



ML Strategies Legislative Update

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ML Strategies 2017 Outlook: Health Care

If Congress chose to do nothing other than what it absolutely has to address, it would have three very consuming legislative policy issues on its plate in 2017: the various User Fee Acts (UFAs) reauthorization, the reauthorization of the Children's Health Insurance Program (CHIP), and the expiration of the Medicare outpatient therapy caps exceptions. We will touch on all three issues below, as they will certainly be addressed in some form or fashion in 2017, but the Affordable Care Act (ACA) stands atop the health care agenda for the incoming administration and a GOP-controlled Congress is eager to initiate what has become its holy grail – repeal of the ACA.

The first step in this process was passage of [S.Con.Res. 3](#), a budget resolution last week by the House and Senate which included reconciliation instructions targeting the ACA.

Executive Branch Agenda

President-elect Trump ran on a health care platform to “repeal and replace” the ACA. While he has signaled that he will keep certain popular provisions – such as coverage for preexisting conditions – it is clear that Trump and the Republican-controlled Congress will move to overhaul the current system. In addition to repeal, here's a rundown of health care priorities identified by the incoming Administration:

- 1) Pro-life policies related to health care coverage and abortion.
- 2) Reform the Food and Drug Administration (FDA) with a greater focus on patient and innovative medical products.
- 3) Modernize Medicare to meet the challenges of an aging population.
- 4) Maximize state flexibility in administering Medicaid.

Most of the agenda outlined by the incoming Administration appears aligned with Speaker Paul Ryan's A Better Way, the Republican policy [document](#). Congressional Republicans will likely be in the driver's seat for most of the priorities above, although President-elect Trump has been outspoken on a number of issues, such as reigning in prescription drug costs, which could run counter to a conventional Republican platform.

President-elect Trump is likely to buck his own party on certain drug pricing issues, namely by supporting a measure to allow Medicare to negotiate drug prices, a proposal long opposed by Republicans. He is also floating the possibility of tying drug pricing proposals to ACA-repeal legislation, although details remain murky at best. Trump's early attacks on PhRMA are a strong indication that he intends to follow through on his statements to tackle drug pricing, endorsing proposals that could put his GOP colleagues in a difficult position.

Additionally, two of President-elect Trump's Administration nominees – Rep. Tom Price (R-GA), who was tapped to lead HHS, and Rep. Mick Mulvaney (R-SC), who will lead the White House Office of Management and Budget – are strong advocates for Medicare and Medicaid reform, despite Trump vowing not to touch Medicare or Social Security on the campaign trail. GOP leaders, including Speaker Paul Ryan, continue to suggest that Republicans will attempt to convert Medicare from a fee-for-service model to a more fixed per-patient model.

Speaker Ryan has spoken repeatedly of the urgency around long-term Medicare funding. He has championed ideas such as premium support, although it is highly unlikely that any Democrats would go along with such a proposal. Other reforms that could be pursued include raising the retirement age or implementing means testing.

Republicans would be taking considerable risks including Medicare reform in any reconciliation package, and early signals suggest Senate Republicans are not interested in pursuing such a strategy.

Key Trump Administration Political Appointees

Trump's two top Administration officials will likely play key roles in the post-ACA health care world. Rep. Tom Price (R-GA), who is set to lead the Department of Health and Human Services (HHS), is one of the leading Republican voices on health care in the House of Representatives. While his alternative to the ACA, The Empowering Patients First Act, has not been fully embraced by the party, it offers a glimpse into his view on health care reform and areas of overlap with Speaker Ryan's A Better Way.

Mr. Trump's pick to lead the Centers for Medicare & Medicaid Services (CMS), Seema Verma, is known for her work on Indiana's Medicaid program, in addition to numerous other Governor's offices, State Medicaid agencies, and State Departments of Insurance. Her appointment sends a strong signal that state flexibility for Medicaid will be a priority, especially after the Obama Administration was more restrictive when it came to state Medicaid flexibility.

