



ML Strategies Update

Alexander Hecht, AHecht@mlstrategies.com
Eli Greenspan, EGreenspan@mlstrategies.com
Erin Morton, EKMorton@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 1, 2016

Health Care Update

Are Lawmakers and Stakeholders Ready for the Silver Tsunami?

Last week, the [Congressional Budget Office \(CBO\)](#) released [a projection](#) that shows Medicare enrollment will grow by more than 30 percent in the next decade alone, and the number of seniors will steadily rise from 55 million today to more than 80 million by 2036. This is often referred to as the Silver Tsunami. The challenge of responding to this explosive expansion of Medicare is going to drive policy in health care for the next decade.

Regardless of who is the President or what party controls Congress, Medicare's demographic surge will force policy makers to find ways to reduce health care spending to save other spending priorities from being crowded out. On its current trajectory, CBO projects the national debt to increase by \$9.4 trillion to \$30 trillion by 2026. Spending on federal health programs now exceeds spending on Social Security. With interest on the national debt a growing and untouchable line in the budget, the next Administration and Congress will need to reduce health care costs if they want to fund priorities in defense, transportation, education and other discretionary spending.

Policy makers have developed potential solutions that are vague and with unclear expectations of success. The jury is still out on whether Accountable Care Organizations or other Alternative Payment Models will be able to slow the growth of health care costs. Other policy solutions are more certain in their impact but bring significant political dissent. For example, unilaterally cutting payments to all health care providers by 10% - an expansion of the across-the-board cuts in the sequester - would improve the fiscal outlook considerably, but would result in tremendous pushback from those providers impacted by such blunt cuts.

Payments in health care are going to be under significant downward pressure. It is hard to imagine any sector of health care being sacrosanct. Furthermore, there is certain to be a battle to protect providers that may be considered both inefficient and critical (for example, rural providers where scale remains difficult). The challenge for the health care sector is to fight payment reductions generally while making sure any cuts incurred are rational and survivable.

Our coverage of this issue and more can be found at the [Mintz Levin Health Policy & Law Matters](#) blog.

ML Strategies will continue covering the Silver Tsunami and the changing health care tides.

News from the Hill

Mental Health Reform as a Package Deal?: It appears not one but four Senate committees will be taking up legislation on mental health reform, with the ultimate goal of packaging the legislation into a standalone bill for floor consideration. The question will be whether this package is compelling enough for both sides to drop their differences on the issue of linking gun control to this debate, or if it will be another opportunity for each side to force uncomfortable votes on the other to use in an election year.

Mental Health Legislation to be Considered: The Senate HELP committee will consider the Cassidy-Murphy bill, [S. 1945](#), the Judiciary committee will mark up Senator Cornyn's [S. 2002](#), Senate Appropriations subcommittee on health will consider legislation [to be introduced](#) by Senators Stabenow (D-MI) and Blunt (R-MO), and the Senate Finance committee will consider legislation as well. Senator Al Franken's (D-MN) [Comprehensive Justice and Mental Health Act of 2015](#), which has 32 bipartisan cosponsors, will also likely receive consideration. These pieces of legislation will be considered over the course of the next few months.

Opioid Abuse Legislation Poised for Floor Vote: Senate Majority Leader Mitch McConnell (R-KY) said last week that he hopes legislation to address the opioid crisis will be considered before the end of the year. The Senate will likely need to have made meaningful progress by this summer or all bets are off, as the Senate is expected to adjourn for its recess July 15th and not returning until September 6th. Upon their return, the focus will likely be on passing a government spending bill. Writing off this issue now would be shortsighted given a number of Senator's interest in addressing this issue, notwithstanding Majority Leader McConnell's own interest. Legislation he introduced – the Protecting Our Infants Act – addresses prenatal opioid abuse and was signed into law by President Obama late last year (P.L. 114-91).

House Budget Committee Exploring Options With Medicare: The House Budget Committee, which will set in motion the FY 2017 budget resolution, is exploring ways to find savings in Medicare after claiming to have saved \$148 billion in last year's budget. These changes include modifying coverage for post-acute care, and limits on first dollar coverage in Medigap policies. Any changes to Medicare this year would have to have little – direct or indirect – impact on people's Medicare coverage.

FDA Working through Generic Backlog: The Senate HELP Committee began its work last week on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA), which is set to expire at the end of September 2017. GDUFA is designed to improve access to generic drugs by requiring industry to pay user fees to supplement the costs of reviewing generic drug applications. While there are still concerns the generic drug backlog, Janet Woodcock, director of the Center for Drug Evaluation and Research at the FDA, said the agency anticipates taking first action on 90 percent of the applications before the law expires next year.

