



ML Strategies Legislative Update

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## ML Strategies Outlook: Health Care

*"We're going to have to get back next year at entitlement reform, which is how you tackle the debt and the deficit" Paul Ryan, Speaker of the House.*

Happy New Year!?!

2017 was an eventful year for health care, and now we can all sit back and relax with very little concern that major health policy will be on the table in 2018. Right? Why must Speaker Ryan ruin our narrative?

Ryan specifically signaled out the 'health care entitlements,' meaning that Medicare and Medicaid could well be on the table. Entitlement reform has been a Republican priority for years, and a personal priority of Speaker Ryan long before his ascent into Leadership. Still, heading into midterms, is it viable that Republicans could launch a serious effort to reform entitlements?

In 2010, Democrats faced a scenario worth remembering. They devoted much of 2009 to health care reform, having passed the Senate ACA package in late December by a party-line vote, 60-39. The January special Senate election of Scott Brown of Massachusetts, who in large part ran in opposition to the ACA, meant that the Democrats lost their filibuster-proof majority, and the bill would have presumably failed to move forward should it need another Senate vote. Instead, then-Speaker Pelosi and Majority Leader Reid, despite waning poll numbers, pushed ahead and forged a path forward to secure passage of the ACA at all costs.

The resulting process involved passing a bill that was far from preferred by many Democrats and replete with haunting drafting errors some of which would wind up as issues before the Supreme Court. The unpopularity surrounding the bill and the legislative process cost Democrats 63 seats in the House of Representatives in the 2010 midterms, and Republicans picked up six Senate seats.

What Pelosi and Reid did basically was put aside the political consequences to secure passage of a historic piece of legislation. They rallied the troops to do what was right knowing an opportunity to do so might never come again. In other words, a political suicide pact.

Conventional wisdom would suggest that taking on entitlement reform in 2018 is nonsense. The ability to unite the Republican Party on entitlement reform is unlikely. The GOP did not fare well in 2017 elections, barely squeaking out victories in previously safe seats, while losing seats at the state level, and witnessing the energy on the left in Democratic gubernatorial victories in Virginia and New Jersey. The most recent upset victory for Alabama Senator-elect Doug Jones if nothing else has serious consequences for 2018 with the Republican Senate majority now sitting at 51-49. Do you really go all in on entitlement reform in an election year?

Don't reflexively rule it out. Speaker Ryan could go down a similar path on entitlement reform as the Democrats did in 2010, risking their already endangered majorities to take one last shot at passing significant entitlement reform that has eluded Republicans for decades. Much as was the case when the Democrats finished work in 2010 that they started in 2009, Medicaid was on the table extensively in 2017. They wouldn't be starting from scratch. Leader McConnell may not be there today, but if he saw momentum from the House, he'd be hard-pressed to refuse. Assuming entitlement reform can't happen will leave you unprepared if the reform effort does gain traction.

Remember this: from introduction of the American Health Care Act to the moment it was perilously close to passing the House was a mere 18 days.

While a legislative push on entitlement reform is something that we can in some respects prepare for, it's much more likely we see regulatory action on both Medicare, Medicaid, and the Marketplace. Additionally, the Department of Health and Human Services (HHS) will have a new Secretary, Alex Azar. His previous roles were in the pharmaceutical world, so we will be watching how his experience shapes his policies for 2018 and beyond.

In the following preview we look at what to expect in 2018 for Medicaid, Medicare, the Marketplace, and FDA. And it's hard not to be a little anxious about what lies ahead.

## **Finishing 2017**

Much to our chagrin, health care in 2018 begins with finishing 2017. Congress left town without addressing the CHIP-minibus. While we believe the pressure to address issues the CHIP-minibus in January will be significant, with CHIP extended to March, Congress may wait until then to address the CHIP-minibus. Stakeholders dependent upon those provisions will continue to suffer the anxiety of the uncertainty as we continue to wait. Also, the market stabilization provisions that were promised to Senator Collins will also be up first thing in 2018. With another government funding deadline (January 19) staring Congress in the face upon their return, there will be an opportunity for early action on outstanding 2017 policies.

## **Medicaid**

As noted above, Republicans can decide in 2018 to continue pursuing Medicaid financing and structural reforms as we saw throughout 2017. We will likely continue to see and hear proposals on capping Medicaid spending and rolling back Medicaid expansion. Like it or not, Republicans 'normalized' these types of payment reforms in a way that had never been done before. However, the decision to pursue this path comes with consequences. Medicaid advocacy played a significant role in slowing the effort to repeal and replace the ACA. While the House could easily

take up Medicaid again, the margin Republicans have in the Senate just got smaller with the Alabama election, making it increasingly difficult to get any type of major Medicaid reform passed.

