



ML Strategies Update

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OCTOBER 26, 2015

Health Care Update

Senate Working Group Pressing Forward on Telehealth

As Congress focuses on bigger picture policy decisions, including broad budget negotiations and raising the debt ceiling, there are some exciting developments on the telehealth front, this time coming from the Senate, where work on a new telehealth bill continues.

A bipartisan working group of Senators is potentially within weeks from introducing legislation to address telehealth reimbursement under Medicare.

The working group, led by Senators Brian Schatz (D-HI), John Thune (R-SD), and Roger Wicker (R-MI), would expand reimbursements under Medicare in an effort to increase access to telehealth and remote monitoring services. The language under development would expand in-home options for beneficiaries and providers, specifically allowing for telehealth to satisfy the monthly physician “face-to-face” visit requirements for in-home dialysis, as well as for the use of recertification’s for home health and durable medical equipment. The measure would also enable stroke evaluation to be eligible for telehealth reimbursement. Rural health clinics and federally qualified health centers would also be authorized to establish themselves as distant sites, meaning the physician would be eligible to provide telehealth services from those sites.

Finally, the language would also allow for increased access to remote patient monitoring under alternative payment models. The challenge with initiatives expanding telehealth and remote monitoring continues to be with the “score” of such provisions – or how much these will cost. Earlier this year, the Congressional Budget Office (CBO) [cautioned against](#) expanding access to telehealth under Medicare’s fee-for-service model without further evaluation, suggesting a demonstration project conducted in the Medicare fee-for-service model could generate positive insights into how best to assign coverage to telemedicine services.

ML Strategies will continue to monitor this issue over the coming weeks.

All Things ACA

Reconciliation Bill Moves to Senate: On Friday, the House of Representatives approved the reconciliation bill that guts several major pieces of the Affordable Care Act while defunding Planned Parenthood for one year. As reconciliation procedures in the Senate only require a majority vote, this legislation appeared sure to pass. However, the Heritage Foundation opposes the bill because it does not fully repeal the health care law, prompting Presidential hopefuls Senator Marco Rubio (R-FL) and Senator Ted Cruz (R-TX), along with Senator Mike Lee (R-UT), to oppose the bill. This puts the Republican vote count at 51, meaning only one GOP Senator would have to break from the party to derail the legislation. With Planned Parenthood on people's radar, expect tough decisions from moderate senators in cycle, namely Senators Mark Kirk (R-IL), Kelly Ayotte (R-NH), Rob Portman (R-OH), who are already facing tough battles in their respective states with the 2016 election just over a year away.

South Carolina the Latest Co-Op to Close: As of this writing, South Carolina became the ninth co-op to close its doors as a result of the risk corridor funding shortfall. This comes on the heels of Tennessee, Oregon, and Colorado co-ops closing their doors, which will result in 125,000 residents losing their health care coverage after December 31, 2015. Individuals shopping on the exchange have the option to shop for new plans each year, but the failure of multiple co-ops boosts uncertainty as plans prepare cost estimates for 2017 open enrollment, which could ultimately come back to hurt consumers pocket books.

Senator to Block All HHS Nominations as a Result of Co-Op Failures: On a related note, Senator Ben Sasse (R-NE) said he will block any HHS nomination until the Administration fully explains the failures. These nominations include Assistant Secretary nominee Karen DeSalvo, Deputy Secretary Mary Wakefield, CMS Acting Director Andy Slavitt, and top FDA official Robert Califf, all of whom are awaiting consideration before the Senate.

CMS Clarifies Small-Group Expansion Law: Last week, CMS issued a [frequently asked questions](#) document outlining how it plans to implement the recently passed Protecting Affordable Coverage for Employees (PACE) Act, which allows states to choose whether to subject businesses with up to 100 employees to the small business definition under the ACA for purposes of obtaining health insurance. Originally, the small business definition would have applied to businesses with up to 100 employees on January 1, 2016, but this legislation to make the expansion optional will save \$400 billion over the next decade, according to the Congressional Budget Office (CBO).

Energy & Commerce Committee Continue Investigation into State Exchanges: Last week, Energy & Commerce Chairman Fred Upton (R-MI), Oversight & Investigations subcommittee Chairman Tim Murphy (R-PA), and Health subcommittee Chairman Joe Pitts (R-PA) sent a letter to marketplace officials seeking information on CMS' oversight of funds, how states worked with CMS, and how states used the money. The Chairmen are requesting information as far back as June 2010 by this Wednesday. The states they are seeking information from include California, Colorado, Connecticut, Hawaii, Idaho, Kentucky, Maryland, Massachusetts, Minnesota, Nevada, New Mexico, New York, Oregon, Rhode Island, Vermont, Washington, and the District of Columbia.

Cadillac Tax Repeal Would add \$91 Billion to Deficit: The Joint Committee on Taxation and CBO, in [reviewing](#) the House reconciliation bill, found that repealing the 40 percent excise tax on high-cost health care plans would add \$91 billion to the deficit over the next decade, reducing projected revenue by \$109 billion over that same period.

Addressing Opioid Epidemic Gains Bipartisan Momentum

President Obama Addresses Crisis on Front Lines: Last week, President Obama traveled to West Virginia to host a forum on prescription drug abuse and the heroin epidemic in the state, which has the highest drug overdose death rate in the country. President Obama announced a [number of measures](#) intended to address this epidemic, including providing for additional training for federal health care professionals and formally requesting federal health insurance plans to identify and address barriers to addiction treatment.

