Morgan Lewis

alert

FDA & Healthcare LawFlash

www.morganlewis.com

# New Battlefronts in the Fight Over Healthcare Reform

**March 11, 2011**

In a previous LawFlash, "2011: Healthcare Policy in the New Congress,"[1] we predicted that full-scale repeal and replacement of the 2010 healthcare reform was unlikely and described a number of strategies that Republicans might pursue in an effort to undermine the new law. As opponents implement these strategies, the healthcare reform debate has grown increasingly complex and spread to multiple fronts. In Congress, with the debate on the federal budget deficit as a backdrop, Republicans are complementing their challenges to the healthcare reform law with budget criticisms. Meanwhile, Republican governors' calls for increased flexibility and state budget relief were met with a policy shift by President Obama that could challenge states to find their own methods of achieving universal coverage. In the courts, a multistate challenge to the healthcare reform law has created confusion that can likely only be settled by the U.S. Supreme Court.

## HEALTHCARE REFORM AND CONGRESS: FOCUS ON SPENDING

Implementation of the healthcare reform law requires significant up-front spending as new infrastructures, regulations, and federal offices to facilitate health system changes are established. In contrast, many of the money-saving provisions of the law do not take effect for years. This has given Republicans an opportunity to point to increased budget requests for the Department of Health and Human Services (HHS), Department of Labor (DOL), and Treasury Department as examples of wasteful spending and big government. At the same time, Republicans continue to criticize federal mandates in the law as unconstitutional and use congressional hearings to keep public attention on the law.

### 2011 Appropriations—Down to the Wire

Because Congress did not pass a budget or appropriate money through the regular budget process for FY 2011, the federal government has been funded at 2010 levels through a series of short-term continuing resolutions (CRs). With a government shutdown looming, President Obama signed the most recent CR into law on March 3. This measure funds the government for two additional weeks and expires on March 18. The CR cuts $4 billion from the federal budget for the remainder of 2011. Cuts include

1. Read the January 7, 2011 LawFlash, "2011: Healthcare Policy in the New Congress," available at http://www.morganlewis.com/pubs/FDA_LF_HealthcarePolicyinNewCongress_07jan11.pdf.

elimination of several nonhealth programs targeted by President Obama and elimination of $2.7 billion in 2010 earmark spending.

The two congressional chambers have put forward competing proposals to fund the government after March 18.

***The House***

The House's proposal for a long-term CR through the end of 2011, passed on February 19, includes deep spending cuts as well as a number of "riders" prohibiting spending to implement the 2010 healthcare reform law (also referred to as "de-funding" the law); these provisions block spending for the following areas:

- HHS funding to pay employees or contractors to implement the healthcare law
- IRS funding to enforce the individual mandate
- HHS, Treasury, or DOL funding to define the essential health benefits package as required for insurers to participate in insurance exchanges starting in 2014
- HHS funding to implement and enforce the medical loss ratio requirements for insurers
- Funding to pay the salary of any officer or employee of the Center for Consumer Information and Insurance Oversight
- Funding to pay the salary of any federal officer or employee engaged in implementing the healthcare law
- Funding to pay White House "czars," including the "healthcare czar"
- Any funding to carry out the healthcare law

House Democrats strongly opposed the de-funding riders and the elimination of $57.5 billion in non-defense discretionary spending relative to 2010 levels. Under the proposal, Labor-HHS-Education appropriations would be reduced by $18 billion relative to current funding levels. More than $400 million of these cuts would come from the Centers for Medicare and Medicaid Services (CMS), including the elimination of all funding for demonstration project grants.

***The Senate***

Senate Democrats released their long-term CR on March 4, which would cut 2011 spending relative to 2010 levels by approximately $4.7 billion. The Senate voted on both the Senate Democratic CR and the House-passed CR on March 9, and both measures failed to garner enough votes to pass.

The failure of both CRs to pass in the Senate sets the stage for compromise negotiations. President Obama signaled his willingness to be more involved in the next stage of talks by dispatching Vice President Joe Biden to initialize closed-door talks with congressional leaders on March 3. However, the vice president's exit for a trip to Eastern Europe days later led to accusations that the administration was not doing enough to foster serious talks. Republicans are preparing for the possibility that negotiations on a long-term CR will not be completed by the deadline and have signaled that another short-term measure, containing at least $2 billion in additional cuts per week, will be released on March 11. Senate Democratic leaders have expressed willingness to consider such a proposal.

If no negotiated funding bill is in place by March 18, a government shutdown would occur. A shutdown would have a significant impact on federal health programs, as all nonessential spending must cease. Although staff could be retained to process Medicare claims, capacity would be reduced and, in the case of a long-term shutdown, delays would be likely. Spending for federal contractors, disease monitoring,

health research, and staff to process most administrative tasks would likely be halted. HHS has not yet released any contingency plans or made public statements regarding procedures in the event of a shutdown.