Lastly, President-elect Trump is reportedly considering a handful of candidates to lead the FDA. Dr. Scott Gottlieb, who is already assisting the transition, is reportedly a top contender having previously served numerous roles at the FDA, including deputy commissioner for medical and scientific affairs. Prior to joining the FDA, he was a senior policy advisor to the administrator at CMS.

President-elect Trump recently announced some key staff for the White House Domestic Policy Council. Former HHS staffer Andrew Bremberg will be the new director of the policy council and Paul Winfree, longtime Senate Budget Committee staffer, will be deputy director and director of Budget Policy. Katy Talento, who has spent over a decade in the US Senate, will be a member of the health policy division of the council.

Potential Legislative Activity

In many ways, 2017 will be a year for Republicans to put aside the political rhetoric and articulate a public policy view that is workable. This won't be easy; in fact it has proven to be nearly impossible, if the past eight years have been any indication of the prospects for finding a unifying GOP health care platform. Still, the GOP will own the numbers, and with it, the problems associated with the health care law, and will be tasked with making health care more affordable.

This started with the passage of the budget resolution in the House and Senate. A budget resolution is the first step in the reconciliation process. To initiate reconciliation, the budget resolution will include instructions for various committees to meet certain budget targets. In S.Con.Res. 3, the language sets forth instructions for four authorizing committees to achieve cost savings of up to \$1 billion. The Senate Committee on Health, Labor, Education, and Pensions and the Senate Finance Committee will submit their legislation by January 27, 2017. The House Energy and Commerce Committee, as well as the House Committee on Ways & Means, are expected to markup legislation at the end of January, meaning the House and Senate could finalize a package to send to the President by mid-to-late February.

This assumes Republicans can articulate a path forward following repeal of the ACA that keeps stakeholders at the table, in addition to a smooth confirmation process for Rep. Tom Price. Stakeholders need confidence that the path forward on health reform will provide some stability, or they could move to slow the repeal-by-reconciliation process.

Republicans, first and foremost, must avoid disrupting the insurance market. That can start with collaborating with governors, insurers, and other stakeholders. That process is assuredly well underway, but a process that cannot be taken for granted. Repealing the individual mandate effective 2017, for example, could send the insurance marketplaces into chaos, with fewer insurers and even higher premiums, creating a 2018 plan year that would be politically and economically devastating. While we are beginning to see signs that some members recognize this dilemma, active engagement regarding the consequences will be needed to reach a broader consensus.

The ACA is already interwoven into our health care system. As such, Republicans have an opportunity to target changes to Medicare and Medicaid. However, changes to either program would prompt swift opposition and outrage. Of the two, changes to Medicaid has the clearest path forward as the Administration could grant considerable flexibility to state Medicaid programs via the waiver process. Work requirements, continuation of coverage requirements, and other proposed initiatives that force beneficiaries to have "skin in the game" should now be taken seriously.

An early bump in the road is signals from a handful of Republican governors that repealing the law without a replacement would be disastrous. This week, Republican governors and lieutenant governors from 10 states are meeting with Republicans from the Senate Finance Committee to discuss the ACA and the future of Medicaid. States that expanded Medicaid – over half led by Republicans – would face serious financial consequences if funding were halted or dramatically altered.

The key word here is *transition*. The next four years will be about transitioning away from Obamacare towards a more conservative view of health care, one that will undoubtedly be rooted in key reforms made by the ACA. If Republicans go it alone, they risk jeopardizing what capital they have to reform the health care system. Given this process is set to pick up dramatically once Mr. Trump takes office, it is important stakeholders are engaged at every turn.

