. The law includes carrots and sticks to prod health care providers to invest in HIT, addresses concerns

with interoperability of HIT systems, and adds controversial new privacy standards for individuals' health information. Key elements of the HIT provisions include:

- *State Grants for Investment in HIT architecture* ($2 billion), providing loans to a broad array of health care providers and funds to integrate HIT into clinical education.
- *Medicare and Medicaid incentive payments to physicians, hospitals and clinics* ($17.2 billion). These payments could result in substantial funds for providers shown to be "meaningful electronic health record (EHR) users." Beginning in 2015, the bill will cut payments to providers who fail to embrace EHR.
- *Privacy and Enforcement*. The law makes significant changes to existing HIPAA privacy and security standards. Among the most significant are a new mandatory notification provision in the case of a breach of unsecured protected data, and the extension of HIPAA privacy rules to business associates of covered entities, who will be subject to the same civil and criminal penalties as covered entities for security requirement violations. The law also places restrictions on marketing and fundraising communications and permits states' attorneys general to enforce federal privacy standards.
- *EHR Interoperability Standards*. The law codifies the Office of the National Coordinator for Health Information Technology and requires the Office to develop HIT interoperability standards by the end of 2009.

- **Medicaid Funding to States**. The law significantly raises the federal share of Medicaid funding so that states can maintain their current Medicaid eligibility standards while absorbing continuing increases in their Medicaid rolls caused by the recession.
  - *Federal Matching Assistance Percentage (FMAP) Increases*. The law provides roughly $86.6 billion in new FMAP funding, split between a 6.2% across-the-board increase to all states and additional bonus distributions based on each state's unemployment percentage. To claim these FMAP increases, states may not restrict their Medicaid eligibility standards, and they must comply with requirements to pay providers promptly, including new prompt pay requirements that benefit hospitals and nursing homes.
  - *Temporary increases in federal funding for Medicaid Disproportionate Share Hospital payments* ($500 million). The law increases federal DSH allotments by 2.5% in each of 2009 and 2010.
- **Health Insurance for the Unemployed**. The law provides a 65% COBRA premium subsidy for up to 9 months for employees who lose their health insurance coverage due to an involuntary termination of employment through December 31, 2009 and who elect to continue that coverage under COBRA ($24.7 billion). The law also extends the Medicaid transitional medical assistance (TMA) program through December 31, 2010, and expands eligibility for the program ($1.3 billion).
- **Community Health Centers**. The law provides $1.5 billion for renovation and construction of community health centers (CHCs) and to enable CHCs to acquire HIT systems. The law also provides $500 million in new operating funds for CHCs.
- **Capital Support**. The law generally expands the marketability of tax-exempt bonds, including to commercial banks, which could be of particular assistance to certain hospitals ($3.8 billion).
- **Research Funding**. The National Institutes of Health is set to receive $8.2 billion for scientific research, $500 million for federal facilities renovations, and $1.3 billion for non-federal research facility renovations.
- **Comparative Effectiveness Research**. The law includes $1.1 billion for research into the comparative effectiveness of covered treatments. While the law removed an earlier Senate amendment to limit the research results to clinical applications, the conference report states that comparative effectiveness research is not intended "to be used to mandate coverage, reimbursement, or other policies for any public or private payor."
- **Prevention and Workforce Funding**. The law provides $1 billion for prevention and wellness programs. It also provides $500 million to address health care workforce shortages.
- **Blocking Bush Administration Regulations**. The law extends Congressional moratoria on three controversial final Medicaid regulations (relating to provider taxes, school-based administration and transportation costs, and targeted case management) through June 30, 2009, and blocks an additional Medicaid regulation related to hospital outpatient services. The law also reverses the phase-out of the Medicare hospital Indirect Medical Education (IME) adjustment factor for capital payments for 2009, blocks a Medicare payment cut to hospice providers, and makes technical corrections to long term care hospital Medicare payment provisions. Finally, lawmakers included a "Sense of the Congress" resolution that the Administration should not finalize three proposed Medicaid regulations relating to intergovernmental transfers, graduate medical education, and rehabilitative services.

