

2011: Healthcare Policy in the New Congress

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Following tremendous changes for healthcare in the 111th Congress, stakeholders can expect continued focus on healthcare reform in the 112th Congress. The Obama administration and Democrats will be defending the 2010 healthcare reform law against Republican attempts to repeal or significantly alter the law. Republican focus on “repealing and replacing” the entire law is likely to give way to a more targeted approach, and other health policy challenges continue as issues in the 112th Congress.

On January 5, the House convened, with new Speaker of the House John Boehner (R-Ohio) setting the terms of debate for the coming year. The Speaker called for civility, open debate, and dialogue between the two parties. The Senate also convened on January 5, under the continued leadership of Senator Harry Reid (D-Nev.). Both leaders face a challenging time ahead as they fight for their parties’ priorities in a sharply divided Congress. The recent bipartisan legislation passed during the “lame duck” congressional session raised hopes for future bipartisan compromises, but achieving compromise could prove difficult in the wake of the divisive 2010 election and as the 2012 presidential race rapidly approaches.

New Majority—New Rules

At the beginning of each session of Congress, the House passes a resolution setting out the rules governing administration of the House. As the Republicans took control of the House this month, one of their first actions was to adopt new operating rules for the chamber. Several rule changes under GOP leadership will make the creation or expansion of government programs much more difficult and may affect the implementation of the new healthcare reform law. First, the “pay-as-you-go rule” (renamed the “cut-as-you-go rule”), requiring all new direct spending to be offset over the course of a *10-year* budget window, was modified to require offsets for *one-year*, *five-year*, and *10-year* windows. This rule is designed to stop Congress from passing laws that implement the benefits of a new program immediately while delaying payment for the program, sometimes by many years. Republicans have criticized the healthcare reform law for raising much of its revenue late in the budget window. House Republican leaders had stated earlier that they would like to go even further, requiring by rule that direct spending increases be offset with cuts rather than revenue increases. Though this language was not included in the House-passed rules package, the appetite in Congress for creating new revenue streams is low.

The new rules create an exception to the cut-as-you-go rule for legislation repealing or modifying the healthcare reform law. Therefore, the cost of repealing the law will not need to be offset with tax increases or spending cuts. On January 5, the nonpartisan Congressional Budget Office (CBO) estimated the cost of repealing the healthcare reform law to be \$230 billion over 10 years. Republicans disagree with the CBO's assumptions.

The Healthcare Reform Law

Repeal and Replace?

The new GOP House majority has announced that the House will vote on the Repealing the Job-Killing Health Care Law Act (H.R. 2) as one of its first orders of business. The repeal bill is expected to pass in the House; however, it will be nearly impossible for the GOP to pass the bill in the Senate and overcome a presidential veto. The vote is therefore largely symbolic, aimed at fulfilling the GOP's campaign promise to hold a vote on repeal. House Democrats have railed against the upcoming repeal vote, and the special exception in the budget rules, accusing Republicans of violating their pledge to reduce the deficit.

Also in furtherance of their campaign promise, House Republicans have introduced a resolution that instructs the chairmen in the four House committees with jurisdiction over healthcare issues (i.e., Education and Workforce, Energy and Commerce, Judiciary, and Ways and Means) to develop legislation proposing changes to existing law that will replace the healthcare reform law. The resolution outlines 12 goals for such legislation: eliminating certain policies and regulations in order to encourage economic growth, lowering healthcare premiums, allowing people to keep their existing plan, providing affordable coverage for those with preexisting conditions, reforming the medical liability system, increasing the number of insured Americans, protecting the doctor-patient relationship, increasing state flexibility over Medicaid programs, incentivizing personal responsibility for healthcare coverage, prohibiting taxpayer funding of abortions and providing conscience protection for providers, reducing spending and bureaucracy, and not accelerating the insolvency of entitlement programs or increasing taxes. The chairmen have not yet indicated their timelines or strategies for developing this legislation.

Federal Strategy—Beyond the Symbolism

Following the initial votes solidifying GOP commitment to repeal, Republicans are likely to pursue a multipronged strategy of targeted repeals, funding limitations, administrative oversight, and new legislative initiatives. These pressures could make implementation of healthcare reform more difficult, and change the way state and agency officials put the law into practice.

- *Attack the unpopular?* Failing outright repeal, the GOP will likely target specific, unpopular bill provisions for repeal through more focused legislation. For example, repealing the mandate for individuals to buy insurance, the Form 1099 tax filing requirement for business purchases above \$600, and the Independent Payment Advisory Board (IPAB) tasked with reducing Medicare growth could be just a few of the options put forward. Republicans believe they may succeed in stopping some of these new provisions because they are unpopular with the public. Again, piecemeal changes to the healthcare law should fall within the exception to House rules for "cut as you go" budgeting. So Republicans will not have to put forward offsets for these modifications. No such exception applies in the Senate. House Republicans plan to move these issues forward in hopes that enough Democratic senators will defect from their party to reach the

60-vote threshold needed to break a Democratic filibuster. Even if this effort proves impossible, Republicans can use those votes to target vulnerable Democratic members in 2012.

