



## ML Strategies Update

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## Health Care Update

### What to Expect from Congress this Work Period

The next Hill work period basically runs from February 22nd to March 23rd. As Congress returns, here's a brief look at the pending health care issues on the radar for this work period.

As much as health care policy experts think the world revolves around health care, there are other issues in play that can affect consideration of health care issues. First, there is consideration of the FY 2017 Budget. It is unclear whether House and Senate Republicans are ready to move forward with a budget this year (the 2015 year-end deal deemed the process for this year complete), but many key GOP players, including House Budget Chairman Tom Price (R-GA), are pushing for Congress to pursue a budget resolution this year. Any budget is certain to have health related provisions. While not incredibly influential for the process this year, a budget exercise employs resources that could be used on other issues. It also provides an opportunity for members to speak out publicly on policy ideas and proposals.

The more politically relevant issue is the Senate's reaction to the Supreme Court vacancy created by the death of Justice Scalia. At some point this election year, it will become clear that Congress is no longer able to consider bills of even remote consequence due to political dynamics and a very limited calendar of legislative days. The battle over the upcoming nomination will undoubtedly increase the political temperature in the Senate. It is not clear to what extent it could impact progress on other issues, such as opioid legislation, mental health reform, the chronic care initiative, the Senate version of 21<sup>st</sup> Century Cures, and others that are sure to progress over the next few months.

As always, ML Strategies will be closely following developments on Capitol Hill and in the regulatory space.

For our complete coverage of this issue, please view the [ML Strategies Advisory Alert](#).

## All Things ACA

**Kentucky Ex-Governor to Fight Health Care Rollback:** Former Democratic Governor Steve Beshear, who was succeeded by Republican Governor Matt Bevin following his two terms, has established a non-profit group to begin public engagement against Governor Bevin's plans to dismantle Kentucky's successful Medicaid expansion program, or Kynect, as a result of the Affordable Care Act.

**Utah Taking Steps to Expand Medicaid:** The Republican-controlled Utah legislature is moving towards expanding Medicaid for the poorest of the poor, with the potential to further expand the program in future years. How Utah Senators Orrin Hatch and Mike Lee respond to this move will shed light on how Republicans view some of the recent wave of success within Medicaid.

**Wyoming Fails to Advance Expansion Efforts:** Despite Wyoming Governor Matt Mead (R) calling on legislators to consider expanding Medicaid as they consider the upcoming budget, legislators in the state senate failed to agree which effectively ends any hopes of expanding the program this year.

**Indiana Medicaid Model Draws CMS Scrutiny:** Last week, CMS informed Indiana health officials that it would be conducting a review of the state's Medicaid expansion model to ensure it is not limiting access to care. A number of states are looking to replicate some elements of Indiana's program, and this review could slow those efforts.

**CMS Also Checking In On Arkansas:** Arkansas plan to reform its Medicaid expansion was met with some skepticism from CMS earlier this month, who said the plan will require a waiver from the federal government. Governor Asa Hutchinson said there are "fundamental differences" in how Arkansas and the federal government view Medicaid expansion.

## News from the Hill

**CMS Releases Proposed Rates for Medicare Advantage:** CMS plans to increase rates by 1.35 percent, with a proposed coding trend to account for discrepancies that could increase plans by a total 3.55 percent. The next month and a half before final rates are published will be heavy on the lobbying front.

**Both Chambers Request No Cuts to Medicare Advantage:** The lobbying blitz to prevent any further cuts to Medicare Advantage is underway with 61 Senators and over 300 Representatives calling on CMS to maintain Medicare Advantage rates. With proposed rates published, this will be interesting to watch play out.

**Senate to Vote on Califf Nomination Today:** The Senate is scheduled to vote on the nomination of Robert Califf for FDA Commissioner today, despite objections from three Democratic Senators. Senators Ed Markey (D-MA) and Joe Manchin (D-WV) plan to discuss their opposition at a press conference today, while Minority Leader Harry Reid remains quiet on the issue.

**House E&C Subcommittee on Health Looking at State Provider Tax:** Chairman Joe Pitts (R-PA) and Vice-Chairman Brett Guthrie (R-KY) are seeking clarification from CMS regarding how the agency oversees state Medicaid programs use of provider taxes to finance the program where federal funding does not. GAO expressed skepticism in 2014 over state use of provider taxes. Given the state of play, it will be interesting to see what action the House takes in an election year with the Senate unlikely to consider it.

