



ML Strategies Update

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Health Care Update

CMS Getting New Leadership Roles: Department of Health and Human Services (HHS) Secretary Sylvia Burwell [announced](#) a series of management changes designed to strengthen the Obama Administration's implementation of the ACA. The Centers for Medicare & Medicaid Services (CMS) will now have a new Principal Deputy Administrator for agency-wide policy and operational program coordination, a single Marketplace Chief Executive Officer, and a Marketplace Chief Technology Officer. Andy Slavitt, most recently the Group Executive Vice President for Optum, will be joining the agency as the Principal Deputy Administrator. One of the intended consequences of the recent management moves is to establish a visible leader, in charge of overseeing all aspects of the health insurance marketplaces (exchanges).

While many groups hailed the latest moves by the new HHS Secretary to improve operational capacity and accountability, some GOP lawmakers have raised concerns over the hiring of Slavitt, who was until recently, an executive with one of the leading contractors involved with marketplace implementation. Recently, Republican Senators Charles Grassley (R-IA) and Orrin Hatch (R-UT) [wrote](#) to Secretary Burwell questioning the role of UnitedHealth Group subsidiary, Optum/QSSI, and its role as "senior advisor" to HealthCare.gov. The letter follows a report by the Senate Finance Committee Republicans, titled [Red Flags: How Politics and Poor Management Led to the Meltdown of HealthCare.gov](#).

What the recent leadership changes indicate, however, is that the Obama Administration is prioritizing operational experience heading into the next two years of ACA implementation. This prioritization is reflected in the decision to install Burwell as HHS Secretary. For stakeholders, the most likely effect of the recent leadership changes, and those to come, will be to understand how proposed policies will either help or hurt the various elements that affect successful implementation and that increase the public's trust in the ACA and the Administration's ability to implement it.

Implementation of the Affordable Care Act

CMS Coverage to Care Initiative: CMS announced a new initiative, “[From Coverage to Care](#),” which would help consumers get the most out of their new health insurance. The initiative includes a [roadmap](#) for accessing care, outlining benefits, defining common health care terminology, and explaining in- and out-of-network care.

House Democrats on Enrollment Projections: House Oversight and Government Reform Committee Democrats released a [fact sheet](#), using data gathered by the Committee majority, to show that ACA enrollment has exceeded insurance company projections by 4 percent. While the Democrats fault the methodology used to gather the data, Ranking Member of the Committee Elijah Cummings (D-MD) said it shows a “strong demand” for “quality, affordable insurance.”

CMS FAQ on Terminated Insurance Policies: CMS has released a FAQ on how health insurers should tackle reinstating customers who have erroneously lost their plans due to technical glitches. The FAQ advises insurers to add consumers back to the rolls and reconcile the changes with CMS at a later time.

HHS Finds Premium Choice and Affordability: A [report](#) released by HHS found that consumers in silver plans, with tax credits, paid an average of \$69 a month. In the federal Marketplace, 69 percent of enrollees who selected Marketplace plans with tax credits had premiums of \$100 a month or less, and 46 percent of enrollees had premiums of \$50 a month or less after tax credits.

CBO on Estimating the Effects of the ACA: In response to [questions](#) from the record from a February Senate Budget Committee hearing, the CBO [said](#), because the health care law is mostly implemented, the agency cannot conduct “a retrospective analysis of the ACA that is analogous to the cost estimate provided by the agencies in 2010.”

Other Federal Regulatory Initiatives

FDA Issues Social Media Guidance: The Food and Drug Administration (FDA) issued [draft guidance](#) outlining recommendations for the presentation of risk and benefit information for prescription drugs or medical devices using Internet/social media sources with character space limitations. For example, under the guidance companies would need to include products’ risks in their communications. In [separate guidance](#), the agency also provided recommendations to companies that choose to correct third-party information, such as on Wikipedia, related to their own prescription drugs and medical devices.

Expands non-Regulated Mobile App List: The FDA added additional items to a list of examples of health care mobile applications which it would not regulate. The [additions](#) can be found in a supplemental appendix to last year’s FDA guidance.

FDA Draft Guidance on Medical Devices: The FDA released [draft guidance](#) stating it does not intend to regulate hardware or software that transfers, stores, converts, or displays medical device data because these activities pose “low risk” versus the importance they play in digital health. The agency will update 2013 mobile applications guidance to reflect this. In a [blog post](#), a senior policy advisor at the FDA said the guidance will allow further innovation and stronger products.