Senator Calls for Federal Response to Zika Virus: Senator Jeanne Shaheen (D-NH) sent a letter to Cabinet officials urging them to coordinate a federal response to the Zika outbreak spreading across the Americas. Efforts to discover a vaccine are just getting underway, and some federal officials are eager to get out in front of the virus to prevent it from becoming a political issue, much in the way the Ebola crisis did in 2014.

Senators Place Hold on Califf FDA Nomination: Senators Lisa Murkowski (R-AK), Ed Markey (D-MA), Joe Manchin (D-WV), and Bernie Sanders (I-VT) all have placed holds on the nomination of Robert Califf to be the next head of the FDA. Sanders cites a lack of commitment on lower drug prices as his primary reason for placing the hold while Markey's hold stems from the FDA's approval of [OxyContin for children](#) and its overarching opioid prescribing policies. Senator Manchin's hold has to do with Califf's ties to the pharmaceutical industry. Lastly, Senator Murkowski's hold deals with genetically modified salmon, although that issue looks [mostly resolved](#) as of Friday. In an election year, these holds are certainly a complicating factor for Mr. Califf's nomination.

All Things ACA

Cadillac Tax Issue Not Going Away: Even with a two-year delay of the Cadillac tax signed into law last December, advocacy efforts are expected to continue on further delay or permanent repeal. Broad swaths of

stakeholders, across the political and policy spectrum, argue that the financial impact of the Cadillac tax would almost certainly be passed down from insurers to employers to the employees. Whether politicians seek to eliminate the program entirely, or push for a delay every few years, will likely depend on the ACA's outlook in 2017. A new administration could seek to permanently eliminate it, or it could become a legislative vehicle where members could tack on various priorities, similar to the SGR-patch that lasted over a decade.

Senator Opens Separate Investigation into Failed Co-Ops: Senator Ron Johnson (R-WI), Chairman of the Senate Committee on Homeland Security and Governmental Affairs, sent a letter to CMS Acting Administrator Andy Slavitt regarding the failed co-ops, giving CMS until February 2nd to reply with the requested information. Of note, Senator Johnson is requesting information regarding the agency's relation with actuarial firm Milliman Inc, which could open up a new front on the co-op issue for the GOP.

CMS Publishes FAQ on Co-Op Program: Co-Ops across the nation continue to struggle and some think more are on their way out this year. However, CMS Acting Administrator Andy Slavitt indicated his intent to fully support the remaining Co-Ops and [this guidance](#) is the first step in that direction. According to the guidance, "CMS is exploring what changes could be made to help Co-Ops diversify their boards and grow and raise capital, while preserving the fundamentally member-run nature of the Co-Op Program."

Georgia Next in the Medicaid Expansion Pipeline?: Georgia State Senator Fran Miller told a local TV station last week that Medicaid expansion is inevitable in Georgia, citing the state's preference for more control of its health care delivery. This will likely be an issue for 2017 as the state considers its options.

Prescription Drug Costs

Merck Hepatitis C Drug Approved: Merck's new hepatitis C treatment, Zepatier, will cost one-third of the price of Gilead's Sovaldi, which sparked outrage in late 2013 when it was listed at \$84,000 for a 12-week regimen. These treatments pose challenges to Medicaid programs nationwide, and Merck's entrance into the market should alleviate some of that burden. It could also lead to bigger discounts for insurers who shop around among the various makers of hepatitis C drugs.

Hillary Clinton Calls Out Valeant: Former Secretary of State Hillary Clinton had choice words for Valeant Pharmaceuticals and their high drug costs, calling their business practices "predatory pricing." The company's stock price dropped nine percent that same day. Saying drug prices are too high is easy, but finding a solution with even tacit buy-in from the pharmaceutical industry is a much taller task.

Trump Supports Ending Medicare Non-Interference Clause: Republican Presidential nominee Donald Trump said this week that he would allow Medicare to negotiate drug prices directly with pharmaceutical companies. While Republicans have traditionally opposed this clause, the challenge for PhRMA now will be educating a new generation of Republicans who were not in Congress for the health care debates of the late 1990s and early 2000s.

In Other News

AHIP Takes on Medicare Advantage Funding: AHIP CEO Marilyn Tavenner, who previously served as CMS Administrator, has called on the agency to address how it funds Medicare Advantage. The Senate Committee on Finance is exploring ways Medicare Advantage could better serve patients in its chronic care initiative, and Medicare Advantage is sure to receive attention given it has grown in enrollment by nearly 30 percent in the past five years. AHIP's concerns, in part, stem from an Avalere study, [found here](#).

NextGen ACOs Utilizing Telemedicine: A number of the newly established Next Generation Accountable Care Organizations will be incorporating telemedicine into their practices this year. NextGen ACOs do not have to abide by Medicare's stricter telemedicine policies, leading many advocates and stakeholders to believe that NextGen ACOs will be a litmus test for greater use of telemedicine services. Everyone is wondering the same thing when it comes to ACOs and telemedicine – can it really save money?