- *Starve the beast?* Through the appropriations process (by which Congress funds the activities of federal agencies), the GOP will attempt to limit or eliminate funding to implement the healthcare reform law. Congress did not complete the appropriations process for 2011 in the last congressional session, instead turning to a short-term continuation of 2010 funding levels. This “continuing resolution” expires in early March, setting the stage for an early battle between House and Senate leaderships over proper funding levels. The GOP will try to block funding for the Department of Health and Human Services (HHS), Labor, and the Internal Revenue Service (IRS) as these agencies seek to increase staffing for reform implementation. Speaker Boehner has stated that he believes funding for any new agency programs should come from cuts to other parts of the agency. With all of the new responsibilities placed on the executive branch, experts estimate that relevant agencies will need billions of dollars in increased funding over the coming years to meet the demands of the new law. In one extreme scenario, a stalemate over funding levels could lead to a government shutdown similar to the one that occurred 1995.
- *Increase accountability?* New Republican House committee chairs will likely call HHS Secretary Kathleen Sebelius, Centers for Medicare and Medicaid Services (CMS) Administrator Donald Berwick, Food and Drug Administration (FDA) Commissioner Margaret Hamburg, and other officials to Capitol Hill for regular hearings on healthcare reform implementation. Several incoming chairmen have indicated that they intend to conduct extensive oversight and investigation. Chairmen to watch include Fred Upton (R-Mich.) of the Energy and Commerce Committee, his health subcommittee chair Joe Pitts (R-Pa.), Dave Camp (R-Mich.) of the Ways and Means Committee, and his health subcommittee chair Wally Herger (R-Calif.). Darrell Issa (R-Calif.), chairman of the Committee on Oversight and Government Reform, will have broad subpoena power and has been vocal about his ambitious and wide-ranging oversight plans, which will likely include healthcare reform. Hearings could serve to highlight problems and tie up administration officials, although they could also serve to educate the public on lesser-known aspects of the bill. Democrats still hold committee chairmanships in the Senate, and administration officials are working with key committees to call their own series of hearings to highlight benefits of the new law.
- *What Republicans want.* In its Pledge to America, unveiled by Republican leaders on September 23, 2010, the GOP prioritized malpractice reform, the ability to purchase insurance across state lines, health savings accounts, and expanded access for those with preexisting conditions. Many Republican members, including Speaker Boehner and Minority Leader Eric Cantor (R-Va.) as well as newly elected members, have endorsed the pledge as an alternative to the policies of President Obama. The pledge advocated requiring insurance companies to cover people with preexisting conditions, expansion of state high-risk pools and reinsurance programs, elimination of lifetime and annual limits, and prevention of recessions—requirements similar to features of the enacted healthcare reform law.

In November 2010, now Budget Committee Chairman Paul Ryan (R-Wis.) and budget expert Alice Rivlin put forward a plan to reform Medicare and reduce spending. The Ryan-Rivlin plan recommends eliminating government-run coverage and replacing it with an annual government payment, which seniors could use to individually purchase insurance through a newly created “Medicare Exchange” insurance market. Ryan also advocates increasing the Medicare eligibility

age to 67. Though many conservative groups support this approach, it is unclear if these ideas will play a prominent role in the Republican's 2011 legislative agenda. Deciding to pursue these proposals could create division within the Republican caucus, as these dramatic changes may be unpopular with broad segments of the population.

States—A Divided Country

State governments already face serious challenges in meeting the requirements of the new healthcare reform law, such as streamlining Medicaid enrollment to expanded populations and setting up state insurance exchanges. With a number of new Republican governors and a shake-up of state insurance commissioners, the willingness and ability of many states to implement reform could further decrease. Should states fall behind on their mandated tasks, congressional Republicans could draw attention to these delays as evidence of the healthcare reform legislation's failure. Even in states where Republican officials have begun to set up insurance exchanges, their efforts may subject insurers to fewer restrictions, pressuring federal regulators to make tough enforcement decisions on which state standards comply with the law. In addition, a number of states have requested waivers from the new minimum medical loss ratio requirements specifying that 80% to 85% of insurer revenue must go to healthcare spending. Some state officials fear that implementing the regulations too quickly could cause many insurers to close their doors in the state. HHS could face pressure to grant waivers for other state requirements in the future. The administration's willingness to entertain such requests remains to be seen.

States are also pursuing judicial challenges to the healthcare reform law. Wisconsin is the newest state to join a 21-state lawsuit questioning the constitutionality of the new law's individual mandate to buy insurance coverage. Individual lawsuits questioning this mandate have resulted in more than a dozen dismissed cases, as well as one decision, in Virginia's Eastern District, that found that the individual mandate to buy insurance coverage violates the Constitution. Several appeals are pending, and many experts predict that the case will eventually reach the Supreme Court. If the requirement to buy individual insurance coverage is overturned in the courts, many of the popular provisions in healthcare reform, such as coverage of preexisting conditions, could become more difficult to implement.

