

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

February 17, 2015

Health Care Update

Open Enrollment Update: On February 11th, the Department of Health and Human Services (HHS) announced that since the beginning of Open Enrollment, 7.75 million consumers selected a plan or were automatically re-enrolled through HealthCare.gov—which includes the Federally Facilitated Marketplaces, State Partnership Marketplaces and supported State-Based Marketplaces. An additional 275,676 people selected plans between January 31st and February 6th.

While Open Enrollment was scheduled to end on February 15th, technical glitches prompted HHS to extend the deadline one week to accommodate users who were affected. Those consumers who could not complete enrollment due to technical issues or longer than normal wait times at the Marketplace Call Center will have until February 22nd to enroll.

On top of the extension for those experiencing difficulties, several Senators sent a **letter** to HHS Secretary Burwell requesting that the agency allow individuals who were uninsured in 2014 and subject to the individual responsibility payment an additional opportunity to enroll for health insurance. The Senators, all Democrats, led by Tammy Baldwin (D-WI), wrote, "a special enrollment period would increase coverage in affordable private health insurance and reduce the costs that the uninsured pass along to the insured. We are confident that this special enrollment period would build on the success of the law by allowing even more uninsured Americans to benefit from the health and financial security provided by the Affordable Care Act."

Secretary Burwell further said last week that the administration might offer some enrollment flexibility around the April 15 tax deadline, in order to offer relief for people who suddenly realize they face a penalty for remaining uninsured. With the coming conclusion of a relatively quiet, but mostly successful, open enrollment period, the Obama Administration is likely to continue their recent activity around payment and delivery reform initiatives as policymaker scrutiny shifts away from coverage issues and more towards costs.

Implementation of the Affordable Care Act

HHS Releases Average Monthly Tax Credit: HHS announced that 6.5 million of consumers using HealthCare.gov qualify for an average advance premium tax credit of \$268 per month and that 8 in 10 individuals had the option of selecting a plan with a premium of \$100 or less after tax credits.

Other Federal Regulatory Initiatives

FDA Commissioner Urges Vaccination: The Food and Drug Administration (FDA) Commissioner Margaret Hamburg urged Americans to get the measles vaccination in a blog post on Tuesday. She wrote that vaccinations are safe and vital weapons against the spread of disease.

FDA Releases Compounding Draft: The FDA released draft guidance to assist compounding pharmacies covered by the Drug Quality and Safety Improvement Act implement regulations. The guidance lays out criteria for voluntarily registering with the FDA and clarifies standards for repackaging drugs and mixing products.

White House Reviews Ebola Capacity: A White House fact sheet provided a summary of the progress made fighting Ebola in the U.S. and abroad outlining the steps the Administration took to contain, prevent, and treat the disease.

CMS Finalized MA and Part D Rules: The Centers for Medicare & Medicaid Services (CMS) released final rules for 2016 private Medicare Advantage (MA) plans and Part D prescription drug coverage. The rule targets quality improvement and chronic care improvement requirements. It also clarifies that MA plans and Medicare Part D sponsors must have plans in place to restore essential operations within 72 hours of an emergency.

CMS Meaningful Use Report: CMS announced that 34 percent of penalties that the agency assessed to doctors this year who did not meet meaningful use standards were \$250 or less—another 21 percent will be penalized between \$250 and \$1,000. Approximately 257,000 professionals will be penalized.

GAO Finds HHS Footing Too Big a Bill for Medicaid Enrollees: The Government Accountability Office (GAO) reports that the government is overpaying on health care coverage for some of the nearly 7.5 million Americans who are enrolled in Medicaid and covered by a private insurer. GAO claims that private insurers should be paying for more of this coverage but that they aren't because of a lack of coordination between stakeholders.

GAO Lists Federal Health Care and Health IT Programs As "High Risk": The GAO added DoD, VA, and CMS programs to a list of programs that are "high risk" due to vulnerabilities in fraud, waste, abuse, and mismanagement. Specifically under scrutiny are the DoD and VA's \$11 billion electronic health records program and CMS's issue with improper Medicaid payments, which increased to \$17.5 billion in FY 2014.

