



ML Strategies Update

Alexander Hecht, AHecht@mlstrategies.com
Eli Greenspan, EGreenspan@mlstrategies.com
Erin Morton, EMorton@mlstrategies.com

FOLLOW US ON TWITTER: [@MLStrategies](https://twitter.com/MLStrategies)

ML Strategies, LLC
701 Pennsylvania Avenue, N.W.
Washington, DC 20004 USA
202 434 7300
202 434 7400 fax
www.mlstrategies.com

FEBRUARY 17, 2016

Health Care Update

The Administration is Ramping Up Drug Pricing Response

The President's budget makes clear for all to see that the Administration wants to do something related to drug pricing. Unfortunately for the Administration, most of their proposals require Congressional authority that has virtually no chance of passing this year. Therefore industry stakeholders **MUST** be on high alert for actions the Administration might take where they already have authority.

The budget is chock full of proposals that would save billions of dollars, mostly funded by drug and biologic manufacturers. Many proposals we have seen before such as: (i) the Part D rebate proposal, (ii) moving Part B payments from ASP+6 to ASP+3, (iii) allowing government negotiation for high-cost drugs and biologics, or (iv) reducing the exclusivity period for biologics from 12 to 7 years. These proposals all could have a tremendous impact on stakeholders, but it is extremely unlikely any of them could get through the current Congress.

Industry stakeholders would be well advised to focus on what the Administration can do without Congress. The Affordable Care Act created the Center for Medicare and Medicaid Innovation (CMMI) and granted it broad authority. Essentially, if CMMI thinks a policy idea could save money, it is empowered to implement said policy.

Last Friday, CMS posted an agency notice to contractors of the intent to test new payment methodologies through CMMI for Part B drugs. Currently, Part B drugs are reimbursed under the ASP +6 regime. CMS quickly pulled the notice from their website and have publicly retreated from the notion that any policy changes are forthcoming. But due to the beauty or horror that is the internet, nothing every truly goes away. When you look at the notice, CMS is not kidding. While details are not absolutely clear from the notice, it certainly suggests CMS has put significant work into preparing to test new methodologies.

It's hard to miss the big proposals in the budget with the big savings numbers attached. But the far more interesting action is with CMS's "now you see it, now you don't" notice that could lead to real policy changes in 2016.

ML Strategies will continue following congressional and regulatory efforts to address drug pricing and how policy considerations impact the market. For more coverage on this issue, please visit the Mintz Levin [Health Law & Policy Blog](#).

News from the Hill

Senate HELP Committee Marks Up First Series of Cures Package: Last week, the Senate HELP Committee marked up its first series of legislation it is considering for its version of the House-passed 21st Century Cures Act. The hearing was relatively painless, with some the committee advancing some bills without remarks from the introducing members. Senator Elizabeth Warren (D-MA) did state her strong opposition to the lack of increased funding for NIH and the FDA in her opening remarks, which could be a source of contention at future hearings, but Chairman Lamar Alexander (R-TN) and Senator Richard Burr (R-NC) expressed openness to increasing funding at the two agencies.

American Hospital Association (AHA) Objects to Senate HELP IT Bill: The AHA is speaking out against one of the bills that secured passage in the HELP committee mark up last week. S. 2511, the Improving Health Information Technology Act, would develop recommendations to reduce the administrative burden on providers while maintaining high standards of quality. AHA spoke out against certain provisions of the bill, namely the information blocking provisions, which enable HHS' OIG to investigate and establish deterrents to information blocking practices. The committee approved the legislation 22-0.

HELP Committee, White House Working towards Comprehensive Mental Health Package: Following news that multiple Senate committees would be considering legislation centered on mental health, the White House has entered the fray and begun working with HELP committee staff to develop a comprehensive mental health package that goes beyond current proposals. Timing on this package is uncertain – as is the House of Representative's willingness to take part in a package delivered in part by the White House.

Republican Rep. Wants Congress to Appoint MACPAC Members: Representative Morgan Griffith (R-VA) intends to introduce legislation that would give Congress the power to appoint members to the Medicaid and CHIP Payment and Access Commission. Current law stipulates that the U.S. Comptroller General appoints members.

FDA Nominee Robert Califf to Receive Floor Vote: Senate Majority Leader Mitch McConnell filed a motion Thursday clearing a path for a vote on the nomination of Robert Califf to be the next FDA Commissioner. The FDA will establish proper labeling forms for genetically modified salmon, satisfying Senator Murkowski's (R-AK) primary objection to the nomination. Senator Ed Markey (D-MA) immediately reiterated his opposition to the nomination following McConnell's announcement, but whether he receives any assurances from the FDA remains to be seen.

