

#### ML Strategies Update

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# **Health Care Update**

**CMS Releases Final Payment Rules (IPPS, IRF, LTCHs, Hospice, and Psych):** At the end of last week, the Centers for Medicare and Medicaid Services (CMS) released a set of final 2016 payment rules affecting acute care hospitals and other providers such as psychiatric and long-term care hospitals. Overall, payment updates were within most analyst expectations, but the larger story is the continuing movement tying payment to quality and also adoption of electronic medical records.

For example, acute care hospitals that report quality data and are also meaningful users of electronic medical records will receive a 0.9 percent increase in Medicare operating rates. Alternatively, hospitals that do not report quality data or are meaningful users would be cut by a quarter or half of their market basket update respectively.

Additionally, CMS calculated they would pay \$1.2 billion less in Medicare Disproportionate Share (DSH) Hospital uncompensated care funds in FY 2016 than in FY 2015, in part because of the decline in the uninsured population.

One of the provisions that did not change in the final rule, despite heavy lobbying from stakeholders, was an extension of the enforcement delay on the two midnight policy that expires on September 30th. CMS had proposed a new policy that takes effect January 1, 2016, but did not extend the enforcement delay in the gap period as many commenters had asked for during the proposed rule comment period.

The final rule will be published in the Federal Register Aug. 17 and stakeholder comments are due Sept. 29.

**Lawmakers Introduce Bipartisan Post-Acute VBP Bill:** Although Congressional lawmakers are focusing on a vote to defund Planned Parenthood today in the Senate, another pair of influential House members have introduced a bill entitled the "Medicare Post-Acute Care Value-Based Purchasing Act of 2015" (H.R. 3298) to create a single value-based purchasing (VBP) system for post-acute care. Reps. Kevin Brady (R-TX) and Ron Kind (D-WI) – both members of the Health Subcommittee on Ways and Means – believe the bill would be a preferable replacement to CMS' mandatory home health VBP pilot that was proposed in the 2016 Home Health proposed rule.

The Brady-Kind legislation would focus only on spending per Medicare beneficiary and eliminate the other quality measures by which the proposed CMS home health VBP model would evaluate providers. Although some stakeholders have been critical of the proposed CMS model, the Brady-Kind bill received some push back from key stakeholders such as the American Health Care Association, which noted that focusing only on financial outcomes could hurt quality.

#### **Implementation of the Affordable Care Act**

CMS creates permanent special enrollment period for domestic abuse victims: CMS will make permanent an ACA special enrollment period for victims of domestic abuse or spousal abandonment, the agency said in guidance. The move will let individuals sign up for plans on the federal exchange outside of the regular open enrollment window, which for the 2016 plan year will begin Nov. 1 and end Jan. 31.

Health care gains under ACA more pronounced in Medicaid expansion states: Access to health care has improved significantly under the ACA, but those gains are more pronounced in states that have implemented the law's expansion of Medicaid, according to a study published in JAMA. The overall rate of uninsured has fallen by 7.9 percentage points since full implementation of the law in 2014. In addition, the number of Americans reporting that they don't have a personal physician decreased by 3.5 percentage points, while the number who couldn't afford care dropped by 5.5 percentage points.

**Exchange competition leads to better prices:** The Department of Health and Human Services (HHS) released a report demonstrating a slight decline in premium prices in counties experiencing a net gain of insurers. The exchanges saw greater competition overall this year, according to the report. Of those eligible to purchase exchange plans, 86 percent could choose from at least three insurance companies — an increase from 70 percent in 2014.

**GAO:** Medical device profits grew under the ACA: Medical device sales on average grew before and after Obamacare took effect in 2010, and profits have climbed since the law's medical device tax kicked in three years later, according to a Government Accountability Office (GAO) review of 102 companies. The report found that profits increased on average 19 percent in the tax's first year and 7 percent last year.

**OIG:** Co-op health plans unable to pay back loans: Almost all nonprofit co-op plans established with loans under the Affordable Care Act are losing money and failing to meet enrollment targets, according to a HHS inspector general report. Just over half of the co-ops had enrollment significantly below expectations in 2014, their first year of operations. All but two lost money last year.

#### **Federal Regulatory Initiatives**

**Health spending to rise annually:** According to CMS, health spending is expected to rise by 5.8 percent annually over the next decade. The growth in spending is being driven by the coverage expansion provisions of the ACA, the continuing economic recovery and a population that's steadily aging.

**CBO explains rationale for position on telemedicine in Medicare:** The Congressional Budget Office (CBO) argues that offering telemedicine to rural enrollees could improve the quality of care that such enrollees receive and could be more convenient for them. Doing so might not reduce Medicare spending on their care. CBO further explained its position on telemedicine cost estimates, reiterating that many congressional proposals seek to expand access to care with the technology and therefore would open up new lines of spending.