NIH Extends Clinical Trial Comment Period: The National Institutes of Health (NIH) announced that it has extended the comment deadline until March 23rd for stakeholders to share with the agency's thoughts on the clinical trial results reporting guidance.

NIH Provides Precision Medicine Details: In a meeting to discuss the Precision Medicine Initiative and how to build a large U.S. research cohort, NIH Director Francis Collins said that the initiative will be a "national study of health" with the goal of linking advances in medicine to technological innovation.

Congressional Initiatives

Senate HELP on Vaccines: The Senate Health, Education, Labor, and Pensions (HELP) Committee heard testimony on vaccine-preventable diseases. The Committee heard from CDC's National Center for Immunization and Respiratory Diseases, the University of California San Diego, Rady Children's Hospital, and the Tennessee Department of Health.

Republican Senators Ask for Co-Op Answers: Senators Deb Fischer (R-NE), Joni Ernst (R-IA), and Chuck Grassley (R-IA) wrote to CMS requesting the agency provide details on how it will help enrollees with costs if they were a part of a failed CoOportunity program.

House E&C Examines ICD-10 Implementation: The House Energy and Commerce Subcommittee on Health held a hearing to examine the implementation of the International Classification of Diseases, 10th revision (ICD-10). The Subcommittee reviewed progress of the implementation, how it will improve the health system, and stakeholder preparation for the changes.

House E&C Investigates Federal Mental Health: The House Energy and Commerce Subcommittee on Oversight and Investigations held a hearing to review findings of the GAO on the shortcomings of the federal mental health system. Witnesses from the GAO, HHS, and Substance Abuse and Mental Health Services Administration (SAMHSA) testified.

Senate Commerce Holds Hearing on "Internet of Things": The Senate Commerce Committee held a hearing Wednesday on the "Internet of Things." The Committee explored how to harness Internet technologies to make devices, such as wearable applications that gauge health, smarter and more dynamic. Senator Kelly Ayotte (R-NH), Cory Booker (D-NJ), Deb Fischer (R-NE), and Brian Schatz (D-HI) requested the hearing.

House E&C Committee Approves Health Bills: On February 11th, the House Energy and Commerce approved the Ensuring Patient Access to Effective Drug Enforcement Act (H.R. 471) and the Improving Regulatory Transparency for New Medical Therapies Act (H.R. 639), which would amend the Controlled Substances Act by tackling prescription drug abuse. The Committee also approved the Access to Life-Saving Trauma Care Act (H.R. 647), which provides aid to hospitals that treat traumatic injuries.

Other Health Care News

Organizations Call for ACO Tech Report: A group of 17 health care organizations wrote to CMS to inform the agency that its proposed rule that would require Medicare ACOs to describe how they plan to use technology for better care coordination is an administrative burden.

AHA on Ebola Recoupment: The American Hospital Association (AHA) wrote to HHS Assistant Secretary for Preparedness and Response Nicole Lurie requesting the agency considers using a portion of the \$576 million in Ebola emergency funds to repay hospitals that investing in raising their level of preparedness.

RAND Calls for Attention to Health IT: The RAND Corporation released a study calling for additional research to examine the costs, benefits, value over time, and user perspectives on the use and impact of health information technology (HIT).

Study Highlights ACA Drug Costs: A study from Avalere found that ACA exchange plans place 20 classes of drugs used to treat highly complex diseases, such as HIV and cancer, in the highest drug formulary cost-sharing tier.

Study: Phones Beat Wearable at Counting Steps: Compared to wearable devices that track the steps people take, smartphone applications may be more accessible, affordable, and effective, a study published in the Journal of the American Medical Association concluded Tuesday. The study reached this answer after comparing a pedometer and two accelerometers to three wrist wearables: the FitBit, Jawbone and Nike Fuelband.

Upcoming Congressional Hearings

Congress is in Recess.

* * *

Boston · Washington www.mlstrategies.com

Copyright © 2014 ML Strategies LLC. All rights reserved.