Children's Health Insurance Program Reauthorized and Expanded

In an early demonstration of the change in direction of health care policy, on February 4th the 111th Congress passed and the president swiftly signed a revised and somewhat expanded version of legislation reauthorizing the popular Children's Health Insurance Program (CHIP). Similar legislation had been vetoed twice by President Bush, and on each occasion Congress failed to override the veto. The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) reauthorizes CHIP through September 30, 2013, expanding the program to provide health insurance to more than 4 million additional children. The estimated $33 billion five-year price tag of the law will be financed primarily through a tobacco tax increase. The final version of CHIPRA passed the Senate 66-32 and the House 290-135. Nine Senate Republicans and twenty House Republicans voted for the legislation.

While some Congressional Republicans opposed the law as a first step toward "government-run health insurance," Congressional Democrats and the Obama Administration view it as a first step towards their goal of universal coverage. The bill provides new CHIP funding to states through a revised formula intended to prevent chronic funding shortfalls experienced by some states under the old formula. CHIPRA also includes a number of significant programmatic changes:

- **Coverage of Immigrant Children**. Prior to CHIPRA, legal immigrants were precluded from enrolling in Medicaid or CHIP during their first five years of legal residence in the United States. CHIPRA allows states to waive this enrollment restriction for children and pregnant women whose lawful residence can be established. CHIPRA also eases Medicaid and CHIP citizenship verification requirements.
- **Dental Benefits and Mental Health**. CHIPRA requires states to provide dental coverage for CHIP enrollees and includes an option for states to use CHIP funds to provide dental coverage to underinsured children. The law also requires comparability in CHIP between mental health and medical and surgical benefits.
- **Coverage of Low-Income Children**. CHIPRA contains a number of initiatives to improve coverage and enrollment of low-income children, including a performance bonus system for states that adopt measures to streamline enrollment and an option for states to use findings from other agencies to establish eligibility ("Express Lane Eligibility").
- **Children at Higher Income Levels**. Addressing the controversy over whether the program should permit coverage of children at higher income levels, the bill allows states that currently cover or have plans to cover children above 300% of the federal poverty level (FPL) to receive enhanced CHIP matching rates for that coverage. However, any new states desiring to expand coverage will receive only the regular Medicaid matching rate.
- **Coverage of Pregnant Women**. CHIPRA sets out new prerequisites in order for states to cover pregnant women through CHIP. In particular, states must use Medicaid to cover pregnant women with incomes up to at least 185% of the FPL and must use either Medicaid or CHIP to cover children in families with income up to at least 200% of the FPL.
- **Coverage of Parents and Childless Adults**. CHIPRA phases out coverage of childless adults under CHIP. To continue to provide such coverage, states would have to do so through a Medicaid waiver. The bill permits states to continue existing programs covering parents through CHIP, but at a gradually reduced matching rate. No new states would be permitted to establish such coverage.
- **Premium Assistance**. CHIPRA contains a new state option to subsidize employer-sponsored health coverage that includes children. To qualify, the employer must contribute at least 40% of the costs of coverage, and the coverage must be actuarially equivalent to the CHIP benchmark plan. CHIPRA also amends ERISA to (1) establish gain/loss of Medicaid/CHIP coverage as a "qualifying event" for purposes of eligibility for employer-sponsored coverage, (2) require employers to share information about their group plans with state officials when assessing wraparound services, and (3) require employers to notify employees in writing of state Medicaid and CHIP assistance in plan disclosure documents.
- **Payment and Access Commission**. CHIPRA amends the Medicaid statute to create a new commission, the Medicaid and CHIP Payment and Access Commission (MACPAC), to review Medicaid and CHIP policies affecting children's access to covered items and services. MACPAC is loosely modeled on its Medicare counterpart, the Medicare Payment Advisory Commission (MedPAC).

Other CHIP-Related Developments

CHIPRA did not address a controversial August 17, 2007 directive of the Bush Administration that crippled state efforts to expand CHIP coverage. As subsequently restated and reinforced by a Centers for Medicare and Medicaid Services (CMS) memorandum issued on May 7, 2008, that directive prohibited states from extending CHIP eligibility to children in families with incomes over 250% of the FPL,

unless the states could first demonstrate that their programs already covered at least 95% of children in families with incomes up to 200% of the FPL. However, on February 4th, the day he signed CHIPRA, President Obama issued a one-page memorandum revoking the August 17, 2007 and May 7, 2008 directives, thereby lifting these CHIP restrictions in full.