## The 2012 Budget and Appropriations Process

On February 14, President Obama released his budget for fiscal year 2012. The budget proposal includes a five-year freeze on domestic discretionary spending, while including targeted increases in areas that the administration asserts are crucial investments in the country's future. On health policy, the president proposes eliminating funds for certain "low priority" programs and makes a number of legislative proposals aimed at cutting costs and improving program integrity in federal health programs. However, many fiscal conservatives criticize the president for not including deeper discretionary cuts and/or reductions in entitlement spending. House Republican leaders have indicated that their 2012 budget proposal will include entitlement reform, setting the stage for a public debate over Medicare, Medicaid, and Social Security spending.

The president proposes to increase spending for HHS by nearly $80 billion in 2012. This increase is designed to implement the 2010 healthcare reform law and the FDA Food Safety Modernization Act[2] as well as provide targeted increases such as $745 million for additional research at the National Institutes of Health. The budget also includes 19 new legislative proposals to reduce waste, fraud, and abuse and several additional cost-saving initiatives that produce a total of $62 billion in savings over 10 years.

If passed, many of the president's legislative proposals could significantly impact healthcare industry stakeholders. We have highlighted some of these proposals below:

### *Providers, Suppliers, and Hospitals*

- The Medicare sustainable growth rate (SGR) formula would be patched for two years, resulting in a 0% update to physician payments through 2014.
- Medicare providers that utilize "sweep accounts" for Medicare payments would be subject to reporting requirements and additional scrutiny.
- Providers and suppliers that do not update their enrollment records would be subject to civil monetary penalties.
- HHS would have additional authority to exclude providers from participation in federal healthcare programs if they are affiliated with an entity that has been sanctioned.
- High prescribers and utilizers of Medicaid prescription drugs would be subject to increased state monitoring.
- States would be further limited in their ability to use provider taxes.
- Power wheelchair claims would automatically be placed on prepayment review.
- Providers would utilize a new electronic claims-ordering system for high-risk services such as durable medical equipment (DME) and home health.
- Federal Medicaid reimbursement for DME would be limited based on Medicare's competitive bid rates.

2. Read about the FDA Food Safety Modernization Act in our December 23, 2010 LawFlash, "FDA Food Safety Modernization Act Greatly Expands FDA Enforcement Powers," available at http://www.morganlewis.com/pubs/FDA-LF_FoodSafetyModernizationActExpandsFDAEnforcementPowers_23dec10.pdf.

- Safety-net hospitals would face a 2021 rebasing of their disproportionate share hospital (DSH) payments that would result in a $4 billion reduction.

***Insurers***

- HHS would extrapolate the error rate from any risk adjustment data validation (RADV) audit to apply to a Medicare Advantage (MA) plan's entire MA contract.

***Pharmaceutical Manufacturers***

- Biologic drug manufacturers would receive seven years of exclusivity on new biologics, down from 12 years in the 2010 healthcare reform law. Brand-name manufacturers would also be prohibited from extending their exclusivity period by revising the innovator biologic.
- Brand-name drug manufacturers would be prohibited from entering into "pay for delay" agreements with generic manufacturers.
- Manufacturers would be required to repay states for improperly reported Medicaid-covered prescription drugs.
- Manufacturers would face broadly defined "regular audits" and "increased penalties" related to their compliance with Medicaid drug rebate agreements.

***Targeted Cuts***

The budget also slashes or eliminates funding for numerous smaller programs that are not considered priorities or have not shown "evidence-based results." For example, funding for the Children's Hospital Graduate Medical Education Payment Program is eliminated in favor of more money for primary care provider workforce training. Also, the Preventative Health and Health Services Block Grant Program at the Centers for Disease Control (CDC) would loose its entire $100 million budget, cutting 256 different grants. These cuts would not require a change in law, but do require the approval of congressional appropriators. The administration has proposed some new health grants and relies on other new programs from the 2010 healthcare reform law to replace the eliminated funds.

***Republican Scrutiny***

As hearings continue on the federal budget, Republicans will continue efforts to de-fund implementation of the healthcare law and reduce overall discretionary spending levels. Increased funding for HHS, DOL, and the Treasury Department to implement the healthcare law will be challenged as wasteful and fiercely targeted for elimination. Additionally, House Speaker John Boehner (R-Ohio) has stated that the House Republican budget proposal for 2012 will include entitlement reform, and Senate Budget Committee Chairman Kent Conrad (R-N.Dak.) has signaled a willingness to examine the issue.

**Debt Limit on the Horizon**

The federal government is limited by law in how much money it can borrow to pay its obligations. The Treasury Department estimates that U.S. borrowing may hit its "debt ceiling" between April 5 and May 31, 2011. The Treasury Department can implement some emergency measures to forestall a default on government debt, but delay could threaten the stability of U.S. bond markets and increase borrowing rates. Though the debt limit debate is unlikely to directly affect federal healthcare spending, conservative Republicans may leverage this issue in an attempt to secure additional concessions to undermine the healthcare reform law. Leaders in both parties have indicated that they have no desire for a fight over the debt limit. However, a January 12 Reuters poll indicates that 71% of the public oppose

raising the debt limit, and conservatives may be tempted to capitalize on that sentiment for political gain.