Other Issues of Importance

UFA reauthorization: The user-fee acts authorized by Congress gives the Food and Drug Administration (FDA) the authority to collect user fees which are used to provide greater resources to the FDA in its review of drug and device applications. The UFA reauthorization encompasses prescription drugs (PDUFA), medical devices (MDUFA), generic drugs (GDUFA), biosimilars (BsUFA), Animal Drugs (ADUFA), and Animal Generic Drugs (AGDUFA). The process to reauthorize UFAs, as it is collectively known, has been underway since 2015. The process will pick up rapidly with negotiations this spring and summer, culminating in an expected five-year reauthorization.

This delicate public-private process of negotiating the activities the user fees will be statutorily dedicated to is one that could bottleneck other unrelated congressional issues, as well as become a vehicle for other health care related initiatives. At issue is timing. A failure to reach a timely agreement can lead to job furloughs at the FDA. IN FY2016, user fees accounted for nearly 42 percent of the FDAs total program level. Absent FY18 funding, which begins October 1st, hundreds if not thousands of jobs could be in limbo.

For stakeholders, the door is open for early engagement. However, engagement and advocacy will only become more challenging as we get closer to October 1st, when the spotlight is on the FDA, stakeholders, and policymakers to secure an agreement.

Children's Health Insurance Program: CHIP was created to help states provide health care coverage to low-income children up to age 19 whose families fall above the Medicaid eligibility threshold but are unable to afford private insurance. In recent years, the percentage of uninsured children has steadily declined, in large part due to the better benefits at lower costs it can provide compared to the exchanges. However, viewing CHIP through the lens of imminent ACA repeal, policymakers will be forced to question whether coverage variations should continue past 2017.

CHIP is one of the last remaining vehicles for policymakers to attach health care initiatives to its reauthorization. For years, the process of repealing the sustainable growth rate (SGR) – or delaying its imminent repeal – created a vehicle for other initiatives to advance. CHIPs latest extension, which expires September 30th, 2017, was last extended through the actual repeal of SGR and the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

CHIP will now assume the role of the vehicle, setting the stage for a fierce debate over the future of the program amid questions about health care delivery.

Medicare Outpatient Therapy Caps: Medicare beneficiaries currently have a cap on outpatient physical therapy, occupational therapy, and speech-language pathology services. MACRA extended the therapy cap exception process through December 31, 2017, meaning the exception will have to be extended this Congress, or perhaps the cap will be repealed. Sen. Ben Cardin (D-MD) and Sen. Susan Collins (R-ME) introduced a bill last Congress to permanently repeal the cap, which garnered 36 bipartisan cosponsors.

The deadline on addressing outpatient therapy caps poses another potential vehicle for health care stakeholders to advance issues that may otherwise be lost in the shuffle.

House v. Burwell: The case of *House v. Burwell* alleges that the Obama Administration wrongly spent billions of dollars in the past two years to reimburse insurance companies for providing subsidies for health coverage to low- and moderate-income consumers. These payments are known as "cost-sharing reductions."

The cost-sharing reductions are designed to lower deductibles, co-pays, and out-of-pocket costs for millions of people, and are expected to total \$9 billion in 2017. If these payments were to stop, Congress would likely be forced to act to stem the financial consequences for insurers, hospitals, and individuals who benefit from the subsidies.

In May, U.S. District Judge Rosemary Collyer upheld the House's claims, but did not take immediate action, opting to put her decision on hold to allow for it to be challenged. The D.C. Court of Appeals is expected to rule whether or not to uphold Judge Collyer's decision this year.

If the decision is upheld, or the incoming Administration drops *its* (the Obama Administration's) challenge to the Collyer decision, the judgement would do incredible harm to the insurance market and likely compel Congress to act.

Telemedicine: In times of intense partisanship, Congress may look for unifying issues that it can work together on. One such issue is telemedicine, namely the CONNECT for Health Act. The CONNECT for Health Act, introduced by Sen. Brian Schatz (D-HI), had 18 bipartisan cosponsors in the previous Congress. In a space where stakeholders are highly engaged, this is an area where both the House and Senate could look to make advances after the long-awaited introduction of the Sen. Schatz-led bill.

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