**Zika Spending Will Need an Offset:** Speaker Paul Ryan said last week that money intended to combat the spreading Zika virus will need an offset somewhere else in the budget. The White House requested \$1.8 billion for Zika efforts, but Congress will explore offsets before making any decisions. The House appears a ways away from treating this as a public health issue that requires emergency spending.

**GOP Members Call on White House to Use Ebola Funds:** House Appropriations Chairman Hal Rodgers (R-KY) wrote to the Administration calling on them to use funds provided for Ebola to respond to the Zika virus, a sign that the \$1.8 billion request for Zika does not have much support yet. The White House swiftly rejected that idea.

**Legislation Regarding Device Identifiers Forthcoming:** Members of Congress are working on legislation to require insurance forms to include the unique identifying numbers of each medical device used by a patient. The FDA has backed the use of unique identifiers, but CMS has expressed some concerns. This may result from the duodenoscopy-related outbreak last year that affected 68 patients. Still, this is a very contentious issue with uncertain bipartisan support.

**Insurer, Provider Disputes Addressed in Budget:** The Administration's budget would "eliminate surprise out-of-network healthcare charges for privately insured patients." This proposal would require physicians working in hospitals to accept in-network rates even if they aren't in the insurer's network. While hospitals would have to take

reasonable steps to ensure patients see in-network doctors that may be easier said than done. This would put physicians in a tough position, which some states are beginning to recognize by establishing an arbitration process.

**HHS Calls on Congress to Boost Medicaid Funding for Puerto Rico:** HHS is urging Congress to act proactively to boost federal Medicaid funding. Federal officials expect the territory's Medicaid funding to dry up by the end of fiscal year 2017, which could mean 600,000 people lose coverage. A hearing on Puerto Rico is expected in the House this week.

## Opioid Crisis

**Opioid Legislation to Offer Glimpse at Senate Post-Scalia:** The Senate is scheduled to vote on the Comprehensive Addiction and Recovery Act in the coming weeks, but how the Senate unfolds following the passing of Supreme Court Justice Antonin Scalia should help in forecasting the prospects of passing this legislation.

**Baltimore Steps Up Efforts to Curb Opioid Overdoses:** The city of Baltimore is launching a new campaign, DontDie.org, to help curb opioid overdoses in the charm city. The campaign will help city residents receive online naloxone training so they can be certified to deliver the life-saving medication. The city trained 7,000 people last year, and their efforts will likely be followed closely as other localities deal with similar issues.

**Massachusetts Exploring Ways to Address Opioid Crisis:** Citing "far too casual prescribing policies," Massachusetts Governor Charles Baker [eliminated](#) \$500,000 in funding for a program intended to curb inappropriate prescribing of opioids by physicians. Instead, the Governor will [expand access](#) to services for medicated-assisted treatment, the development of a youth drug prevention curriculum, and training for law enforcement, among other initiatives through \$2.5 million in federal grants to support District Attorney's and other criminal justice agencies in strengthening efforts to combat heroin and opioid abuse in the state.

## Prescription Drug Costs

**FDA Grants Breakthrough Therapy Designation for Cancer Drug:** The FDA approved AstraZeneca's new cancer treatment drug, durvalumab, as a treatment for bladder cancer. Breakthrough designation expedites the development and review of medicines intended to treat serious or life-threatening diseases. Health care observers will be paying close attention to see how the drug is priced.

**Canada Breaks Off Talks with Alexion Over Drug Cost:** The pan-Canadian Pharmaceutical Alliance, which negotiates drug prices on behalf of Canadian provinces, was engaged in coverage talks with Alexion Pharmaceuticals over its Soliris treatment before breaking off talks, citing a lack of justification over the price of its product. This is not the first time Canadian officials have gone toe-to-toe with Alexion, but it sure bears watching considering the non-interference debate going on in the U.S.

**Washington State Sued Over Hepatitis C Availability:** Washington State is being sued for illegally denying Medicaid patients access to hepatitis C treatments based on its cost. CMS has expressed concern over Medicaid programs imposing limits on expensive hepatitis C drugs like Sovaldi and Harvoni, so whether or not this lawsuit goes through, this is an issue that won't be going away anytime soon.