MACPAC Considering Policy Options for Children: The CHIP program, which covers 8 million children, expires at the end of fiscal year 2017. Proponents are already working towards a reauthorization proposal, and are

cognizant of the 2019 sunset of a maintenance-of-effort requirement for state Medicaid programs which could result in fewer children being covered. MACPAC intends to offer recommendations for lawmakers to consider in the 115th Congress as work on reauthorization will be a priority for lawmakers.

Drug Shortages Result in Questionable Rationing Practices: The American Society of Health-System Pharmacists list 150 drugs and therapeutics as having inadequate supplies. The reasons - ranging from business decisions to manufacturing problems to federal safety issues - cause shortages but also lead to rationing, which forces medical institutions to make decisions on who and when people receive what limited drugs are available.

FDA Approved Record High Drugs in 2015: The FDA's Center for Drug Evaluation and Research (CDER) announced last week that the FDA approved 45 new medicines in 2015, the highest number in nearly two decades. Nearly half of these new drugs treated a rare disease, while a third were first-in-class treatments, meaning they offer a completely new way to treat a disease.

'Cancer Moonshot' Marks Opportunity for Private-Public Collaboration, Though Questions Remain: President Barack Obama announced at last month's State of the Union that Vice President Biden will be leading a task force with the heads of 13 federal agencies. The primary focus of the group will be: increasing the country's understanding of cancer, improving patient access and care, addressing regulatory barriers, and considering ways to speed up administrative reforms. The goal for 2016 will be to develop recommendations to accelerate the development of treatments; however, a primary barrier for government officials will be bringing researchers and their work together in a collaborative manner.

Regulatory Developments

FCC Ruling Pinching Medical Debt Collection Industry: The FCC, responding to calls for reforming the Telephone Consumer Protection Act, issued a ruling over the summer which clarified that debt collectors are responsible for confirming express consent before autodialing a cellphone. The fallout from that ruling is finally being felt in California, where Prospect Medical Group's Southern California Hospital has been slapped with a [lawsuit](#) for not getting express consent before autodialing an individual on their cellphone.

CMS Proposes Changes to ACO Benchmarks: CMS Acting Administrator Andy Slavitt announced last week that CMS is proposing changes to the way it evaluates accountable care organizations (ACO) in the Medicare Shared Savings Program. Specifically, he wants to see CMS analyze trends in regional fee-for-service costs to see if ACOs actually save money.

Certain Telemedicine Services Acceptable in Home-Health Cases: Last week, CMS issued a [final rule](#) which permits face-to-face encounters to include telemedicine if necessary to get timely services to home health Medicaid patients. While telemedicine is without a doubt picking up a steam in health care policy circles, applicability is still an issue being worked out by stakeholders and regulators alike.

Hearings

House of Representatives

On Thursday, February 4th, at 9:00 AM, the House Committee on Oversight and Government Reform will hold a hearing titled, "Developments in the Prescription Drug Market."

On Thursday, February 4th, at 10:00 AM, the House Energy and Commerce Subcommittee on Health will hold a hearing titled, "Examining Implementation of the Biologics Price Competition and Innovation Act."

United States Senate

On Monday, February 1st, at 10:30 AM, the Senate Special Committee on Aging will hold a hearing titled, "Fighting Against a Growing Epidemic: Opioid Misuse and Abuse Among Older Americans."

The Last Word

FDA Mixed Signals Leading to Confusion Over Digital Health Innovation: Drug companies are increasingly looking into digital health as a way to improve delivery of products, thus increasing sales, but are encountering unintended roadblocks due to FDA oversight, which the agency is still sorting out. One product in particular – a small grain-sized sensor developed by Proteus Digital Health and embedded in a drug used to track when patients take their prescriptions – is as exciting as it is frustrating as the FDA approved the device from its device center but is still reviewing it through the Center for Drug Evaluation and Research, a process which could take up to a year. Both the Center for Devices and Radiological Health and the Center for Drug Evaluation and Research have some jurisdiction over these products, but there is no streamlined process in place for combination products.

This has added months to reviews and approvals for products, and slows the development of innovative new products across a variety of markets. At a time when the FDA should be fostering the development of effective and compliant products, it appears to be doing the opposite. Senator Johnny Isakson (R-GA) introduced [legislation](#) last year that would affect oversight of [combination products](#), which are products that “are therapeutic and diagnostic” and “combine drugs, devices, and/or biological products,” according to the FDA. .

Senator Isakson’s legislation, the Combination Product Regulatory Fairness Act of 2015, currently has six bipartisan cosponsors and will likely be considered as a part of the Senate HELP Committee’s initiative to pass its version of the House-passed 21st Century Cures Act.