## FOCUS ON THE STATES

The annual meeting of the National Governors Association (NGA), held February 26–28 in Washington, D.C., brought with it a renewed focus on state implementation issues. Most significantly, the president announced his support for additional state flexibility in key areas of healthcare reform, and Republican governors made headlines by demanding greater flexibility to reduce Medicaid enrollment in the face of state budget crises.

### Obama to Governors: Can States Innovate Early?

President Obama used the opportunity of the NGA meeting to announce his support for amending the law to immediately allow states to opt out of key 2014 mandates, including the individual mandate to buy insurance and the employer penalties for failure to provide coverage. States would need to show that they could provide coverage and cost-sharing protections against out-of-pocket costs that are at least as affordable as federal mandates, cover a comparable number of people, and not increase the federal deficit. Current law does not allow this opt-out until 2017.

Early opt-out was introduced in February by Senators Ron Wyden (D-Ore.) and Scott Brown (R-Mass.) in the Empowering States to Innovate Act of 2011 (S. 248). The healthcare reform law currently allows states to opt out of federal mandates only in 2017, *after* requirements have been in effect for three years. S. 248 would allow opt out in 2014. This would exempt states from creating expensive systems to temporarily meet the federal mandates, removing a barrier to state innovation.

Through his support for this bill, the president has challenged Republicans to come up with alternative proposals that accomplish the same coverage goals as the healthcare reform law. Simultaneously, he has pleased liberals by allowing states like Vermont to more easily move toward a single-payer system. By offering flexibility, while defining it on his own terms, President Obama attempts to counter a key Republican argument that federal mandates are overly burdensome and state flexibility would lead to better outcomes. Congressional Republican leaders immediately opposed this approach, saying that flexibility was an illusion because states would still need to cover the same number of people with the same level of coverage as the healthcare reform law.

### Governors' Perspective

The governors were primarily focused on state budgets. In that context, many Republican governors argued that the Affordable Care Act's "maintenance of effort" (MOE) requirements for their state Medicaid programs were unworkable in the face of state budget crises. The MOE provisions prohibit states from reducing Medicaid eligibility levels. As pressure continues to mount on state budgets, governors may use the historically utilized tools of reducing spending by paying providers less and/or cutting back on nonmandatory benefits.

Some governors emphasized the need for greater flexibility to develop health programs that fit their states' residents. Mississippi Governor Haley Barbour, in testimony before the House Energy and Commerce Committee, requested unrestricted block grant funding in lieu of Medicaid to cover low-income residents in his state. Predicting that a state-run system would save money, Governor Barbour promised to accept half of the annual national increase in Medicaid spending in return for a block grant.

Other governors have signaled their desire to move Medicaid enrollees into private insurance through exchanges.

## LEGAL CHALLENGE—A REPRIEVE FOR THE ADMINISTRATION

On March 3, Judge Roger Vincent issued a stay in his ruling in a 26-state lawsuit to overturn the 2010 healthcare reform law. Disagreement regarding interpretation had led states to take varying approaches in implementing his original ruling. Alaska's governor, Sean Parnell, had initially interpreted the judge's decision to mean that states no longer needed to comply with the healthcare reform law, while other states took a more conservative approach. Following the stay, Governor Parnell indicated that Alaska, like most other states, would follow the law, pending appeal. Judge Vincent's stay order resolves uncertainty for the time being, and the Justice Department's recent move to file an expedited appeal means that this case may progress quickly through the courts. Due to split rulings by multiple courts, it is likely that a case involving the healthcare reform law's constitutionality will eventually reach the U.S. Supreme Court for final resolution.

## OUR COMMITMENT

The healthcare reform debate has entered a new and complex phase. "Repeal and replace" no longer fully captures the extent of Republican efforts to challenge the law as the battle moves to multiple fronts. Morgan Lewis will continue to closely monitor key legislation, agency releases, court rulings, and budget and appropriations developments. Uncertainty over the fate of healthcare reform combined with a steady flow of new federal regulations present significant risks for healthcare businesses. Policy decisions made daily can potentially alter the landscape of multiple sectors of the healthcare industry. Morgan Lewis is dedicated to both helping clients cope with the shifting environment and advocating for our clients' needs with federal agencies and Congress.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the authors, FDA and Healthcare partner **Joyce Cowan** (202.739.5373; jcowan@morganlewis.com) and legislative and policy analyst **Stephen Bloom** (202.739.5152; sbloom@morganlewis.com).

**About Morgan, Lewis & Bockius LLP**
With 22 offices in the United States, Europe, and Asia, Morgan Lewis provides comprehensive transactional, litigation, labor and employment, regulatory, and intellectual property legal services to clients of all sizes—from global Fortune 100 companies to just-conceived startups—across all major industries. Our international team of attorneys, patent agents, employee benefits advisors, regulatory scientists, and other specialists—nearly 3,000 professionals total—serves clients from locations in Beijing, Boston, Brussels, Chicago, Dallas, Frankfurt, Harrisburg, Houston, Irvine, London, Los Angeles, Miami, New York, Palo Alto, Paris, Philadelphia, Pittsburgh, Princeton, San Francisco, Tokyo, Washington, D.C., and Wilmington. For more information about Morgan Lewis or its practices, please visit us online at www.morganlewis.com.