



## ML Strategies Update

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APRIL 4, 2016

## Health Care Update

### FDA Reform Tops Spring Work Period Agenda

The next work period basically runs from April 4 to May 27, with a both chambers adjourning for a week long recess the week of May 2<sup>nd</sup>. Following this work period, there will be five weeks left on the legislative calendar before Congress recesses for the summer. This means that legislative initiatives will have to make significant progress this work period if they stand any chance of being addressed before the election.

#### Atmospherics

Republican leadership are expected to prioritize appropriations this work period, highlighting the “return to order” by moving the 12 annual appropriations bills before the summer recess. They will also have to devote time to issues like the reauthorization of National Defense Authorization Act (NDAA), as well as reforms to the FAA and the energy package. Senate Democrats will likely continue their call for a hearing for Supreme Court nominee Merrick Garland, and how that is received inside the Beltway and outside could play a factor in how issues are addressed moving forward. The time devoted to addressing these big ticket items will affect the likelihood that health care legislative items have enough time to be addressed this Congress. Here’s what is on our radar:

#### 21<sup>st</sup> Century Cures

This week, the Senate HELP Committee will hold its third and final mark up for its biomedical innovation package with the goal of bringing it to the floor this month. Chairman Lamar Alexander (R-TN) is committed to striking a deal with Ranking Member Patty Murray (D-WA) over mandatory NIH funding, but how to offset that funding has yet to be determined. Senate Democrats, led most strongly by Senator Elizabeth Warren (D-MA), have threatened to stop the HELP Committee package on the Senate floor without additional funding for NIH. It remains to be seen if a deal can be reached or if Warren’s resolve will be tested on the Senate floor first.

Other issues that will certainly be addressed this work period include drug pricing issues, which could come up at the FDA hearing on Wednesday. Mental health reform, addressing the opioid crisis, the Flint water crisis, and Zika will also continue to receive consideration from lawmakers.

For a more detailed outlook, please view our latest Congressional outlook, which can be viewed [here](#).

As always, we are here to answer your questions.

## All Things ACA

**Will Hold Outs Take Medicaid Money?:** One question in the waning days of the Obama Administration is whether the states who continue to hold out on expanding Medicaid will hold out indefinitely. Following the Democratic gubernatorial victory in Louisiana, it became the first state of the holdouts to announce its intention to expand Medicaid. While we may be running out of time for more states to expand in 2016, the question is whether they will continue holding out in 2017 post-Obama.

**One-Third of ACA Enrollees Kept Plan:** A [study](#) by Avalere Health found that only one-third of exchange customers kept their insurance plan. While this may be welcome news to those promoting the need for competition in the marketplace, it also raises questions about addressing chronic care management delivery.

**503,000 Jobs Created in Health Care in One Year:** It appears that the increased number of insured is contributing to job opportunities across a variety of sectors, namely hospitals, but also in home health and dental care.

**CBO Budget Projects Small Deficit:** The Congressional Budget Office recent evaluation of the ACA increased the estimated costs associated with ACA insurance provisions by \$136 billion. While the revised cost is still 25 percent lower than initial projections, budget deficits will continue to be a driving force in health care policy discussions.

## Opioid Crisis

**CMS Finalizes New Opioid Measures:** CMS will require insurers to implement by 2018 a system that will reject claims for opioid prescriptions at pharmacies for patients who have reached painkiller prescription thresholds. The agency says it will also not approve plans that would hinder access to medication assisted treatment for substance use disorder.

**Physician Groups Resist Calls for Pill-Tracking Databases:** State and national monitoring systems for prescription drugs are getting increased attention as policymakers look at ways to address substance abuse. Despite calls from the White House recommending that doctors check databases before prescribing, among other recommendations, physician groups are pushing back, arguing the new requirements are overly burdensome. Determining who controls the database as well as making it more user-friendly will be significant policy questions as this debate moves forward.

## Drug Pricing

**Sanders Calls on NIH Regarding Xtandi:** A prostate cancer drug known as Xtandi costs more than \$129,000 in the United States and Bernie Sanders, along with eleven other lawmakers, is calling on the National Institutes of Health (NIH) to override its patent. This authority is known as invoking march-in rights, which would allow HHS to ignore the patent in order to grant approval to similar drugs at a lower cost. This will be an interesting case to follow as it could affect how future Administration's seek to address prescription drug costs.

**Doc Group Makes Policy Recommendations:** The American College of Physicians is calling for [new policies](#) to stem the costs of prescription drugs, calling for Medicare and other public health programs to have greater authority to negotiate drug costs.

**CMS Encouraging Plans to Provide Value on Drugs:** Among those efforts is a recommendation that sponsors inform beneficiaries when additional formulary drugs become available midyear as these drugs may provide more value.

## In Other News

**U.S. Spends \$3B on Unused Cancer Drugs:** A recent report found U.S. hospitals and doctors throw out approximately three billion in excess cancer drugs. Time will tell whether Congress looks to the potential savings of this as a way to fund other projects.

**Alzheimer's Association Releases Survey on Financial Impact of Dementia:** Last week, the Alzheimer's Association released a survey which highlights a growing concern among seniors. Many relatives and friends taking care of people with dementia are being forced to dip into their own financial savings in order to care for these individuals. While those on Capitol Hill are slowly warming up to the fact that a number of Long-Term Services and Supports policy options have to be considered, determining how best to pay for it will be its greatest hurdle.

**Hospices Costs to Medicare Inappropriate:** One-third of hospice's stays for general inpatient care were found to be inappropriate, according to a new OIG report. The [report](#) says this costs Medicare \$268 million.

**FDA Seeking Comments on Biosimilars:** Last week, the FDA recommended that labeling of biosimilars use data gathered by the product the biosimilar is matching. Our Mintz Levin colleagues did an in depth report on this draft guidance, which can be found on the [Health Law & Policy Matters](#) blog.

## The Last Word

**CMS Releases Final 2017 Payment Policies:** CMS estimates that the overall 2017 payment policies finalized will result in a 0.85 percent increase in payments. The increase is lower than the 1.35 percent increase projected in February, which CMS said was lowered after a technical error was made when calculating the proposed payments. Overall, total revenue for health plans is estimated to increase 3.05 percent in 2017.

While the overall numbers will take the headlines, it is often the fine print where policymakers and stakeholders will go to seek information on technical or programmatic changes which could affect business models and certain long-term planning. One issue in particular is the Employer Group Waiver Plans, also known as the Medicare Employee Retiree Plans, which was another issue that CMS was lobbied on hard on behalf of employer groups like unions. In February, CMS proposed a 3-4 percent rate cut. The final rule created a two-year transition that will phase in the rate changes gradually for the employer plans.

While this is not the outcome many had hoped for, especially given the aggressive lobbying effort, a two-year transition period does give time for insurers and employers to prepare while also setting the stage for another lobbying push next year. Whether or not Congress seeks immediate changes to these finalized rates should play out over the next couple weeks.

As noted in the update, there are also changes to Part D and the inclusion of drug pricing measures and opioid-related provisions. These are significant because they can forecast where the Administration would like to see further action or review, setting the stage for potential action 2017.

ML Strategies will continue monitoring changes to Medicare Advantage and other initiatives addressed in this [final rule](#).

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