DOD Releases EHR Modernization Plan: The Department of Defense (DOD) released the [third iteration](#) of its draft DOD Healthcare Management System Modernization (DHMSM) solicitation. The \$11 billion contract for EHRs would cover close to 10 million active duty and retired members of the military and their dependents.

Other Congressional and State Initiatives

House Democrats Push for Sovaldi Hearings: Representatives Henry Waxman (D-CA) and Diana DeGette (D-CO) [wrote](#) to the House Energy and Commerce majority requesting the Committee and the Oversight Subcommittee hold hearings into Sovaldi and the price of the drug.

Senate Commerce Examines E-Cigs: In a Senate Commerce Committee [hearing](#), Senate Democrats slammed the industry for marketing e-cigs toward youth—citing concerns over flavoring and marketing tactics featuring cartoons and celebrities.

House E&C Examines Insurer Risk Protections: The House Energy and Commerce Oversight Subcommittee met to hear testimony from industry and CMS Deputy Administrator Mandy Cohen on risk adjustment programs within the ACA. In a [letter](#) on the risk corridor program sent the same day, Secretary Burwell told lawmakers that the program is an important safety valve and that the GAO has weighed in on HHS’ budget authority to operate the program.

House E&C Releases White Paper on 21st Century Cures: A [white paper](#) released by the House Energy and Commerce

Committee as part of its 21st Century Cures initiative states that Congress should pursue how eHealth can accelerate medical research and development while balancing the need for privacy. The Committee will hold a [roundtable](#) on June 24th to explore these issues further.

House E&C Marks up Series of Bills: On June 19th, the House Energy and Commerce Health Subcommittee [marked up](#) a series of health care bills, including: H.R. 4771, the Designer Anabolic Steroid Control Act; H.R. 4250, the Sunscreen Innovation Act; H.R. 4701, the Vector-Borne Disease Research Accountability and Transparency Act; H.R. 594, the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments; H.R. 669, the Sudden Unexpected Death Data Enhancement and Awareness Act; and H.R. 4290, the Wakefield Act.

Senators Introduce Hospital Readmissions Bill: Senators Joe Manchin (D-WV), Roger Wicker (R-MS), Mark Kirk (R-IL), and Bill Nelson (D-FL) introduced the [Hospital Readmission Accuracy and Accountability Act](#), which would direct CMS to take into account the socioeconomic status of a hospital's patients when calculating readmissions penalties.

FY2015 Funding Tackles DOD-VA Interoperability: The [report language](#) to the Pentagon FY2015 spending bill that was approved by the House contains limited funding to harmonize DOD-Veterans' Affairs EHRs.

Other Health Care News

JAMA on Meaningful Use: A [report](#) released in the JAMA Internal Medicine journal found that doctors meeting requirements for stage 1 of meaningful use did not necessarily or consistently provide improved health care. The study interviewed 858 physicians, 540 of which had moved to stage 1 of meaningful use.

Avalere Premium Analysis: According to an [analysis](#) of proposed rate increases in nine states, Avalere predicts that the average premium for a silver plan will rise modestly from \$324 in 2014 to \$350 in 2015.

GPhA Finds Generic Drug Label Concerns: A [survey](#) released by the Generic Pharmaceutical Association (GPhA) and the National Coalition on Healthcare found that providers have strong reservations about the FDA's rule on generic drug labelling.

Many Previously Uninsured on Exchanges: A [survey](#) by the Kaiser Family Foundation has found that approximately 57 percent of those now covered on the exchange were previously uninsured.

Deloitte Report on Disrupter Technology: A Deloitte [report](#) finds that the "health care industry is ripe for disruptive innovation as systemic challenges continue to face the industry and stakeholders demand increased value."

Upcoming Hearings and Markups

Senate

On June 25th, the Senate Special Aging Committee will hold a [hearing](#) titled "State of Play: Brain Injuries and Diseases of Aging."

House

On June 24th, the House Energy and Commerce Committee will hold a [roundtable](#) on Digital Health Care.

On June 25th, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) titled "Medicare Program Integrity: Screening Out Errors, Fraud, and Abuse."

On June 25th, the House Veterans' Affairs Committee will hold a [hearing](#) titled "VBA and VHA Interactions: Ordering and Conducting Medical Examinations."

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