**IRS lacked data to verify healthcare tax credits:** According to a GAO report, the Internal Revenue Service (IRS) was unable to verify the accuracy of many of the tax credits provided to ACA recipients in 2014 because of data transmission problems between the IRS and CMS. The IRS was uncertain whether the problems would persist beyond the first year of exchange operations, the GAO report says.

**Medicare prescription drug premiums projected to remain stable:** CMS projected that the average premium for a basic Medicare Part D prescription drug plan in 2016 will remain stable, at an estimated \$32.50 per month.

**FDA** report outlines progress made since 'mission at risk' declared in 2007: The Food and Drug Administration (FDA) provided a report detailing the steps it's taken to improve operations since 2007, when external advisors to FDA's commissioner declared that FDA "suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities."

**AMA lays out recommendations on opioid abuse:** The American Medical Association (AMA) is urging physicians to register for and use state-based prescription drug monitoring programs when they consider treatment options for patients. AMA is also increasing its efforts to educate docs on evidence-based prescribing, which will include a new website with info on PDMPs.

White House updates HIV strategy through 2020: The White House released an update to its 2010 National HIV/AIDS Strategy, marking major developments over the past five years and laying out goals through 2020. The goals include reducing the number of new diagnoses by at least 25 percent, increasing the percentage of newly diagnosed individuals who are linked to HIV care within one month to at least 85 percent and increasing the share of individuals adhering to treatment to 90 percent.

**NIH releases budget request increase for Alzheimer's research:** The National Institutes of Health (NIH) unveiled its first "bypass budget" request for Alzheimer's, revealing a \$323 million increase in requested funds. It's the amount the agency estimates it will need in 2017 beyond its baseline budget to meet the goal to treat and prevent the disorder by 2025.

**FDA would receive limited funding in "Cures" legislation:** The FDA is concerned regarding its lack of funding in the House's 21st Century Cures legislation. Both FDA and CBO have estimated the bill includes \$900 million in new duties for the FDA, but provides only \$550 million in new funding.

### **Congressional Updates**

**BPC** report calls for interoperable electronic health records: The FDA needs to better integrate data collected from electronic health records (EHR) in the drug approval and oversight process, according to a report from the Bipartisan Policy Center, which hopes ideas from the report will be incorporated into legislation under development in the Senate Health, Education, Labor, and Pensions (HELP) Committee. To make integration possible, federal health IT should double down on efforts to make EHRs interoperable, in order to realize the full potential of medical innovation.

Senate Finance Committee releases letters on Medicare-chronic care initiative: Senate Finance Committee Chairman Orrin Hatch and Ranking Member Ron Wyden released 530 letters responding to the committee's initiative to improve coordination of care for Medicare patients living with chronic conditions. Many of these letters called for an expansion of CMS' payment for telemedicine.

Committee leaders question HHS on flu preparedness: Chairman Fred Upton (R-MI), and several members of the Oversight and Investigations Subcommittee, wrote a letter to HHS Secretary Sylvia Burwell seeking documents regarding the administration's lessons learned from the previous flu season as well as documents detailing preparedness efforts for the upcoming season. "The mismatched seasonal influenza vaccine and the high death rate among the elderly and other high-risk populations in the U.S. during the 2014-2015 influenza season highlight the need for an improved response, including making seasonal influenza vaccines more effective and promptly available."

**Senators introduce first eating disorder treatment legislation:** Senator Amy Klobuchar (D-MN) introduced the Anna Westin Act, a bipartisan bill that addresses eating disorders. The bill requires insurance companies to cover residential treatment for eating disorders and tasks the NIH with raising awareness about eating disorders and training primary care physicians and school personnel to detect eating disorder symptoms.

Representatives move to block breast cancer screening recommendations: Representatives Renee Ellmers (R-NC) and Debbie Wasserman Scultz (D-FL) introduced legislation that would prevent the United States Preventive Services Task Force from finalizing draft recommendations against routine mammograms for women under 50.

House E&C Committee probes Department of Defense on live anthrax shipments: The House Energy and Commerce Committee held a hearing to review the Federal Select Agent Program after an internal Defense Department investigation revealed that live anthrax had been shipped to 86 facilities across seven countries, 20 states and the District of Columbia.

**78 Representatives sign IPR letter:** A letter to support a pharmaceuticals exemption from a streamlined patent review process gained support from 78 lawmakers. The sign-on letter had circulating in late June as part of the industry's push to get the carveout included in the Innovation Act, a reform bill meant to help fight patent trolls.

## **Upcoming Hearings**

On Thursday, August 6, the Senate Committee on Health, Education, Labor and Pensions will hold a business meeting to consider S 799, A bill to combat the rise of prenatal opioid abuse and neonatal abstinence syndrome; S 1893, A bill to reauthorize and improve programs related to mental health and substance use disorders; and S 481, the Improving Regulatory Transparency for New Medical Therapies Act, as well as the nomination of Karen DeSalvo to be the assistant secretary of Department of Health and Human Services for Health.

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