Prohibition on Physician-Owned Hospitals Not Adopted

The initial House version of CHIPRA contained a provision authored by Representative Pete Stark (D-CA) that would have effectively prevented new physician investment in specialty hospitals. However, the Senate bill did not contain similar language; and, as it was this version that the Congress ultimately passed and sent to the president for signature, the Stark restrictions did not make it to final passage.

Who's Who: Old Hands, New Faces and Some Surprises as the Health Reform Team Takes Shape in Washington

The unexpected withdrawal of former Senator Tom Daschle as nominee for the twin roles of HHS Secretary and head of the new White House Office of Health Reform has left a major gap at the head of the Obama health care team, with rampant speculation on who and how to fill the void. Daschle's rare combination of policy expertise, Washington know-how, deep congressional ties and a close personal bond with the president uniquely qualified him to steer the president's ambitious reform agenda. With the failure of the Daschle nomination, many expect a more traditional model to emerge in which the HHS Secretary conducts the Department's programs and day-to-day business, while a health reform "czar" housed in the White House focuses on shepherding a reform bill through Congress.

Despite the Daschle setback, the new president has been assembling a health care team notable for its extensive ties to Capitol Hill and experience with previous efforts to reform the health care system. Obama's key health care appointments include:

- **White House**. *Jeanne Lambrew*, a highly respected health care policy "wonk" and co-author of Daschle's book on health reform, has been tapped as Deputy Director of the White House Office of Health Reform. Lambrew served in various health policy positions throughout the Clinton administration, at HHS, at the Office of Management and Budget (OMB) and in the White House, where she played a critical role in the design and enactment of the CHIP program. *Peter Orszag*, former director of the Congressional Budget Office (CBO), has been confirmed as Director of OMB, which will oversee Obama's regulatory agenda and play a key role in designing a health reform plan. As head of CBO, Orszag had advocated for health reform as a means of addressing what he views as the single largest threat to the nation's fiscal health—rising health care costs. And, not least, President Obama's Chief of Staff, former Illinois Representative *Rahm Emanuel* (D), is also a veteran of the Clinton White House health reform efforts and a long-standing advocate of expanded coverage for children.
- **Department of Health and Human Services**. Prior to Daschle's withdrawal, two former Daschle staffers were named to key HHS positions. *William (Bill) Corr*, Daschle's former Chief Counsel and HHS Chief of Staff under Secretary Donna Shalala, is awaiting Senate confirmation as Deputy Secretary. *Mark Childress*, another former Daschle aide, was named to be the Chief of Staff. Childress, along with several other HHS staff appointees with extensive Washington experience, has been working out of temporary HHS offices as they await the nomination and confirmation of a new Secretary. It is unclear how these appointments will fare under a change in leadership. And as of this writing, the administration has not named anyone to head the Centers for Medicare and Medicaid Services (CMS) or the Food and Drug Administration (FDA).

At the other end of Pennsylvania Avenue, there are many familiar faces at the helm of the key health care committees. In the Senate, Senators *Max Baucus* (D-MT) and *Charles Grassley* (R-IA) will continue to lead the Finance Committee as the Chair and Ranking Member. Senator *Edward M. Kennedy* (D-MA) remains at the helm of the Health, Education, Labor and Pensions (HELP) Committee with Senator *Michael Enzi* (R-WY) as Ranking Member. Senator Kennedy, whose presence will loom large over the health reform debate even during his absences from the Senate, has appointed a trio of HELP Committee members to spearhead working groups on various aspects of reform. Senator *Barbara Mikulski* (D-MD) will lead a task force on health care quality; Senator *Tom Harkin* (D-IA) will head a group focused on prevention and public health; and Senator *Jeff Bingaman* (D-NM) has been put in charge of health insurance coverage issues.

In the House, Representatives *Henry Waxman* (D-CA) unseated Representative *John Dingell* (D-MI) as Chairman of the House Energy & Commerce Committee, but has tasked the Michigan congressman to lead the Committee's efforts to draft health reform legislation. Representative *Joe Barton* (R-TX) continues to serve as Ranking Member. The committee shares jurisdiction with the Ways and Means Committee over parts of Medicare, and has sole jurisdiction over Medicaid and most discretionary health care programs. The powerful

Ways and Means Committee is presided over by Representative *Charles Rangel* (D-NY) with Congressman *Pete Stark* (D-CA) in charge of the Health Subcommittee. On the Republican side, Representatives *Dave Camp* (R-MI) and *Wally Herger* (R-CA) have assumed the ranking Republican positions for the full committee and health subcommittee, respectively. Ways and Means has jurisdiction over Medicare and tax issues.

