

ML Strategies Update

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Health Care Update

Health Care Narrative Shifting to Delivery & Payment Reform: With open enrollment behind us, policymakers have begun to shift their focus on the rising cost of health care in a significant way. For Republicans, who are still largely running against the Affordable Care Act (ACA) leading up the midterm elections, health care costs and 2015 exchange plan rates will likely be an important part of the narrative on whether the ACA is working or whether it is contributing to a rise in health care costs. For ACA supporters, recent actions are a sign of how important other factors are to blame for the high cost of health care. The starkest example of this was the recent letter sent by high ranking House Democrats to the manufacturer of Sovaldi, asking them to justify the high price of its Hepatitis C drug, causing Gilead's stock to take a significant dive on fears that policymakers or other stakeholders would intervene to limit the price of the costly drug.

Last week, a prominent physician professional society, the American Society of Clinical Oncology (ASCO), convened a task force to develop an algorithm that could be used to determine the clinical effectiveness and known side effects associated with specific treatments and integrate those factors with the costs, putting further pressure on biopharmaceutical companies to reduce the cost of their products. Meanwhile, a recent survey showed two-thirds of accountable care organizations (ACOs), one of the most prominent delivery reform initiatives, would not plan on continuing in the ACO program if forced to face two-sided risk amidst reports that CMS is considering significant changes to the ACO program.

Finally, health care stakeholders are keenly interested in the elevation of Sean Cavanaugh to head the CMS Office of Medicare. Mr. Cavanaugh was most recently Deputy Director at the CMS Innovation Center, the component of CMS most visibly tackling delivery and payment reform.

Implementation of the Affordable Care Act

GAO Reports Sebelius Solicited Help: The Government Accountability Office (GAO) released a report which found that outgoing Department of Health and Human Services (HHS) Secretary Kathleen Sebelius solicited the CEOs of five organizations to provide technical assistance and financial support for Enroll America.

Healthcare.gov Heartbleed Vulnerability: Healthcare.gov reset passwords on consumers' Marketplace accounts due to concerns regarding the Heartbleed bug. However, they stressed that there is no indication that any personal information was ever at risk.

CBO Baseline Suggests Benefits to States: The Center on Budget and Policy Priorities posted an analysis of the CBO baseline released last week, showing that CBO now estimates that the federal government will pay for more than 9% of the total cost of the Medicaid expansion, resulting in states spending only 1.6% more on Medicaid and CHIP than they would have without the Affordable Care Act (ACA).

400,000 Enroll in CO-OPs: The National Alliance of State Health CO-OPs announced that over 400,000 people enrolled in CO-OP health insurance plans in the first year of enrollment.

Republican's Support Johnson's OPM Lawsuit: Thirty eight Republican members of the House and Senate filed an amicus brief in support of Senator Ron Johnson's (R-WI) lawsuit against the Office of Personnel Management to revoke the Administration's contribution to the healthcare plans of members of Congress and their staff.

CMS Administrator Leaving: Principal Deputy Administrator of the Centers for Medicare and Medicaid Services (CMS) Jonathan Blum will be leaving on May 16. He will be replaced by Sean Cavanaugh, who is currently the Deputy Director of the Center for Medicare and Medicaid Innovation.

Nunn Opposes Contributions in Ad: Democrat Michelle Nunn, who is currently running for the Georgia Senate seat, released an ad opposing federal contributions to the healthcare plans of members of Congress and their staff.

Rep. Black Asks for Fraud Update: Representative Diane Black (R-TN) wrote to CMS Administrator Marilyn Tavenner requesting an update on the progress implementing GAO recommendations to reduce fraud.

Other Federal Regulatory Initiatives

FDA Proposes to Regulate E-Cigarettes: The Food and Drug Administration (FDA) has proposed a new regulation deeming tobacco products, including e-cigarettes, cigars, pipe tobacco, nicotine gels, waterpipe tobacco, and dissolvables not already under its authority.

EHR Incentive Program Progress: The CMS Health IT Policy Committee released data on the number of eligible providers and hospitals who have received electronic health records incentive payments. More than 90% of eligible hospitals and 65% of eligible professionals have received a payment.

GAO Report on IRS Budget Cuts: The GAO released a report about the effect of budget cuts on the IRS, which found that performance was uneven and that enforcement efforts and phone service have been particularly damaged by the cuts.

FDA Proposes Expedited Medical Devices Program: The FDA has proposed an expedited access program to provide high-risk medical devices that meet unmet medical needs. The program would create a collaborative approach and provide greater engagement with FDA staff during product development.

HHS Announces HIPAA Settlements: Concentra Health Services and QCA Health Plan, Inc., have collectively paid \$1,975,220 to resolve potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules for failing to encrypt laptops with protected health information that were later stolen.

FDA Rejects New Painkiller: The FDA Anesthetic and Analgesic Drug Products Advisory Committee voted 14-0 against recommending that the FDA approve Moxduo, an opioid that combines oxycodone and morphine, arguing that there was insufficient evidence it provided additional benefits and that it could be more easily abused.

Other Congressional and State Initiatives

Representatives Question Generic Drug Labeling Changes: Republican Members of the House Energy and Commerce Committee sent a letter to FDA Commissioner Margaret Hamburg expressing concern about the proposed changes to generic drug labeling and asking for information about the role of the Association of Trial Lawyers of America in developing the proposal.

McDermott Urges Investigation of Consolidation: Ranking Member of the House Ways and Means Subcommittee on Health Jim McDermott (D-WA) sent a formal comment to the Federal Trade Commission (FTC) urging them to investigate health care consolidation and examine how it is impacting prices and competition.

Other Health Care News

Stakeholders Press CMS on ICD-10: Premier, Inc., an association of hospitals, wrote to CMS asking the agency to implement the new ICD-10 medical codes on October 1, 2015—the earliest date it has authority to do so.

CVS Launches Premium Payment Service: CVS/pharmacy announced that it will be launching "Bill Pay at CVS/pharmacy," a service which will allow consumers to pay their insurance premiums at any CVS/pharmacy store at no additional cost.

CSPI Encourages Salt Limits: The Center for Science in the Public Interest (CSPI) is pressuring the FDA to adopt the Institute of Medicine's recommendations to set limits on sodium in processed foods with a counter that shows the number of people who have died due to salt-related health problems since the report was released in 2010.

Study Examines ACOs' Accountability: A new study by Harvard researchers found that a third of Medicare beneficiaries assigned to Accountable Care Organizations (ACOs) in 2010 or 2011 were not assigned the same ACO in both years and that much of their specialty care was provided outside of the assigned ACO, suggesting that changes must be made to ensure organizational accountability.

Upcoming Hearings and Markups

House

On April 29th, the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee will hold a hearing titled "Examining the Growing Problems of Prescription Drug and Heroin Abuse."

On April 30th, the Ways and Means Health Subcommittee will hold a hearing on ideas to improve Medicare oversight and reduce waste, fraud, and abuse.

On May 1st, the Health Subcommittee of the House Energy and Commerce Committee will hold a hearing titled "Telehealth to Digital Medicine: How 21st Century Technology Can Benefit Patients."

Other

On April 30th, the CMS Medicare Evidence Development and Coverage Advisory Committee will hold a meeting to consider whether Medicare should cover annual screenings of smokers using low-dose CT scans to detect early-stage lung cancer.

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