However, one thing that is for certain is that the Administration and state Medicaid agencies have significant authority and flexibility in changing and restructuring the Medicaid program without legislative action. Specifically, they can make major changes to the Medicaid program through waivers.

Back in March, former Secretary Price and Administrator Verma sent a [letter to the Governors](#) indicating that CMS is open for business on Medicaid reform. They would welcome state-based solutions as well as streamlining the waiver approval process. They also noted in this letter that they would approve Section 1115 waivers that would tie work requirements to the Medicaid program. This was reiterated by Administrator Verma at the [National Association of Medicaid Directors \(NAMD\) conference this November](#).

The Obama Administration previously denied specific parts of the waiver that included provisions such as work requirements, premiums for beneficiaries below 100% of the Federal Poverty Line (FPL), and lock outs for failure to timely renew eligibility. Most recently, the Trump Administration has [approved Iowa's Section 1115 Medicaid waiver, known as the Iowa Health and Wellness Plan](#). New to this waiver is allowing the state to eliminate retroactive coverage for nearly all new Medicaid applicants. (Pregnant women and infants younger than one year old are not subject to this change.) However, it is important to remember that the Arizona, Indiana, and New Hampshire 1115 waivers also included a provision similar to this and were approved by the Obama Administration. The major difference is that the Arizona, Indiana, and New Hampshire waiver's limit on retroactive coverage did not apply to seniors and people with disabilities, while Iowa's newly approved waiver does. Regardless, limits on retroactive eligibility is likely to be further explored by other states.

For 2018, we will be watching the status of the pending waiver 1115 waivers. Of note, pending waiver applications from Arizona, Arkansas, Indiana, Kentucky, Maine, Utah, and Wisconsin include a [work requirement provision](#). The Indiana, Maine, Utah, and Wisconsin waivers include a time limit on how long certain beneficiaries can receive Medicaid coverage. The Wisconsin waiver also includes a drug testing requirement. The Massachusetts 1115 waiver, which is also pending, is seeking to address the increasing drug costs in the Medicaid program by establishing a formulary to limit the number of medicines the state has to pay for. If these provisions are approved it is likely other states will submit waivers to implement these or similar provisions.

Remember, it takes two to tango. When CMS attempts to make changes that force all states to make changes in their Medicaid programs, it is highly controversial. Changing Medicaid through waivers involves states voluntarily working with CMS. Therefore, the battle over waiver changes will be fought out state by state. We firmly expect these battles to include litigation challenging CMS authority to approve the waivers.

## **Medicare**

The nomination of Alex Azar to serve as HHS Secretary marks a shift into the regulatory arena for this Administration on health care. Azar is well-respected, has served in high-level positions at HHS, has a strong conservative track record, and has the institutional knowledge that matters to Republican

lawmakers. Mr. Azar helped implement the Medicare Part D prescription drug benefit, as well as oversaw other regulatory efforts while Deputy Secretary during the George W. Bush Administration. As we shift to the new Secretary we will also see the Administration's first real take on the annual Medicare payment policies updates. The Administration has significant leeway over the direction and evolution of Medicare payment policies. Given that implementation of MACRA is well underway, we should expect additional action as more information and data becomes available. In 2018, especially as we look ahead to 2019, we will see the Trump Administration's direction on Medicare payment policies and to what extent delivery system reform impacts spending.

In November 2017, CMS issued a final rule addressing changes to the Medicare physician fee, the Medicare Shared Savings Program, and in a separate rule the Quality Payment Program (QPP). The QPP allows eligible clinicians to participate through one of two pathways: the Advanced Alternative Payment Models (APMs) or through the Merit-based Incentive Payment System (MIPS). While both MIPS and APMs have received their fair share of criticism, APMs have considerably more buy-in and the current Administration has expressed open interest in building on successful models.

Given that many of the Medicare payment models are managed through the Center for Medicare and Medicaid Innovation (The Innovation Center), we can expect new "innovations" coming out of CMS. CMS recently [announced](#) its intention to reimagine the Innovation Center's guiding principles and what programs will continue, expand, or be eliminated moving forward. While CMS did not put forth a timetable, CMS anticipates greater participation in APMs moving forward. In other words, CMS is exploring opportunities to increase participation in these models in a way that fit the Agency's view of health care delivery.

