



ML Strategies Update

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Health Care Update

Cadillac Tax Repeal Garner Bipartisan Support; Prospects for Implementation Delay Increase

Last week, the Senate passed its reconciliation package by a vote of 52-47, sending it back to the House for approval and moving it one step closer to President Obama's desk. While the reconciliation measure faces a certain veto, Congressional efforts do not appear to be a complete exercise in futility, as some major reforms to the Affordable Care Act could be acted on in the coming weeks.

For example, an amendment to repeal the Cadillac tax, introduced by Senators Dean Heller (R-NV) and Martin Heinrich (D-NM), cleared the Senate by an overwhelming 90-10 vote. While it was merely a messaging point in the reconciliation package, this action on the Senate floor could signal potential action on the tax extenders front or as part of another end-of-year legislative vehicle, with negotiators meeting around the clock to hammer out an agreement. One potential outcome is that the Cadillac tax would be delayed two years from its 2018 implementation date.

A permanent repeal of the 40-percent tax on high cost health plans would take roughly \$90 billion away in federal revenue over the next 10 years. However, folding an implementation delay, as opposed to a permanent repeal, into a much larger extenders package, would likely provide political cover to weary Democrats while not altering the trajectory of the Affordable Care Act dramatically.

If the Administration and Congress can compromise regarding the Cadillac tax, it may be an indication that they are open to working with Congressional Republicans on other tweaks to the law in President Obama's final year in office.

The situation with end-of-year funding legislation remains fluid. ML Strategies will continue monitor this issue over the coming weeks.

News from the Hill

Medical Device Tax May Also Be Delayed: Word from the Hill is that the latest from the tax extenders negotiations is a two-year delay of both the Cadillac tax and the medical device tax. The 2.3 percent tax on the sale of certain medical devices has been in the crosshairs of Republicans since it was implemented in 2013.

Senate Special Committee on Aging to Host Drug Pricing Hearing: On Wednesday, Chairman Susan Collins (R-ME) and Ranking Member Claire McCaskill (D-MO) will follow up on the launch of their drug pricing investigation with a hearing into the sudden increase in off-patent drugs.

FDA Commissioner Facing Multiple Hurdles: Senator Lisa Murkowski (R-AK) is joining Senator Ben Sasse (R-NE) in holding the nomination of Robert Califf to head the FDA. Sasse's is awaiting answers from HHS regarding the failure of the co-op program, while Murkowski's hold has to do with the labeling genetically modified salmon.

Senate Telemedicine Legislation Could Be Introduced This Month: A bill to expand Medicare reimbursement for telemedicine may be introduced before the end of the calendar year. The Senate working group crafting the legislation, which includes Senators Brian Schatz (D-HI) and John Thune (R-SD), are hoping to fold the legislation into the Senate Finance Committee's chronic care initiative, which should be coming out early next year.

Democrats, Advocacy Groups, Call for Gun Research at CDC: A number of Democratic members of Congress, as well as Doctors for America, are calling on Congress to enable the CDC to conduct gun research. You can see a complete statement [here](#).

All Things ACA

Rep. Chaffetz Demands Documents Over Co-Op Failures: Last month, House Oversight Committee Chairman Jason Chaffetz (R-UT) demanded HHS hand over all relevant documents relating to the financial viability of co-ops, with a deadline of this past Friday. Stay tuned for further coverage this week as both chambers of Congress seek answers regarding the troubled program.

Senator Rubio Makes Another Run at Repeal of Risk Corridor Program: Last month, Senator Marco Rubio sent a letter to the leaders of both Chambers calling on them to repeal the risk corridors program as part of the Omnibus package. Senator Rubio should largely be credited for the dismantling of the co-op program, as he fought for a policy rider in last year's spending bill that barred HHS from tapping into other accounts to fund the temporary risk corridors program. Requiring the program to be budget-neutral severely hampered the Administration's efforts to support the co-ops, and could lead to higher premiums in states where co-ops are no longer operating. The risk corridor program was designed as a cushion for insurers during the volatile early years of operating in a new marketplace.

Numerous studies support the claim that increased competition in states has led to lower premiums; however, the collapse of 12 co-ops with no relief in sight could have implications going forward with respect to individual's premiums. In addition, providers in a number of states – Kentucky, Louisiana, Nevada, New York, Oregon, and Utah – could end up with unpaid bills as a result of the failed co-ops.

Wyoming Governor Calls for Medicaid Expansion in Budget: Wyoming has joined Louisiana and South Dakota as the latest batch of states considering Medicaid expansion. In Wyoming, the move would cover an additional 17,000 low-income adults. Only time will tell how the legislature responds to this move as they have rebuffed past efforts.