Other Health Policy Challenges

Healthcare reform is not the only health policy issue that will require congressional attention in 2011. A number of less publicized issues will continue to play an important role in congressional actions, each of which will challenge lawmakers to reach common ground. GOP pledges to reduce spending will be tested, as some areas may require additional funding.

Food Safety

In the lame-duck session, Congress passed the Food and Drug Administration (FDA) Food Safety Modernization Act (H.R. 2751), which creates a sweeping overhaul of the federal food safety enforcement system. The bill, passed in response to various national food contamination crises, expands the FDA's authority to regulate food manufacturing, processing, and distribution facilities. More significant provisions include expanded food facility inspections and mandatory recall authority for FDA-enhanced manufacturing and recordkeeping requirements, and greater due diligence over imported

food. The bill passed both chambers of Congress with wide bipartisan margins. However, implementation will require an estimated \$1.4 billion in additional funding.¹

Medicare Physician Payment

Though a looming 25% cut to Medicare physician reimbursements was delayed by one year in the lame-duck session through passage of the Medicare and Medicaid Extenders Act (H.R. 4994), the issue of automatic cuts based on the sustainable growth rate formula (SGR) will need to be addressed next year. This year's delay, also incorporating the extension of a number of expiring Medicare and Medicaid provisions, came at a cost of \$15 billion, and the price tag continues to increase each year. A permanent repeal of the SGR is estimated to cost well in excess of \$200 billion. Republicans will need to find an approach to this issue in the context of their calls to reduce spending and reform entitlements.

Regulatory Enforcement

An important issue for the healthcare sector, not much discussed during the campaign, is the regulatory enforcement environment. In Medicare fraud enforcement, not much is likely to change. Increased penalties for fraud and the provision of additional funding for antifraud efforts have been bipartisan endeavors. Republican control in the House will not reduce the heightened antifraud enforcement environment. On the other hand, proposed FDA enforcement approaches to revive use of the *Park* doctrine for criminal prosecutions of individuals for FDA violations may be subject to questioning by House Republican oversight committees.

Biologics

Manufacturers of brand-name and follow-on biologic drugs await the release of proposed regulations from the FDA on a pathway to approval for "biosimilars." Outstanding questions remain, including how abbreviated the approval pathway will be, the need for clinical trials to establish similarity, the use of proprietary drug names for biosimilar products, and a requirement for generic companies to disclose proprietary information to branded drug makers for patent certification. Congressional leaders on this issue have already shown an active interest in monitoring FDA's interpretation through a recent letter to the FDA commissioner clarifying congressional intent. This issue is likely to remain contentious in the current congressional session. Many in the industry anticipate the need for legislation to change the patent certification disclosures, and expect congressional oversight hearings as regulations are implemented.

Medical Devices

Within weeks, the FDA is expected to announce specific reforms to the 510(k) process for FDA clearance of medical devices, in addition to an implementation plan and timeline. FDA will also identify those recommended reforms that will be deferred pending findings from the Institute of Medicine.

1. For more information on the FDA Food Safety Modernization Act, consult Morgan Lewis's 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, and its companion section-by-section summary, available at http://www.morganlewis.com/pubs/FDA_FoodSafetyModernizationActSummary_jan2011.pdf.

Depending on the type and extent of reforms, the medical device industry could face significant challenges and increased costs in pursuing future 510(k) filings. These issues will affect novel devices as well as enhancements to currently marketed devices. Members of Congress, including House Energy and Commerce Health Subcommittee Chairman Joe Pitts, have already expressed their concerns about this new process in letters to the FDA Commissioner regarding the potential impact on the medical device industry. We expect that Chairman Pitts's subcommittee will subject FDA to additional scrutiny in the coming session.

Stem Cells

An appeals court ruling on the legality of President Obama's 2009 executive order allowing federal funding for embryonic stem cell research is expected in 2011. Should the appeals court affirm a lower court decision to ban federal funding, the administration may have to cease all federal embryonic stem cell funding and destroy all embryonic stem cell lines in federal labs. Democrats tried and failed to enact legislation in the last session protecting embryonic stem cell research, and Republican opposition will block any such bill in the coming session. Additionally, Chairman Pitts strongly opposes President Obama's policy of using federal funding for embryonic stem cell research. He has stated that he intends to hold a congressional hearing on pluripotent adult stem cell research and use its findings to help address the Obama policy.

Our Commitment

Much remains to be seen in the coming months and years. The healthcare reform law will not disappear overnight. For the near future, Republicans will be bound by the basic framework of the new healthcare reform law, and Republicans and Democrats alike will face numerous choices and challenges around healthcare reform implementation and other health policy issues. Morgan Lewis will continue to closely follow legislative and regulatory changes as they unfold.

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

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