MIPS' future is far less certain following the Medicare Payment Advisory Commission (MedPAC) finalizing proposed recommendation to repeal MIPS. While this is solely a recommendation, it carries weight at both CMS and on Capitol Hill. MedPAC argues that MIPS is flawed in its evaluation methods as well as it contains burdensome reporting requirements. While the program is relatively new, and some expect providers to realize the benefits of the program as soon as 2019, one can expect Capitol Hill to consider and discuss alternatives.

As noted above, Medicare is facing threats from Capitol Hill and within the Administration. Medicare spending was 15 percent of total federal spending in 2016, and is expected to increase over the next decade. The financing challenges facing Medicare over the coming decade are significant and will need to be addressed. Some of what was outlined above fits into addressing that problem, insofar as the programs achieve appropriate savings. As long as there is Republican control in Congress, reconsideration of the Medicare programs financing structure will remain near the table if not on it.

## **Marketplace**

Has coverage in the Marketplaces created through the ACA succeeded or failed? 8.8 million Americans are estimated to receive coverage through Marketplace plans in 2018 according to the most recent enrollment data. When state-based enrollment is counted, the total number may grow to 12 million. But the most recent data shows that 12.7 million people have an exemption from the mandate to purchase coverage and 6.5 million people chose to pay the mandate rather than

purchase coverage. Setting aside labels like 'success' or 'failure,' it is clear that the ACA is not covering as many people as intended. There are actions that could be taken to improve the Marketplace. Repealing the individual mandate is not one of them.

The tax reform bill that passed Congress in the closing days of 2017 included repeal of the individual mandate. The repeal of the individual mandate will likely not affect plan year 2018 enrollment. Plan year 2018 enrollment ended, generally, on December 15<sup>th</sup>, and we are waiting on the numbers to come in. The real impact of the repeal will be witnessed beginning in 2019.

[CBO estimates](#) that approximately 13 million people will lose health insurance coverage as a result of repealing the individual mandate in the Senate's tax reform bill. In its analysis, CBO determined that five million people currently on Medicaid, five million people receiving coverage through the Marketplace, and about two million people receiving coverage via an employer will drop coverage due to the repeal of the individual mandate.

However, the CBO's Medicaid numbers are difficult to understand. Five million people losing coverage through Medicaid raises eyebrows – at least our eyebrows. If someone has been getting Medicaid for the last several years, would they necessarily exit? Are the people most likely to drop off non-utilizers? Again, lots of legitimate questions about the Medicaid impact.

On the Marketplace side, there are other concerns beyond repeal of the individual mandate that could have negative effects. These negative effects of repeal of the individual mandate could be compounded by the administration's move to allow for association health plans (AHP) and short term limited duration insurance (STLDI) plans.

The Administration is set to publish proposed regulations and/or guidance on AHP and STLDI in response to the [October 12, 2017 Executive Order](#). AHPs will potentially allow employers to form groups that allow for health insurance coverage across state lines. STLDI plans are not subject to ACA standards, thus offering less coverage and likely to be cheaper than the current qualified health plans (QHPs). The Secretary of Labor is expected to publish the proposed regulations or guidance in relation to AHPs, while the Secretaries of the Treasury, Labor, and Health and Human Services are expected to publish the proposed regulations or guidance in relation to STLDI.

How these plans affect the Marketplace depends on the details of the final regulation. However, a theory is that, absent the individual mandate to buy comprehensive coverage, individuals currently on the Marketplace would likely leave their current plans for a STLDI plan, which would be cheaper but offer less coverage. This would leave only the sickest people on the Marketplace; leading to a death spiral, which would be further accelerated by the repeal of the individual mandate where people will just drop coverage all together. For AHPs is less clear how these will affect the Marketplace, since it largely depends on their structure and uptake.

However, as noted above, 19.2 million people either pay the penalty or file an exemption from the individual mandate. We can expect that these individuals, currently out of the Marketplace, will be some of the first to join STLDI. The IRS reports that, in 2015, 12.7 million people claimed one or more health care coverage exemptions to avoid having health insurance coverage. Of those 12.7 million people claiming an exemption – the most common exemption was for people who had income below a certain threshold in a state that did not expand Medicaid. The 2nd most common

exemption is by U.S. citizens living abroad and certain noncitizens. The 3rd most common exemption was that the health care coverage available to the individual is considered unaffordable. Additionally, another 6.5 million people actually just pay the penalty/tax. Of those individuals, 58% were from a household with an adjusted gross income of below \$50,000.

