

# ML Strategies Update

Joseph P. Hammang, PhD, JPHammang@mlstrategies.com Alexander Hecht, AHecht@mlstrategies.com Andrew Shin, AJShin@mlstrategies.com Abby Matousek, AMatousek@mlstrategies.com

FOLLOW US ON TWITTER: @MLStrategies

ML Strategies, LLC
701 Pennsylvania Avenue, N.W.
Washington, DC 20004 USA
202 434 7300
202 434 7400 fax
www.mlstrategies.com

OCTOBER 27, 2014

# **Health Care Update**

• Ebola Response Taking a Multifaceted Approach: In the past week, federal regulators announced a number of additional measures to combat the spread of Ebola in the United States. The Centers for Disease Control (CDC) tightened its guidance for healthcare workers caring for patients with Ebola. Department of Homeland Security Secretary Jeh Johnson announced additional travel restrictions in light of the Ebola crisis, including additional screening at ports of entry for those travelling from affected West African countries. In addition, The National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases began conducting an early phase trial to evaluate another potential Ebola vaccine, called VSV-ZEBOV.

In addition to this push, Dr. Karen DeSalvo, until recently National Coordinator for Health IT, announced she would leave the Office of the National Coordinator (ONC) at the request of Secretary Burwell to assist on the Administration's efforts responding to Ebola. DeSalvo's biography has already been added to the Department of Health and Human Services (HHS) website, listing her as the Acting Assistant Secretary of Health.

Although the Federal government continues to address the spread of the virus, states have sought to augment these measures through additional screening and quarantine. Some states (i.e. New York, New Jersey, Illinois, and Florida) are taking heat for instituting a mandatory quarantine for travelers returning from West Africa. The White House has asked all states to reverse their mandatory quarantines, citing medical experts calling such policies unnecessary and warning they could discourage health workers from assisting to combat the virus. This tracks the Administration's message during Friday's House Oversight Committee hearing to explore the multiagency response to Ebola, in which witnesses discouraged such quarantine policies.

Nevertheless, some prominent Republicans are urging additional travel restrictions, calling the Administration's screening efforts "insufficient." Chairman of the House Judiciary Committee Bob Goodlatte (R-VA) said the Administration must "do more to protect Americans," saying he plans to introduce a resolution to block all entry of foreign nationals from countries with high rates of Ebola infection. Other policymakers have floated suspending visas. Both the global health community and industry are against such restrictions, warning that restrictions could impede efforts to fight the disease in affected countries—including limiting access to personnel and supplies. A broad swath of industry stakeholders also oppose further travel restrictions—especially those sectors doing business in West Africa and the travel and airline industries.

## Implementation of the Affordable Care Act

HHS Announces \$840 million to Improve Care and Lower Cost: HHS Secretary Sylvia Burwell announced a program to fund applicants who will work with medical providers to "rethink and redesign their practices, moving from systems driven by quantity of care to ones focused on patients' health outcomes, and coordinated health care systems." Through the Transforming Clinical Practice Initiative, HHS will invest \$840 million over the next four years to support 150,000 clinicians.

**CMS** Releases Basic Health Program Rule: The Centers for Medicare and Medicaid Services (CMS) issued a proposed notice establishing the "methodology and data sources necessary to determine federal payment amounts made in program year 2016 to states that elect to use the Basic Health Program to offer health benefits to low-income individuals otherwise eligible to purchase coverage through the Marketplace."

**CMS Announces Medicaid Enrollment Up:** The monthly report on state Medicaid and Children's Health Insurance Program (CHIP) data for October revealed that Medicaid enrollment grew to 67.9 million in August—an increase of 8.7 million people since before ACA open enrollment began.

**TIGTA Calls for Additional IRS Oversight:** The Treasury Inspector General for Tax Administration (TIGTA) released a report calling for additional oversight by the Internal Revenue Service of the ACA Exchanges in order to protect the confidentiality of Federal Tax Information (FTI).