House Subcommittee on Health Examines Proposals to Combat Drug Abuse: Last week, the House of Representatives reconvened a hearing from earlier this month to discuss legislative proposals to address our

nation's drug abuse crisis. The hearing, which reviewed several pieces of opioid abuse-related legislation, also spoke with drug control and policy experts.

CDC Releases Study on State Prescription Drug Monitoring Programs: A recent CDC study found that prescribing practices varied widely among states, underscoring [the need to](#) curb overprescribing. "States are on the frontline of witnessing these overdose deaths. This research can help inform their prescription overdose prevention efforts and save lives," CDC director Thomas Frieden said in a statement.

AMA, AAFP Join Fight Against Prescription Drug Abuse: The American Medical Association, along with the American Academy of Family Physicians, and others, have committed to training more than 540,000 providers in opioid prescribing, as well as doubling the number of doctors certified to prescribe buprenorphine, in the next two years.

CVS Increases Access to Naloxone in 14 States: CVS [announced last month](#) that the drug Naloxone, used to reverse opioid overdoses, is now available without prescription in CVS pharmacies in Arkansas, California, Minnesota, Mississippi, Montana, New Jersey, North Dakota, Pennsylvania, South Carolina, Tennessee, Utah, and Wisconsin. Typically, state law would have to be changed to allow pharmacies to dispense naloxone without a prescription.

Regulatory Developments

Federal Court Rejects HHS Interpretation of 340B Program Orphan Drug Rule: Last week, the U.S. District Court for the District of Columbia rejected a Health Resources and Services Administration (HRSA)-led alteration to the 340B program which would have narrowed the exclusion placed on orphan drugs. HRSA has been trying for years to narrow the exclusion as it simultaneously explores ways to reform the 340B program. Public comments on HRSA's [340B Drug Pricing Omnibus Guidance](#), which was released over the summer, are due by October 27, 2015.

SAMHSA Announces Excellence in Mental Health Planning Grants: The Substance Abuse and Mental Health Services Administration (SAMHSA) announced last week that 24 states will receive \$23 million in planning grants established by the Excellence in Mental Health Act. Eight states will be selected for a pilot program to test a prospective payment system for mental health care providers. As you may recall, the Excellence in Mental Health Act was folded into the Protecting Access to Medicare Act (P.L. 113-93) in 2014, the vehicle for delaying the now-repealed Sustainable Growth Rate.

New Report Suggests Digital Health Monitoring Could Save Billions: A new [report](#) by Accenture suggests digital health tools like home monitors and digital medical assistants could save the U.S. health system up to \$10 billion a year.

FDA Electronic Cigarette Regulations One Step Closer to Release: Last week, the FDA submitted its final rule to the White House Office of Management and Budget (OMB) for final review. Technically, OMB has 90 calendar days to review the rules, but the FDA said the window could be extended.

Hearings

House of Representatives

On Tuesday, October 27, the House Committee on Veterans Affairs will hold a joint subcommittee hearing on information technology titled, "VA and DOD IT: Electronic Health Records Interoperability."

United States Senate

On Thursday, October 29, the Senate Committee on Health, Education, Labor, and Pensions will hold a hearing titled, "Mental Health and Substance Use Disorders in America: Priorities, Challenges, and Opportunities."

On Thursday, October 29, the Senate Committee on Finance will hold a hearing titled, “Welfare and Poverty in America”

Other Events

On Monday, October 26, the American College of Preventive Medicine will hold its first Health Payment Learning and Action Network Summit, with Acting Director at CMS Andy Slavitt delivering keynote remarks.

On Thursday, October 29, the Medicaid and CHIP Payment and Access Commission, or MACPAC, will hold a public meeting.

The Last Word

Prescription Drug Costs Drawing Bipartisan Attention: It's not every day that Senator Bernie Sanders (I-VT) and Senator Marco Rubio (R-FL) agree on something, but there appears to be some mutual interest in an issue that has been on our radar for some time – the high-cost of prescription drugs. You may recall Senator Sanders [launching an investigation](#) last year to examine why the cost of generic drugs are skyrocketing. In May, Senator Sanders introduced S. 1364, [the Medicaid Generic Drug Price Fairness Act of 2015](#), which would pay a rebate to Medicaid when prices for generic drugs increase at a rate steeper than inflation. Last week, at a private campaign event, Presidential hopeful Senator Marco Rubio called out pharmaceutical companies for increasing prices dramatically, “because they can.” While his spokesman tried to clarify the comments, it's clear this is an issue with bipartisan support.

Additionally, former Secretary of State Hillary Clinton sent letters to both the FDA and FTC last week, urging them to look into “price gouging,” particularly to address the 5000-plus percent increase in cost for the drug Daraprim. She asked the FDA to accelerate the review of applications for generic drugs similar to Daraprim, in an effort to boost competition, or to consider allowing the temporary importation of similar drugs, an issue that has had some bipartisan support in the past.

This was an issue that garnered bipartisan attention last year when then-Senate Finance Committee Chairman Ron Wyden (D-OR) and then-Ranking Member Chuck Grassley (R-IA) requested pricing information on a costly Hepatitis C drug, known as Sovaldi. Given the attention on senior's issues lately, namely the still unresolved Medicare Part B increase issue, as well as increases in Part D premiums and the lack of an increase in Social Security payments in 2016, ML Strategies will closely be following this issue and will keep you updated as issues arise.