



## ML Strategies Update

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## Health Care Update

**CMS Publishes Long-Awaited “Health Plan Innovation Initiative” RFI:** Last Thursday, October 2<sup>nd</sup>, the Centers for Medicare and Medicaid Services (CMS) [published a Request for Information \(RFI\)](#) seeking broad industry input on initiatives to test innovations in plan design, including value-based insurance design; care delivery; beneficiary and provider incentives and engagement; and network design in Medicare health plans and Medigap and Retiree Supplemental health plans. CMS Innovation Center (CMMI) officials have discussed for some time that this type of initiative is a priority for 2014 and that developing a demonstration could either provide regulatory and programmatic rule-relief for plan innovations and/or funding to help implement and evaluate various tests.

CMS is seeking input from stakeholders about their experiences with, and perspectives about, the following types of products that are made available to Medicare and/or Medicaid beneficiaries:

1. Stand-Alone Medicare Prescription Drug Plans
2. Medigap and Retiree Supplemental health plans
3. Medicare Advantage and Medicare Advantage Prescription Drug Plans
4. Medicaid Managed Care Plans

Areas where CMMI has focused on changes to Medicare rules around technology such as telehealth and remote monitoring, integration of Accountable Care Organizations (ACOs) with Medicare Advantage and Medicare Advantage Prescription Drug plans, and more aggressive Medicaid waivers. It is possible that CMS could turn around an initiative by early 2015, based on the design of the initiative. Comments are due to CMS by November 3, 2014.

### Implementation of the Affordable Care Act

**Big Insurers Participate in Most ACA Exchanges:** The Government Accountability Office (GAO) [found](#) that insurance companies who covered most of a state's market in 2012 participated in two-thirds of health care exchanges formed in 2014 as part of the ACA. The average individual marketplace had six issuers; the average small-business exchange had three.

**CMS Renews Contract with Terremark for Work on HealthCare.gov:** CMS has [extended](#) its contract with Terremark, which will receive \$15 million to refine the Enterprise Identity Management tool to ensure users secure access to HealthCare.gov.

### Other Federal Regulatory Initiatives

**CMS Posts Millions of Physician Payments:** CMS posted the records of \$3.5 billion in payments that physicians received from the pharmaceutical industry on the [Open Payment database](#).

**CMS Releases Guide on Managed Care Rate Certifications:** CMS [published](#) the 2015 Managed Care Rate Setting Consultation Guide for states to consult when they create their Medicaid managed rate certification packages.

**FDA Reopens Comment Period for Two Guidances:** The Food and Drug Administration (FDA) is [reopening](#) the comment period for 30 days for individuals and organizations to submit their input on two draft social media guidances the agency published in June. The first [guidance](#) would require prescription drug companies to post products' risks on social media. The [second](#) would advise companies seeking to correct misinformation on third-party sites, such as Wikipedia, to request changes in a clearly-defined forum.

**FDA Releases Draft Lab Test Framework:** The FDA released a draft [framework](#) for oversight of laboratory developed tests (LDTs). The guidance "describes FDA's priorities for enforcing premarket and postmarket requirements for LDTs as well as the process by which FDA intends to phase in enforcement of FDA regulatory requirements for LDTs over time." The FDA also released [draft](#) industry reporting requirements for LDTs.

**FDA Finalized Cybersecurity Guidance:** The FDA released [final guidance](#) for medical device manufacturers managing cybersecurity in medical devices. The guidance "recommends that manufacturers consider cybersecurity risks as part of the design and development of a medical device, and submit documentation to the FDA about the risks identified and controls in place to mitigate those risks."

**FDA Releases Roadmap:** The FDA released a strategic [roadmap](#) for 2014 to 2018 to set forth the FDA's mission and priorities. Among other things, the FDA lists enhanced oversight of FDA-regulated products, improvement and safeguarding access to FDA-regulated products, promotion of better information decisions of FDA-regulated products, and strengthening the agency's internal management.

**No New Cases of Ebola in Nigeria and Senegal:** The Centers for Disease Control (CDC) [reported](#) that no new cases of Ebola have been identified in Nigeria as of August 31 and in Senegal as of August 29. The agency hailed this news as proof that African governments' coordinated public health responses have been effective.

**Survey Reports Widespread Use of Illicit Drugs:** The 2013 National Survey on Drug Use and Health [found](#) that 24.6 million people over the age of 11 used illicit drugs last month.

**President Signs Muscular Dystrophy Bill:** President Obama signed into law [H.R. 594, the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014](#). The bill updates surveillance, research, and education activities to reflect scientific developments and continue the support of research and patient support initiatives across all forms of Muscular Dystrophy.

### Other Congressional Initiatives

**Lawmakers Push Back on Home Health Cuts:** Senators Mike Johanns (R-NE), Lamar Alexander (R-TN) and Representative Tim Walberg (R-MI) led an effort joined by 12 other Republican Members [requesting](#) that Department of Labor Secretary Tom Perez suspend a rule, *Application of the Fair Labor Standards Act to Domestic Service*, that "dramatically increases costs of non-medical, in-home personal care services."

**Democrats Demand Hearings on Ebola:** House Energy and Commerce Committee members Henry Waxman (D-CA), Frank Pallone (D-NJ) and Diana DeGette (D-CO) [urged](#) Chairman Fred Upton (R-MI) to hold committee hearings on the threat of Ebola.

**Lawmakers Launch Investigation into Generic Prices:** Senator Bernie Sanders (I-VT) and Representative Elijah Cummings (D-MD) began an [investigation](#) into rising generic drug prices. The lawmakers produced a [fact sheet](#) on price increases using data from the Healthcare Supply Chain Association.

**Other Health Care News**

**NGA Urges States to Account for Growing Role of PAs:** The National Governors Association (NGA) [published](#) a report on the growing need for physician assistants and their expanding role in the health care system.

**Upcoming Congressional Hearings and Markups**

*The Senate and House and in Recess.*

On Friday, October 10<sup>th</sup>, the House Homeland Security Committee will hold a [field hearing](#) in Dallas, Texas titled “Ebola in the Homeland: The Importance of Effective International, Federal, State and Local Coordination.”

On Thursday, October 16<sup>th</sup>, the House Energy and Commerce Oversight and Investigations Subcommittee will hold a [hearing](#) titled “Examining the U.S. Public Health Response to the Ebola Outbreak.”

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