



ML Strategies Update

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Health Care Update

Drug Pricing Issues Heat Up Following HHS Forum

Last week, the Department of Health and Human Services (HHS) hosted a forum on prescription drug costs which featured players from every corner of the industry, including top government officials. HHS Secretary Sylvia Mathews Burwell kicked off the event by calling for greater support for innovation, access, and affordability when it comes to prescription drugs.

There seemed to be agreement that value-based contracting – payments based on the value of care delivered – should be increased across health care delivery. However, the topic of value and how it should be defined remains a barrier to this idea moving forward. Ken Frazier, Chairman and CEO of Merck, stated that different constituencies define value in different ways, making the identification of positive outcomes more challenging. Acting CMS Administrator Andy Slavitt stated that an open dialogue is needed and a shared set of facts is critical to ensuring innovation in the industry.

Transparency and increased competition were key issues brought up throughout the forum, with Slavitt highlighting the complex factors that go in to determining the cost of a drug as leading to confusion on the consumer side. Some stakeholders argued that increased transparency can already be seen by the level of scrutiny some companies and individuals have faced this year from drug price increases. Others contend that increased competition is needed.

This forum was the latest action by the Administration around this issue, with more action sure to follow as a number of congressional investigations around this issue pick up steam. The recently launched drug pricing investigation in the Senate Select Committee on Aging, as well as the Sen. Bernie Sanders – Rep. Elijah Cummings investigation, are among the handful of investigations already underway.

ML Strategies will continue to monitor these issues and will publish a special alert on drug pricing policy developments next month.

News from the Hill

Congress Leaves Town for Thanksgiving Recess: Both Chambers of Congress are in recess this week, with members from both sides off the Hill working from their respective districts and states. Lawmakers will return to a jam-packed agenda on November 30th. For more information on the legislative agenda, please see this [ML Strategies update](#).

Action on Senate “Cures” Legislation Likely to Stretch into Next Year: The collective wisdom among Hill staff and other stakeholders is that the Senate Committee on Health, Education, Labor, and Pensions is nearing an agreement on funding for NIH and FDA – seen as a major hurdle to getting its version of the 21st Century Cures introduced. Now, it has been said for a number of weeks that they were close, but given how close we are to the end of the legislative calendar, if they do not release it soon it likely will not get marked up until 2016.

Ways and Means Health Subcommittee adds Rep. Erik Paulsen (R-MN): The Health subcommittee, following its most recent shake up, added Rep. Erik Paulsen of Minnesota. Rep. Paulsen introduced legislation to repeal the medical device tax, which passed the House in June of this year. He is also supportive of expanding the use of health-savings accounts, which will be a policy priority among Republicans.

All Things ACA

Lawmakers Request White House Meeting Over Cadillac Tax: A bipartisan, bicameral group of lawmakers hope to meet with the Administration to discuss the provision known as the Cadillac tax in an effort to find some common ground. With negotiations over tax extenders underway, there is the possibility of repeal, but a delay in implementation has not been taken off the table. New studies suggest roughly 23 percent of large employers would be faced with the Cadillac tax in 2018.

Democratic Victory in Louisiana: Following State Rep. John Bel Edwards victory over Senator David Vitter for governor of Louisiana, Medicaid expansion is poised to follow, which could affect up to 300,000 people. Additionally, with Senator Vitter announcing he would not seek reelection to the Senate, Democratic hopes of regaining the Senate in 2016 improve. New Orleans Mayor Mitch Landrieu, brother of former Senator Mary Landrieu, is the party favorite for the Democratic nomination.

State Innovation Waiver Supporters Await Regulations: Section 1332 of the ACA, known as the State Innovation Waivers, allows states to pursue “innovative strategies” to provide affordable health care within the confines of the Affordable Care Act. The waiver will be available January 1, 2017, but Senator Ron Wyden (D-OR), Ranking Member on the Senate Finance Committee, is requesting additional details from the Department of Health and Human Services on how they intend to implement the waiver.