**Some Donald Trump Policies Run Counter to Republican Establishment:** Donald Trump continues to campaign on two health policy issues that run counter to the prevailing view of Republican policymakers. He declared that enabling the government to negotiate drug prices would save \$300 billion and also vowed not to raise Medicare's eligibility age. This will put Republicans in a difficult position should Trump secure the Republican nomination and continue to trumpet these issues.

## In Other News

**CMS, Insurers Agree on Quality Measures:** Interesting news in what otherwise was a quiet week on Capitol Hill. CMS and a broad group of health insurers agreed on quality measures they intend to put into practice in an effort to

sync the hundreds of conflicting quality measures providers are required to track and report on. This is an important first step, especially if it is on the road to standardization.

**FDA Monitoring Genomics Testing Closely:** In recent weeks, the FDA has reached out to a number of genomics testing companies regarding the clinical safety of its products. Many of these products claim to detect risk factors associated with different drugs and diseases, which the FDA views as a medical device and subject to more scrutiny. The FDA has a broad regulatory authority when it comes to medical devices. While it may not discourage development of new and innovative devices, it is clear there is a learning gap between manufacturers and regulators that still needs bridging.

**Doc Survey Supports Universal Medical License:** A survey by SERMO, a leading social network for doctors, found that 81 percent of respondents believe there should be a universal medical license so they can easily treat patients across state lines. State Licensing Boards aside, this could open discussions about standardizing medical standards which is an interesting and ongoing issue.

**Sandoz Wants Supreme Court to Review Biosimilar Rules:** Sandoz is urging the Supreme Court to determine when a drug maker that intends to sell a biosimilar medicine must give notice to the manufacturer of the brand-name drug. Biosimilars have been the subject of considerable debate on Capitol Hill so it will be interesting to see if Congress weighs in on the amicus side.

**Rural Hospitals Call for Changes to FCC Program:** A rural hospital in Nevada experience troubles due to poor internet connections recently and are urging the FCC to amend its \$400 million Rural Health Care Program. The program itself has left \$3 billion on the table because outdated statutes, and in part because the application process. Still, Congressional observers point out this program is receiving increased attention from the Hill, which could lead to proposals to expand the applicability of the FCC Rural Health Care Program.

**Court Ruling May Put Pressure on Congress to Address RACs:** A federal appeals court returned a case which would force the government to reduce the RAC appeal process backlog. By returning it to the district court, it is possible the case will receive fresh consideration. Congress has looked into this issue before, but this case may enable some in Congress to be proactive – especially if hospitals step up their advocacy on this one.

**Hollywood Hospital Hacking Crisis Ends:** Hollywood Presbyterian's data hostage crisis, which caused calamity as doctors and nurses shifted back to pen and paper, is over after agreeing to pay \$17,000 ransom. The staff at the hospital was completely locked out of accessing electronic health records for over a week. Congressional hearings should be expected in short order. For more coverage on this, please check out our colleague Kate Stewart's work on the [Health Law & Policy Matters](#) blog.

## Hearings

### House of Representatives

On Wednesday, February 24<sup>th</sup>, the House Energy and Commerce Committee will hold a hearing titled, "The Fiscal Year 2017 HHS Budget." 10:00 AM – [more info](#).

### United States Senate

On Tuesday, February 23<sup>rd</sup>, the Senate Committee on Finance will hold a hearing titled, "Examining the Opioid Epidemic: Challenges and Opportunities." 10:00 AM – [more info](#).

On Wednesday, February 24<sup>th</sup>, the Senate Committee on Health, Education, Labor, and Pensions will hold a hearing titled, "Zika Virus: Addressing the Growing Public Health Threat." 10:00 AM – [more info](#).

## The Last Word

**Public Weighs in on Public Health Crises:** A poll conducted by [Morning Consult](#) found that the general public overwhelmingly supports government action on several public health crises, including lead levels in Flint, opioid abuse, and the Zika virus. The Senate became bogged down by a \$600 million proposal brought to the floor as an

amendment to the Senate energy bill. Last week, Republicans also balked at the price requested by the Administration to address the Zika virus, insisting that the price be offset somewhere else in the budget.

Despite their initial objections, House Republicans are trying to reconcile several public health crises with the tendency to avoid non-offset spending. How this conflict is resolved remains to be seen.

ML Strategies will continue to closely monitor these issues.

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