What to Expect in Health Reform

Now that the CHIP program is reauthorized and the economic stimulus legislation is signed into law, the spotlight will shift to longer-term health system reform. Though President Obama's health reform team is without a leader, watch for the first outlines of the Administration's health reform plans in the preliminary fiscal year 2010 budget that he is expected to release in the next few weeks. Most observers expect the president to seek to avoid the mistakes of the Clinton-era reform efforts and provide only a broad framework for reform, leaving the details to Congress. And Congress has already begun the process.

In November 2008, Senator Baucus released a 98-page "white paper," *Call to Action: Health Reform 2009*, identifying priorities for reform. Although *Call to Action* purports to be a "vision and not a legislative proposal," it is an important starting point in the process. Senator Kennedy, for whom universal coverage is "the cause of my life" and whose leadership is viewed as key to success, has been working on legislation since last fall. The two Senators recently affirmed their commitment to enacting comprehensive health care reform this year. While there are some differences of opinion regarding timing, the underlying commitment is shared by key players on the House side as well. And Republicans in each chamber have designated their own task forces to work on reform. Despite their diminished numbers, Republicans can be expected to take full advantage of the powers of the minority in this process, particularly on the Senate side. Their mark will clearly be left on any reform package enacted into law.

The scope of reform is another unknown. While much attention is focused on how, and how much, to expand coverage, other complex and interrelated issues can be expected to factor into the debate. A few of these items include:

- Strengthening the employer-based insurance system through tax incentives, expanded use of Section 125 cafeteria plans and possibly penalties for larger employers who do not offer coverage;
- Establishing a health insurance "exchange" to provide more choice among private health plans and possibly a public health plan;
- Improving the quality of care by introducing "value-based purchasing," or pay for performance, into the Medicare program;
- Expanding the use of biogenerics by creating an FDA approval pathway for follow-on biologics;
- Adding a public plan under Medicare Part D and authorizing CMS to negotiate drug prices directly with pharmaceutical companies;
- Providing yet another "fix," be it temporary or longer term, to the Sustainable Growth Rate formula that leads to perpetual cuts in Medicare physician fee schedule payments (the current fix expires at the end of the year);
- Reducing payments to Medicare Advantage plans to the level of traditional Medicare;
- Controlling the cost of insurance through a government-sponsored reinsurance mechanism to protect insurers and employers from catastrophic costs;
- Reducing disparities in care and outcomes among racial and ethnic minorities; and
- Reforming entitlements, including Medicare, in keeping with the president's campaign pledge that he would do so.

To be sure, the political, fiscal and policy challenges ahead are not to be underestimated. Yet the president continues to reaffirm his intent to reform the health care system, and at this point the Democratic leadership in Congress is equally committed to the cause. Whether or not a bill becomes law, one thing is certain—expect to see a flurry of activity, a cacophony of debate and wide-ranging policy prescriptions in the weeks and months ahead.

An Interview with Larry Gage

For an insider's perspective, *Health Reform Matters* sat down with Larry Gage, a health care partner in Ropes & Gray's Washington, DC office. Over the years, Mr. Gage, the founder and current president of the National Association of Public Hospitals and Health Systems (NAPH), has been responsible for many Medicare and Medicaid reforms critical to the survival of safety net hospitals. Mr. Gage began his career as staff counsel to the Senate Labor and Human Resources Committee during the Nixon and Ford Administrations. During the Carter Administration, he served as Deputy Assistant Secretary for Health Legislation in the Department of Health, Education and Welfare under Secretary Joseph Califano. Thereafter, he left federal government and founded NAPH. Given his many years inside the beltway as a health care lawyer and policy authority, Mr. Gage offers unique insight into the politics of health reform.

Question: *How would you characterize "health reform" in the United States*?

LG: Health reform, which would create a framework under which all Americans would have access to health insurance, is a goal the nation has been pursuing (with great futility) for nearly half a century. Many have held the vision of true, universal coverage since Congress created Medicare and Medicaid in 1965, if not earlier. Unfortunately, politicians have been unable to agree on an acceptable approach to achieving this coverage.