#### Other Federal Regulatory Initiatives

**FDA Workshop on Cybersecurity:** The Food and Drug Administration (FDA), in collaboration with HHS and DHS, held a two day workshop as part of National Cybersecurity Awareness Month. The event brought together medical device manufacturers, healthcare facilities and personnel, professional and trade organizations, insurers, cybersecurity professions, and the government to identify cybersecurity challenges and ways to address them.

**OIG** Releases FDA Penetration Test: The HHS Office of the Inspector General (OIG) released a report, "Penetration Test of the FDA's Computer Network," finding that problems with the FDA website could lead to unauthorized disclosure of data or tampering with mission critical systems.

Report Finds Mains Contributors to Health-IT-Related Dangers: Health IT-related injuries, hazards, and fatalities stem most often from problems involving communication, record content, workflow confusion, and computer-use interface, per an ONC report. Gerry Castro, director of the Joint Commission's patient safety initiatives, unveiled the report Friday in front of the Health IT implementation, usability and safety workgroup.

**NIH Enhancing Biomedical Research Diversity:** NIH announced that it will award close to \$31 million in FY 2014 funds to develop new approaches that engage researchers from backgrounds underrepresented in biomedical sciences in the NIH-funded workforce.

VA Unveils Telehealth Software: On Thursday, the Department of Veterans Affairs (VA) introduced new telehealth scheduling software to Veteran Service Organizations at the VA Medical Center in Washington.

### **Other Congressional Initiatives**

21st Century Cures Roundtables Continue: Representatives Morgan Griffith (R-VA) and Representative Phil Roe (R-TN) held a 21st Century Cures Roundtable on October 22nd in Virginia to solicit opinions from health leaders, innovators, and academics on the pace of cures.

**Markey Presses Administration on Ebola Hubs:** Senator Ed Markey (D-MA) wrote to the Obama Administration asking the President to consider "designating regional hospital hubs that are prepared to provide specialized treatment and care for diagnosed Ebola patients while also serving as a source of technical assistance and support to other hospitals in the region."

**House E&C Republicans Press President on Ebola:** Twenty-eight Republican members of the House Energy and Commerce Committee wrote to President Obama, Ebola Response Coordinator Ron Klain, and HHS Secretary Burwell asking for answers on the Administration's response to the Ebola epidemic.

**McCarthy Firms Up 114**<sup>th</sup> **Agenda:** Majority Leader Kevin McCarthy (R-CA) outlined the agenda for the 114<sup>th</sup> Congress, including plans "FDA reforms that the Energy and Commerce Committee has already begun" as part of the 21<sup>st</sup> Century

Cures Initiative.

# **Other Congressional Initiatives**

Kaiser Poll Reveals Uninsured Unaware of Open Enrollment: According to the October Kaiser Health Tracking Poll, nine out of ten uninsured Americans are unaware of when the next open enrollment begins. Of this number, 76 percent said they do not know when it is and 13 percent indicated they believed it was a time other than November 2014.

**Online Price Compare Saves Money:** According to a study published in the Journal of the American Medical Association, which examined medical shopping habits of consumers, those that used an online tool for price comparison saved money, including an average of \$125 per advanced imaging service and \$3 per lab test.

**Survey Finds Doctors Improving Antibiotic Treatment:** According to a Consumers' Union survey, doctors have improved their prescription practices. 68 percent of doctors prescribed antibiotics to their patients for the shortest possible time period; 81 percent resisted patients' requests for needless prescriptions; 86 percent recommended patients to take the full course of antibiotics.

**FDA's Premarket Approval Timeline Shrinks:** Although premarket approval for medical devices by the FDA is three to five years longer than it is in Europe, it is shorter than has it been in the last decade, per a report from the California Health Institute.

# **Upcoming Congressional Hearings and Markups**

The Senate and House and in recess.

\* \* \*

Boston · Washington www.mlstrategies.com

Copyright © 2014 ML Strategies LLC. All rights reserved.