White House Budget Upsets NIH Researchers: The research community among the National Institute's of Health (NIH) are worried that the White House budget proposal which would replace \$1 billion in discretionary funding with \$1.8 billion in mandatory funding weakens the NIH funding base long-term. Several NIH-funding debates going on, will this be another one as budget discusses draw near?

Budget Includes Recovery Audit Contractors (RAC) Proposals: The White House included a proposal that would withhold RAC payments if a provider appealed their audits. While RAC reform has been on the slow burn on Capitol Hill, election year politics could create an opportunity for members to own the issue.

Budget Includes Proposals Also in Senate Finance Chronic Care Draft: The White House budget also included provisions to expand telemedicine reimbursements in Medicare Advantage, and to allow rural health centers and federally qualified health centers to be originated sites for reimbursement purposes. How the Congressional Budget Office scores these proposals matters.

Battle Wages on over 340B Program: Last week, AIR340B released a [fact sheet](#) with new findings that show how the growth in 340B hospitals in recent years is undermining the programs original intent. Proponents of the group were quick to point out how program reductions would lead to increased costs for patients. This is a fight that will likely get worse before it gets better, as MedPAC recently agreed to a 10 percent reduction in Part B rates to hospitals, a proposal to be unveiled next month. The American Hospital Association calls the proposal misdirected.

All Things ACA

30M Uninsured Signal New Political Frontier: With the third year of open enrollment complete, and a record low 9 percent uninsured rate, health policy observers point to what may be Obamacare's tallest task - the 30M remaining Americans still uninsured. The [Kaiser Family Foundation](#) breaks the uninsured population into three groups – those who are ineligible for coverage because they live in a state that has yet to expand Medicaid, those who are ineligible because of their immigration status, and those who are eligible but have yet to sign up (and will face a penalty for not doing so). There are a number of proposals designed to incorporate immigrants, or entice states to expand Medicaid, but they are not gaining serious traction this election year.

Chairman Brady Signals Support for White House Cadillac Tax Proposal: House Ways & Means Chairman Kevin Brady (R-TX) indicated his support for a White House proposal to link the Cadillac tax to gold health plans available on the exchange. In other words, this proposal would ensure that no employer plan is taxed if its benefits are less generous than gold plans available on the exchange. This proposal is a step towards cooperation – but it may not be far enough with calls for repeal still strong.

Centene Expanding on Obamacare Enrollees: Despite alarm from some in the industry, Centene Corporation reports that it nearly doubled its enrollment in 2015 and is on pace to meet or exceed 2016 estimates.

Medicaid Expansion Working for Molina: Insurer Molina Healthcare doubled its profits in 2016 thanks in large part to Medicaid expansion. See above, despite fears marketplace is failing, some are finding success and that success in Medicaid should continue if states continue to expand coverage.

Senators Threaten Hold for OPM Nominee: Senator David Vitter (R-LA) and Senator Ron Johnson (R-WI) warned that the nomination of OPM head Beth Cobert will not move forward until OPM answers questions regarding Congress' status on the exchange. Senator Johnson said OPM must first comply with a subpoena due this week, as well as a request from Senator Vitter. Senator Vitter has long questioned Congress' status for members and staff on the exchange, and using the leverage of this nomination could see the issue move forward. However, with Vitter set to retire, and Johnson in a tough reelection battle against former Senator Russ Feingold, the Administration may slow walk this issue – especially if the impacts of not formally confirming Cobert are not significant.

In Other News

CMS Publishes 60-Day Final Rule: Last week, CMS published the long-awaited Final Rule regarding the return of Medicare Part A and B overpayments within 60 days. For complete coverage of this issue, please view our colleagues Brian Dunphy and Laurence Freedman's coverage of the rule at the Mintz Levin [Health Law & Policy Matters](#).

Randomized Controlled Trial Falls Short for Remote Patient Monitoring Advocates: A randomized controlled trial found no significant clinical difference in readmissions or 180-day mortality for over 1400 patients with heart failure. The trial separated two groups into a usual care pool and one with a remote patient-monitoring plus coaching arm. The telemedicine community continues to be in a holding pattern waiting for a data point which can support cost-saving claims.

