



## ML Strategies Update

Jeremy Rabinovitz, [JRabinovitz@mlstrategies.com](mailto:JRabinovitz@mlstrategies.com)  
Joseph P. Hammang, PhD, [JPHammang@mlstrategies.com](mailto:JPHammang@mlstrategies.com)  
Alexander Hecht, [AHecht@mlstrategies.com](mailto:AHecht@mlstrategies.com)  
Andrew Shin, [AJShin@mlstrategies.com](mailto:AJShin@mlstrategies.com)  
Abby Matousek, [AMatousek@mlstrategies.com](mailto:AMatousek@mlstrategies.com)

**ML Strategies, LLC**  
701 Pennsylvania Avenue, N.W.  
Washington, DC 20004 USA  
202 434 7300  
202 434 7400 fax  
[www.mlstrategies.com](http://www.mlstrategies.com)

FOLLOW US ON TWITTER: [@MLStrategies](https://twitter.com/MLStrategies)

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## Health Care Update

- **Stakeholders Urge FDA to Provide Clarity on Biosimilars:** Following the publication of Food and Drug Administration (FDA) [draft guidance](#) in May 2014, industry groups, including BIO, PhRMA, and some of their member companies, are concerned with the guidance. The draft is intended to help companies that design and utilize clinical pharmacology studies demonstrate the similarity between a biosimilar and its reference product. BIO and PhRMA are worried that the FDA's four categories for comparing biosimilars to their reference products do not provide enough clarity and will ultimately result in safety issues with biosimilar medicines. The four tiers designated by FDA are: 1) not similar; 2) similar; 3) highly similar, and 4) highly similar with "finger-print like" similarity. Specifically, stakeholders are asking the agency to eliminate eventual ambiguity and provide additional guidance to differentiate between the tiers, such as the difference between "similar" and "highly similar." Although it is likely that FDA will provide additional clarity between the four tiers, experts believe that the agency is likely to leave a significant amount of ambiguity that gives regulators flexibility moving forward.
- **Ebola Crisis Continues:** The West African Ebola crisis continues, and worsens, with the World Health Organization (WHO) [reporting](#) that additional suspected or confirmed cases of the disease have pushed the outbreak to 2,127 cases of the disease. On August 14<sup>th</sup>, the FDA [warned](#) consumers to be aware of products sold online claiming to prevent or treat the Ebola virus. The FDA issued a reminder that there are currently no FDA approved vaccines or drugs to prevent or treat Ebola, and that experimental treatments are still in the early stages of product development. Additionally, the FDA urged consumers to report fraudulent claims to the FDA so that the agency can act to better protect consumers.

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

**CMS: 310,000 May Lose Coverage:** The Centers for Medicare & Medicaid Services (CMS) released a [map](#) showing the individuals whose citizenship is under question for the purposes of health coverage. These people must submit documents by September 5<sup>th</sup> in order to keep their coverage on the federal exchange.

**White House Announces U.S. Digital Service:** The White House [announced](#) a new U.S. Digital Service team as part of an effort to avoid the issues that plagued the rollout of HealthCare.gov. The U.S. Digital Service “will be a small team made up of our country’s brightest digital talent that will work with agencies to remove barriers to exceptional service delivery and help remake the digital experience that people and businesses have with their government.”

### **Other Federal Regulatory Initiatives**

**CMS Announces New Staff:** Secretary Burwell [announced](#) that Kevin Thurm will be Senior Counselor at HHS. Thurm, previously with Citigroup, “will work closely with the Department’s senior staff on a wide range of cross-cutting strategic initiatives, key policy challenges, and engagement with external partners.”

**OMC Releases Draft on C-CDA:** The Office of the National Coordinator for Health IT working group on Health IT Standards Committee released a [draft](#) of its proposal to improve the documentation framework for health information in Stage 2 meaningful use. The working group calls for clarity on what to include as clinical documentation under the Consolidated-Clinical Document Architecture (C-CDA).

**FDA Approves Colon Cancer Test:** The FDA [approved](#) the test Colonguard, which tests for DNA mutations and abnormally growing cells. This is the first noninvasive test for colorectal cancer, which primarily affects men and women age 50 and over.

**GAO Recommends Oversight for Medicare Claims:** The Government Accountability Office (GAO) released a [report](#) on steps that CMS and HHS have taken to prevent contractors from “conducting certain duplicative postpayment claims reviews.” GAO finds that CMS does not have enough data for sufficient oversight and guidance.

**CDC Report on Sugary Beverages:** The Centers for Disease Control (CDC) released a [report](#) on adult consumption of sugar-sweetened beverages. According to the report more than 25 percent of U.S. adults over the age of 18 drink soda or a similar sugary drink every day.

**HRSA on EHRs:** According to [data](#) from the Health Resources and Services Administration (HRSA), the majority of federally qualified health centers, over 95 percent, use EHRs.

### **Other Congressional and State Initiatives**

**President Signs Public Health Bills:** President Obama [signed](#) into law two bills, H.R. 4631, the Autism Cares Act and H.R. 3548, the Improving Trauma Care Act. Chairman of the House Energy and Commerce Committee Fred Upton (R-OH) praised the news, saying that the “113th Congress will be remembered as the public health Congress.”

**Rep. Black on ACA Income Issues:** Representative Diane Black (R-TN) [wrote](#) to HHS asking the agency to look into ACA eligibility based on income in the same way it screens for citizenship and immigration status.

### **Other Health Care News**

**Venture Capitalists Call for EHR Data:** The National Venture Capital Association (NVCA), in [comments](#) on the House Energy and Commerce 21<sup>st</sup> Century Cures Initiative, urged Congress to help facilitate additional access to post-market clinical data in patients’ EHRs.

**Deloitte Estimates 2014 eVisits:** A Deloitte [white paper](#) predicts that there will be 100 million eVisits globally in 2014. Three-fourth of these eVisits occurred in North America. The white paper goes on to note that these visits could save \$5 billion compared to in-person care.

**RAND Studies 340B Program:** The RAND corporation released a [study](#) on the 340B prescription drug discount program. The report finds that eligibility for the program need to be changed as 7,800 covered entities handle about a third of all hospital outpatient visits and that the method for calculating discounts need to be redefined.

**Report on Employer Telehealth:** The National Business Group on Health released its 2015 Health Plan Design [survey](#). The report finds that 48 percent of large employers will offer telehealth solutions in 2015. A third of employers currently offer telehealth services.

**Upcoming Congressional Hearings and Markups**

*The Senate and House are in Recess.*

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