Prescription Drug Costs

Senate Finance Committee Releases Findings of Investigation into Gilead Sciences: Senators Ron Wyden (D-OR) and Chuck Grassley (R-IA) released the findings of their 18-month long investigation into Gilead Sciences pricing of Hepatitis C drugs Sovaldi and Harvoni. The Committee intends to explore ways to bring increased competition to the marketplace, as well as working to ensure the Medicare program is getting better value for Part D spending.

Senators Urge HHS to Allow Certain Drugs in From Canada: Senators Chuck Grassley (R-IA) and John McCain (R-AZ) are calling on HHS to increase the importation of prescription drugs from Canada and other countries for the benefit of U.S. consumers. As concerns grow regarding the costs of prescription drugs, members from both sides of the aisle are beginning to embrace this proposal. However, lacking enough support on the Senate floor during the reconciliation debate, Senator McCain was forced to pull his amendment on the issue.

American College of Physicians (ACP) Calls for More Generics: ACP is calling on physicians to prescribe generics more frequently, citing the fact that they are equally effective but a fraction of the cost.

Telemedicine Update

Supreme Court Passes on Telemedicine Case: The Supreme Court declined to hear a case which would have had implications for telemedicine providers treating patients absent an initial in-person exam. The issue will continue to be debated at the state level.

New Telehealth Bill Introduced: Senator Gardner (R-CO) and Senator Peters (D-MI) introduced companion legislation that would enable CMS to examine telehealth in its delivery reform models, as well as allow the Center for Medicare and Medicaid Innovation (CMMI) to include telehealth in its demonstration programs.

Regulatory Developments

FDA to Host Public Workshop on Medical Device Cyber Security: The FDA announced last week that will be hosting a forum in January titled, "Moving Forward: Collaborative Approaches to Medical Device Cybersecurity." The forum will discuss the complex challenges in addressing medical device cybersecurity concerns and its overall impact on the industry.

FDA Delays Finalizing Generic Labeling Rule: The FDA has opted to delay finalizing a proposal which would allow generic drug makers to update their safety labels when they learn of new safety risks. The FDA is continuing its review of the proposal, which will likely be published next summer.

HHS OIG Report Outlines Potential 340B Drug Savings: An HHS OIG report found that Medicare paid 58 percent more than the 340B prices set by statute in 2013. Mintz's own Ellyn Sternfield covered this issue over at the Health Law & Policy Matters blog, which can be found [here](#).

HHS, CDC Disagree on Opioid Prescription Guidelines: Last month, the CDC circulated a draft of its opioid prescription guidelines, calling for providers to prescribe non-opioid options when possible, in addition to using the lowest effective dose when opioids are necessary. The NIH Interagency Pain Research Coordinating Committee plans to file a formal complaint against the draft guidelines, which they argue could pose access issues to certain drugs when medically necessary. This discord could lead to delayed regulatory action on this front.

Hearings

House of Representatives

On Tuesday, December 8, 2015, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a hearing titled, "An Overdue Checkup Part II: Examining the ACA's State Insurance Marketplaces."

On Wednesday, December 9, 2015, the House Energy and Commerce Subcommittee on Health will hold a hearing titled, "Examining Legislation to Improve Health Care and Treatment."

United States Senate

On December 8, 2015, the Senate Committee on Health, Education, Labor, and Pensions will hold a hearing titled, "Opioid Abuse in America: Facing the Epidemic and Examining Solutions."

On December 9, 2015, the Senate Special Committee on Aging will hold a hearing titled, "Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines."

The Last Word

Scrutiny on Drug Pricing Continues: On the heels of the Wyden-Grassley investigation, the Senate Special Committee on Aging announced it will be holding a hearing titled, "The Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines." The hearing will investigate incidents of abrupt or dramatic price increases in prescription drugs that are no longer protected by patents. This will be the first in a series of hearings the Senate Aging Committee will conduct.

The committee will hear testimony from Dr. Gerard Anderson, a professor of Health Policy and Management at Johns Hopkins University, Dr. Erin Fox, Director of the Drug Information Service and an Adjunct Associate Professor at the University of Utah, Dr. David Kimberlin, Professor and Vice Chair for Clinical and Translational Research at the University of Alabama, and Mark Merritt, President and CEO of Pharmaceutical Care Management Association.

If you would like ML Strategies complete coverage of this hearing, please respond to Erin Morton at EKMorton@mlstrategies.com. We will continue to closely monitor this issue and will be publishing a special report in the coming weeks, which will cover a number of the Congressional investigations as well as other relevant issues in this space.