These data points could logically suggest the larger wave of people joining STDLI aren't those already enrolled in the Marketplace. Instead it's those that currently do not have coverage due to its cost and there is no Medicaid expansion to cover them. Regardless, predictions of an impending, rapid death spiral without the individual mandate and STDLI are complicated to predict.

Complicating matters further is the interaction between the Marketplace and the Alexander-Murray market stabilization bill and the Collins-Nelson reinsurance bill. The Alexander-Murray bill provides two years of cost-sharing reduction (CSR) funding, streamlines the approval process of Section 1332 waivers, increases flexibility in 1332 waivers by removing some of the ACA guardrails, promotes health insurance compacts, provides outreach and enrollment funding for the Marketplace, and allows individuals over the age of the 30 to purchase lower premium copper plan/catastrophic plans. The Collins-Nelson bill is expected to provide \$10 billion over two years to support state efforts to develop reinsurance programs or invisible high risk pools.

Although tax reform included a repeal of the individual mandate, Senator Susan Collins (R-ME) continues to argue she has received commitment to get Alexander-Murray and Collins-Nelson passed. With this issue being punted to the new year, marketplace reforms to offset repeal of the individual mandate will be front and center when Congress returns in January. Also, we have always speculated the Alexander-Murray would beget an Alexander-Murray, The Sequel that might go further to improve the marketplace.

And since we are on the topic of Section 1332 waivers, let's not forget that on March 13, 2017 former Secretary Price sent a [Letter to Governors](#) encouraging states to apply for Section 1332 waivers. (This sentiment was also included the joint Verma-Price letter that was sent a few weeks after, noted above in the Medicaid section.) Section 1332 waivers were created as a way to get out of provisions within the ACA, including the possibilities of eliminating the individual and employer mandates, changing the subsidies structure, waiving exchange coverage provisions, and combining 1332 waivers with Medicaid 1115 waivers. However, there are guardrails put around 1332 waivers that require the waiver to be deficit neutral, cover a comparable number of individuals, and have coverage and affordability equitable to that under the ACA. Administrator Verma and the incoming Secretary Azar will be defining those guardrails in 2018. We might be seeing applications for jumbo 1332-1115 waivers or guardrail guidelines around 1332 waivers starting to change. But similar to the Medicaid waivers – these are state-driven actions. And as is the case with Medicaid waivers, litigation over the authority to approve expansive waivers is almost certain.

### **Food and Drug Administration (FDA)**

One of the few bipartisan accomplishments of 2017 – the FDA Reauthorization Act (FDARA) – reauthorized several user fee programs, which enables the FDA to collect fees from industry to accelerate the review of applications for drugs, biologics, and devices. The funds are used for

increased review staff, training, development, and developing policies intended to expedite the review process, among other things.

Congress will have to reauthorize two outstanding user fee programs in 2018 – the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) – which will both expire on September 30, 2018.

Many of the proposed ADUFA & AGDUFA recommendations deal with reviewing and acting on applications within a certain time frame, if certain conditions are met. The FDA has held its public workshop and recently closed its public comment period on both draft recommendations. Once the FDA takes into account the comments from the open comment period and public meeting, it will revise the draft recommendations as necessary and submit to the relevant Congressional committees.

The implementation of the 21<sup>st</sup> Century Cures Act will continue to be a priority for the FDA and Congress in 2018. A few areas of interest Commissioner Gottlieb highlighted in his recent testimony indicate the FDA will take a robust approach to implementing various aspects of the legislation. For example, the FDA intends to build upon the Oncology Center for Excellence model by evaluating the creation of additional disease-specific offices in the Office of New Drugs (OND). Some areas under consideration include immunology and neuroscience.

The Agency will also be moving forward with the regenerative medicine initiative. In 2017, FDA granted 11 designations under the Regenerative Medicine Advanced Therapy (RMAT) designation program, which is designed to facilitate expedited review of innovative regenerative medicine therapies and improve access to potentially life-saving products. The FDA also recently announced the Agency's Comprehensive Policy Framework for Regenerative Medicine. This framework builds on the current regulatory approach and implementation of the 21<sup>st</sup> Century Cures Act, as well as enforcement priorities related to unapproved cell and tissue products.

