



## ML Strategies Update

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)

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

### 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)

OCTOBER 20, 2014

## Health Care Update

- **Policymakers Scrambling to Contain Ebola Crises:** Over the past week, the Obama Administration, and now Congress, has signaled significant moves to direct funding and federal government support for a variety of initiatives designed to combat the growing Ebola crisis.

On Friday, the House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing to examine the role of U.S. public health agencies and their efforts to prevent the spread of Ebola within the U.S. Issues discussed at the hearing included the preparedness of ports, points of entry, healthcare facilities and other institutions to identify, diagnose, isolate, and treat Ebola patients in a safe and appropriate manner. The same day, the Administration announced the appointment of Ron Klain, former chief of staff to Joe Biden, to lead Ebola coordination across the Obama Administration and with Congressional leaders. Klain will be reporting directly to Lisa Monaco, President Obama's homeland security advisor, and Susan Rice, the President's national security advisor.

Klain's appointment, combined with comments made by senior officials at Friday's hearing, signal an increased commitment to battling the disease on behalf of the Administration. The Biomedical Advanced Research and Development Authority (BARDA) announced last week that it would contract with Profectus Biosciences Inc. to develop an additional vaccine, on top of the FDA's emergency use authorization of two diagnostic tests for the disease. Speaking at the hearing, Luciana Borio, FDA's Assistant Commissioner for Counterterrorism Policy, said the FDA and NIH are working together on clinical trial protocols to evaluate multiple investigational products and President Obama signaled he would be asking Congress for additional funding to fight the virus—the U.S. government currently has \$1 billion authorized to fight Ebola in Africa. These recent developments demonstrate the general interest of the government in having industry as a partner in drug and vaccine development.

Looking ahead, the House Oversight Committee will be holding a hearing on the multi-agency response to Ebola on Friday, October 24<sup>th</sup> and the Senate Appropriations Committee will hold a hearing on Ebola Thursday, November 6<sup>th</sup>.

### Implementation of the Affordable Care Act

**CMS Working to Maintain Marketplace Coverage:** CMS is [encouraging](#) consumers to come back at the start of Open Enrollment on November 15<sup>th</sup>. In order to make sure that consumers update their 2015 applications and enroll in the best plan, CMS is working to ensure consumers have the assistance and information they need. CMS released a five-step enrollment [guide](#) to assist with re-enrollment.

**CMS Announces New ACO Supports:** CMS announced a new [initiative](#) for Accountable Care Organizations (ACOs) participating in the Medicare Shared Savings Program. The ACO Investment Model is designed to further improve quality improvement and care coordination in rural and underserved areas by providing up to \$114 million in upfront investments to up to 75 ACOs across the country.

**Group Sues Over Exchanges:** Judicial Watch filed a [lawsuit](#) which alleges that Congressmen and Congressional staff that enrolled in an ACA health exchange classified as a small business exchange—which is defined as a business with fewer than 50 employees—have done so illegally.

### Other Federal Regulatory Initiatives

**CDC Finds EHRs Help Smoking Cessation:** The Centers for Disease Control (CDC) [Mortality and Morbidity Weekly Report](#) found that an electronic health record (EHR) pay-for-improvement program in New York increased the number of smokers who were documented as such from 24 percent to 27 percent and increased the proportion of smokers reviewing cessation treatments from 23 percent to 54 percent.

**HHS Advanced Third Ebola Treatment:** The Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response [announced](#) the award of a one-year contract with Profectus BioSciences Inc. to provide approximately \$5.8 million in funding to further develop an experimental Ebola vaccine.

**NIH Announces Social Media Awards:** The National Institutes of Health (NIH) [announced](#) more than \$11 million over three years to support research exploring the use of social media to advance the scientific understanding, prevention, and treatment of substance use and addiction.

**ONC Releases Roadmap Resources:** The Office of the National Coordinator for Health Information Technology (ONC) published [summaries](#) of in-person meetings held to develop the 10-year interoperability roadmap, including summaries of meetings with industry subject matter experts (SMEs) and state health IT leaders.

### Other Congressional Initiatives

**Lawmakers Press HHS on Drug Pricing:** In a [letter](#) to HHS Secretary Burwell, Senator Bernie Sanders (I-VT) and Representative Elijah Cummings (D-MD) requested to agency address the “staggering increases in prices being charged for generic drugs.”

**Sen. Markey on Opioid Abuse:** Senator Markey (D-MA) released a series of [recommendations](#) to create a Federal strategy to address America’s prescription drug and heroin crises. The plan focuses on prevention, treatment and enforcement. In announcing the plan, Markey said, “Just as every addict needs support and a strategy for overcoming addiction, our country needs an action plan to attack the scourge of opioid and prescription drug abuse that is ravaging our communities.”

**Senate Republicans File ACA Brief:** Senators John Cornyn (R-TX) and Ted Cruz (R-TX) filed an [amicus brief](#) in support of a rehearing in *Sissel v. US Department of Health and Human Services*. The case argues that the ACA violates the Origination Clause of the Constitution, which requires that legislation that raises revenue originate in the House of Representatives.

**House E&C Examines Ebola Response:** As fears over the spread of the Ebola virus in the U.S. continue, the House Energy and Commerce Subcommittee on Oversight and Investigations held a [hearing](#) to examine the U.S. response to the outbreak, featuring witnesses from the Centers for Disease Control, National Institutes of Health, Food and Drug Administration, Department of Health and Human Services, Department of Homeland Security, and Texas Health Resources. Lawmakers pressed officials on diagnosis and containment and development of vaccines and treatment.

**House Dems Press for Hearing on Cuts:** Democrats on the House Appropriations Committee are [calling](#) on Chairman Hal Rogers (R-KY) and Labor-HHS Subcommittee Chairman Jack Kingston (R-GA) to hold a hearing examining the effect of budget cuts on the U.S. public health infrastructure, particularly in relation to the Ebola outbreak.

**Upcoming Congressional Hearings and Markups**

*The Senate and House and in Recess.*

On October 24<sup>th</sup>, the House Oversight and Government Reform Committee will hold a hearing titled, “The Ebola Crisis: Coordination of a Multi-Agency Response.”

\* \* \*

Boston · Washington [www.mlstrategies.com](http://www.mlstrategies.com)