Nurse Staffing Ratio Debate Flares Up in New York: Nurses in New York are urging lawmakers to pass legislation that would establish [minimum staffing levels](#) at hospitals and nursing homes. While supporters say it would improve patient outcomes, the Healthcare Association of New York State says it would add three billion a year in costs statewide. This is an issue that is being debated across a number of states, and there is legislation in Congress that would address this issue as well.

New Products in the Works on Multiple Sclerosis: Microsoft Corporation's research wing teamed up with Novartis AG to develop technology that could track the diseases progress and help inform treatment options. Using Microsoft's Kinect motion sensor software, this is sure to pique the interest of FDA regulators.

FDA Clears Software for Xbox: Last week, the FDA did grant clearance for Physiotherapy Software for BioGaming's YuGo Microsoft Kinect-bases physical therapy system. This system creates "personalized gameified routines" for patients that can be completed at home.

Minnesota Health Care Homes Saving Billions: Health care homes in Minnesota, which more closely manage patient's care in, have saved state programs more than \$1 billion over five years. Minnesota is considered an incubator for health care innovation and often out in front of health care alternatives.

Senate Moving Forward with Opioid Response: The Senate Judiciary Committee advanced two pieces of opioid-related legislation last week. The Comprehensive Addiction and Recovery Act, introduced by Senator Sheldon Whitehouse (D-RI), would award grants to address prescription opioid and heroin abuse. Senator Orrin Hatch's (R-UT) Ensuring Patient Access and Effective Drug Enforcement Act of 2015 also advanced in committee. His legislation would enable greater collaboration between federal agencies to improve enforcement efforts as they relate to prescription drug diversion and abuse.

Flint, Michigan

Medicaid Coverage for Flint Water Victims: The Administration plans to offer Medicaid coverage to pregnant women and children affected by the Flint, Michigan water crisis. Governor Rick Snyder [formally requested](#) a federal waiver to expand Medicaid services in Flint on Sunday.

Zika Virus Coverage

Zika Virus Hasn't Even Peaked Yet: The CDC issued [guidance](#) on how to protect yourself from the Zika virus, and work on a vaccine is underway, although the CDC cautions it does not have a firm timeline on when it could hit the market. With this summer's Olympics slated for Brazil, the need for a short-term interdiction and long-term strategy are clear. Public health officials are eager to get out in front of this, but will Congress feel the same sense of urgency?

Congress Ramping Up Coverage of Zika: On both sides of Capitol Hill, relevant committees are taking steps to understand how the federal government can respond to the Zika virus. Hearings are being scheduled, with administration officials and public officials expected to attend. This will be a familiar two-step for Capitol Hill who last year encircled the Ebola crisis as the virus ravaged communities across Liberia, Guinea, and Sierra Leone. The question for lawmakers though is whether they can stomach the cost.

Hearings

House of Representatives

Recess, no hearings scheduled.

United States Senate

Recess, no hearings scheduled.

The Last Word

Supreme Court Justice Antonin Scalia Passes Away: The news of the sudden death of long-time Supreme Court Justice Antonin Scalia sent shock waves across the nation over the weekend, and it didn't take long for people to begin assessing the new political landscape as a result. While Senate Republicans were quick (if not too quick) to suggest that President Obama should leave the nomination of his replacement to the next President, the implications of 4-4 split decisions do lend favor to Democratic positions. Two cases in particular in the health care space will be impacted by the vacant seat.

Whole Woman's Health v. Hellerstedt challenges Texas restrictions on abortion clinics, which were upheld by the Fifth Circuit Court. A 4-4 tie would uphold the Texas law, although Justice Anthony Kennedy is considered a potential swing vote.

Zubik v. Burwell is the case which consolidated seven different challenges to the ACA's birth control mandate as it applied to nonprofits, which will centers around the scope of the Freedom Restoration Act. A 4-4 split would uphold that religious nonprofits still must comply the ACA's contraception mandate.

President Obama intends to nominate someone in the next couple weeks. Many observers expect it to be someone who has already been fully vetted and approved by this Senate, which narrows the list to a handful of judges. One name being thrown around is Sri Srinivasan, whose nomination process to U.S. Court of Appeals for the District of Columbia ended with a 97-0 affirmative vote in 2013. Either way, pressure will be on for the Senate to fulfill its Constitutional responsibility in an election year.

ML Strategies will continue to cover this developing story.

* * *

View ML Strategies professionals.

Boston · Washington www.mlstrategies.com