The FDA also continues to implement the digital health provisions of the 21<sup>st</sup> Century Cures Act. The FDA put forth an action plan earlier this year on how to apply a tailored, risk-based approach toward digital health technology. The goal of these efforts is to provide greater certainty regarding the types of digital health technology that are subject to regulation, in particular devices where certain functionalities are within the scope of FDA regulations, but others are not. Significant new guidance, some of which was mandated by the Cures Act, was released in early December. The FDA will continue to put forth guidance on this issue into 2018.

Other topics and programs where FDA action is likely include minimal risk clinical investigations, the Breakthrough Devices Program, 510(k) modifications and exemptions, patient-focused drug development, and combination products, among other programs. Needless to say, the FDA will continue to have a prominent role on Capitol Hill and in the regulatory space given the bipartisan nature of the 21<sup>st</sup> Century Cures Act and FDARA.

## **Opioids and Substance Use Disorders**

The crisis in America with opioids and substance use disorders will continue to horrify the political world. It will continue to lead [national news coverage](#) as we struggle to cope with the

consequences. In an election year, expect Congress to turn up the dial on ... well that's the problem, isn't it? Congress still struggles with writing policies that address the issue. In the absence of direct solutions that make a discernible difference, expect efforts that focus on additional funding. Mental health policy will behave similarly.

## **Drug Pricing**

In September, CNN hosted a health care town hall bipartisan debate between Senators Cassidy (LA), Graham (SC), Klobuchar (MN), and Sanders (VT). The one issue that united the four Senators was drug pricing. In an election year, expect the rhetoric on drug pricing to heat up as the issue resonates with the voting public. While the political rhetoric will target drug manufacturers, Congressional action will focus more broadly on the supply chain and other issues.

Expect Republicans in Congress to emphasize the drug supply chain, especially the opaque role of pharmacy benefit managers (PBMs). While problematic for PBMs generally, it could become a severe threat if legislation affecting the industry becomes bipartisan.

Legislation that directly impacts drug manufacturers like the CREATES Act or efforts to reign in other perceived abusive patent practices should be expected to gain bipartisan, bicameral support. However, these efforts are like to be met by significant resistance from the industry and their supporters in Congress.

The Administration remains an unknown factor. The President said on [October 16<sup>th</sup>](#) that "the drug companies frankly are getting away with murder." However, the Administration has done little to back up that rhetoric this year and one cannot help but notice the highly placed individuals formerly employed by drug companies throughout the Administration, including the nominee for Secretary of HHS. FDA Commissioner Scott Gottlieb has discussed using FDA's authority to reign in perceived abusive practices by drug companies, although FDA can only do so much with existing authorities. We will watch to see if 2018 brings more widespread action to back up the rhetoric.

Also, on the radar for 2018 will be the 340B program. In 2017, the Energy and Commerce Subcommittee on Oversight and Investigation held hearings reviewing the 340B program. We expect that in 2018 the Oversight and Investigation Subcommittee will release a report on the 340B program based on its research and investigation, and some Members of Congress will continue to discuss the program with a focus on transparency and program growth. The Administration also made the 340B program an issue in 2017 with its 2018 Medicare Hospital Outpatient Prospective Payment Program System (OPPS) final rule. December action saw a bipartisan House bill and Senate bipartisan letter aimed at preventing these cuts from going into effect though ultimately Congress adjourned without taking action. This rule is slated to go into effect January 1, 2018 and would cut 340B hospital payments by approximately 30%. A federal court review is pending as of this writing. If the court rules against 340B stakeholders, the rule becomes a very important issue in January.

## Conclusion

2018 leads to 2019. Simplistic as it sounds, it is key to understanding the importance of next year. Many of the policies we discussed above will likely not see their full impact until 2019. For the marketplace, legislative and regulatory action are all about plan year 2019. Plan participation and enrollment for 2019 hinges on the configuration of the repeal of the individual mandate, coupled with CSR payments or lack of CSR payments, and reinsurance funding or lack of reinsurance funding that will occur in 2018. Actions taken in 2018 will determine what 2019 looks like. In Medicaid, the waivers and policies that are approved in 2018 will likely be fully implemented in 2019. Similar in Medicare, the payment policies that are developed in 2018 will have implications for 2019. Next year may not have the existential intensity of 2017, but it is far from inconsequential. We engage in 2018, not just for 2018, but for 2018 and beyond.

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