Future of Insurer Participation in Exchanges Hangs in Balance: UnitedHealth, the nation’s largest insurer, announced last week that it may leave the ACA marketplaces in 2017, citing losses on plans sold through the marketplaces. Conversely, Aetna and Anthem have indicated they do not have intentions to leave the exchanges just yet.

Co-Ops Report Losses, HHS Vows to Pay Back: The 11 remaining co-ops reportedly lost about \$200 million this year, in part to the funding shortfall in the risk corridor program the Administration announced in September. Still, HHS reiterated last week that it intends to pay back the full amount in short order.

Senator Still Blocking Nominations Over Collapsed Co-Ops: Senator Ben Sasse (R-NE) was not pleased with the response to his letter from HHS regarding the failed co-ops and will continue to hold all HHS nominations for the time being.

Prescription Drug Costs

American Medical Association (AMA) Supports Ban on Ads: The AMA recently came out against direct-to-consumer advertising for prescription drugs and devices, saying the practice leads to higher utilization and increased costs.

Trial by Fire: Earlier this month, Harvard Pilgrim Health Care and Amgen reached [an agreement](#) on Amgen's cholesterol-lowering drug Repatha, which costs thousands more than the generic versions. If the drug does not perform as well as it did during clinical trials, Amgen will provide Harvard Pilgrim with a discount.

Acting Administrator Andy Slavitt Addresses Drug Prices: On Friday, at HHS' hosted drug pricing forum, CMS Acting Administrator Andy Slavitt said the high cost of specialty drugs are a barrier to access for consumers.

Telemedicine Update

AMA House of Delegates Fail to Adopt Guidelines: Last week, the American Medical Association's House of Delegates was unable to reach an agreement on new guidelines for telemedicine. Notwithstanding AMAs inability to adopt guidelines, we anticipate the proliferation of legislative and regulatory activity at the state level to continue.

CMS Enables Greater Telemedicine Use for Hip and Knee Replacements: CMS is easing its requirements on telemedicine in a bundled payment program for hip and knee replacements. For the release, [click here](#). For the complete rule, [click here](#).

Regulatory Developments

House Committee Has Mixed Reviews for Laboratory Developed Tests: In a hearing this week, members from both parties questioned the FDAs draft guidance outlining how it envisions regulating laboratory developed tests. Members voiced familiar concerns about regulations that may stifle innovation, but there seemed to be agreement that regulation is needed. Expect an FDA guidance to come out early 2016.

FDA Approves Narcan Nasal Spray: In opioid-related news, the FDA approved a treatment, known as Narcan, to reverse the effects of an opioid overdose. Narcan, which contains the active ingredient Naloxone, comes in nasal spray and is the first FDA-approved nasal spray version of naloxone hydrochloride.

CMS Proposes New Standards for Affordable Care Act Plans: Last week, CMS proposed standardizing plan offering by metal level (bronze, silver, gold), and requiring states to select minimum network adequacy standards, among other provisions, which can be found [here](#).

Hearings

House of Representatives

Congress is in recess; no hearings scheduled.

United States Senate

Congress is in recess; no hearings scheduled.

The Last Word

Reconciliation Inches Closer to White House: Republicans believe that they have found a way to alter the individual and employer mandates, which the Senate parliamentarian ruled earlier this month would violate reconciliation rules and require 60-votes to pass. Under their plan, fines for not complying with the mandates would be changed to \$0, meaning the mandates would effectively be neutralized while preserving requirements to ensure it can pass under reconciliation. Republicans have yet to confirm they will go this route, likely awaiting assurances from the Senate parliamentarian that the measure can be passed under reconciliation.

Even with a 50-vote threshold, prospects are bleak for such an approach in the Senate. Democrats will certainly hold their Republican colleagues accountable for voting to defund Planned Parenthood, even when President

Obama vetoes the legislation. Republican Senators Mark Kirk (R-IL), Susan Collins (R-ME), Lisa Murkowski (R-AK), among others, are on the fence when it comes to defunding the women's health care organization.

The Senate is expected to take up the measure when they return the week of November 30th.

Please stay tuned for ML Strategies coverage of this issue.