Question: *What do you expect to see in the way of substantive health reform over the upcoming months and years*?

LG: Whatever we see will be a compromise. One likely compromise will be between those who favor a governmental, or single-payer, approach and those who would prefer to implement reforms through the marketplace and the private sector. President Obama's campaign proposals preserved significant aspects of the current employer-based system, while expanding and reforming the current Medicaid program. Senator Baucus' white paper similarly maintains the employer-based system and a role for private insurance companies. We have already seen compromising between the branches of government, as President Obama has been consulting and cooperating with Capitol Hill staffers while developing his health care agenda. This approach bodes well for achieving meaningful reform this time around.

Anyone interested in the likely substance of health reform should read (or at least skim) the reports recently released by the non-partisan Congressional Budget Office. The first, *Key Issues in Analyzing Major Health Reform Proposals*, analyzes the economic need for comprehensive health reform and how a combination of subsidies and mandates could achieve near-universal coverage. The second, *Budget Options Volume I*, analyzes the costs/savings of 115 health reform options. Health reform proposals likely will be developed with an eye towards these reports, as they provide ample data to both support and oppose many health reform initiatives. For example, the reports illustrate that two popular proposals, adopting health information technology and providing more preventative care, would lead to only modest reductions in overall costs or even increased spending over the next ten years.

Question: *Process-wise, how do you expect health reform to proceed? For example, will it be incremental, occurring through many separate pieces of legislation, or should we expect a single comprehensive bill?*

LG: Many observers who have been watching Congress develop and pass the stimulus and CHIP legislation, including myself, are of the opinion that we have already started down the incremental path. Those bills promise to close some important gaps in health coverage albeit temporarily. But they clearly represent a "down payment" on reform. And some aspects of the stimulus package - like the HIT infrastructure spending - are clearly laying a foundation for nationwide health reform efforts.

Question: *Could you share your thoughts on the current environment of health reform as compared with previous, largely unsuccessful, health reform efforts? What are the biggest obstacles?*

LG: The environment for reform is as optimistic now as it has ever been. In part, this is due to increasing Democratic control of both Congress and the White House. But reform will require compromises, both with Republicans and within the Democratic party. And there are ongoing issues that will need to be addressed, including the spiraling costs of current programs; increased payer demand for attention to quality, patient safety and improved "value"; and the significant disparities of practice patterns and costs across the country. Expanding coverage to some populations among the uninsured, particularly immigrants, will require engaging in broader societal debates, ones that already are quite contentious. Yet you can't have true reform without addressing these issues.

What is encouraging about the CHIP and stimulus bills is that they begin addressing many of these potential pitfalls. For example, HIT infrastructure spending should make it easier to assess provider quality and efficiency. And the CHIP legislation expands certain benefits to legal immigrants. Even the substantial concerns about entitlement growth is the subject of a bipartisan proposal, pushed by Senators Kent Conrad and Judd Gregg, to create a "base closing" type of commission that would present Congress with proposals to stabilize Medicare, Medicaid and Social Security and that could only be voted up or down, without amendment.

Question: *The American Health Lawyers Association identified "Healthcare Reform and the Uninsured" as the #1 issue for health care lawyers in 2009. How will the firm's clients be impacted by health reform*?

LG: Our clients cannot help but to be impacted by health reform. Health industry participants from providers to manufacturers would see greatly expanded opportunities to sell products if coverage is expanded for the uninsured and underinsured. Many others from financial institutions to employers to colleges and universities also should have opportunities to benefit from reform, both directly and indirectly. My colleagues and I are following the changes closely, and because of the breadth of our expertise, we can analyze and advise on all aspects and implications of the reform measures. At the same time, concern over cost, quality, efficiency, and sustainability will mean new rules and constraints on all players. Ultimately, everyone will need to be prepared to compromise for health reform to succeed. I believe that one of Ropes & Gray's strengths is our ability to analyze health reform

proposals as they are developed and to help our clients understand both the opportunities and potential drawbacks.

Question: *What are the prospects for bringing about health reform while in the midst of such a serious economic downturn?*

LG: The challenge is daunting, but we have to remember that some of our most cherished national programs like Social Security and unemployment insurance grew out of similar periods.