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HEALTH CARE REFORM UPDATE November 11, 2013

- Health care industry stakeholders and lawmakers continued to push for more clarity last week on whether health plans offered on the health care exchange will be subject to the anti-kickback statute. As we noted last week, this could have significant implications for hospitals considering premium cost-sharing, branded drug manufacturers who issue coupons, and pharmacy benefit managers and health plans who are concerned with shifting utilization away from generic drugs. Senator Charles Grassley (R-IA) issued the latest volley in asking HHS and DOJ for a detailed explanation of the issue by November 13th. We anticipate stakeholders who have been largely silent on this issue up to now to remain cautious before further guidance is released.
- This year marks the 30th anniversary of the Orphan Drug Act. The act was intended to focus attention and research on those diseases that impact less than 200,000 patients in the United States. Before this important legislation, there were less than a dozen FDA approved treatments for rare diseases. With the renewed focus, R&D incentives, and with many important advances in science and medicine, there are now over 350 approved drugs that treat almost 450 variations of the rare diseases. However, much hard work remains, as there are over 7,000 rare diseases in the registry of the National Organization for Rare Disorders (NORD). Given the cost of drug development, most or all of these treatments are quite expensive—often more than \$100,000 per patient per year. As the federal government, employers/commercial payers, and consumers continue to push for cost-savings in health care, stakeholders are pushing for a balance that allows drug developers to recoup massive R&D expenditures while making sure that patients have the access to these often life-saving treatments.
- The Obama Administration has previously stated that they plan to announce interim enrollment numbers from the health care exchanges later this week. Expectations for the enrollment figures are likely to be low due to delays in launching the exchanges in some states and the well documented website problems. Further, HHS and White House officials have downplayed the first month of open enrollment, citing similar slow uptake in Massachusetts, where enrollment figures spiked during the Thanksgiving and Christmas holidays. Congressional committees have been pressuring senior Administration officials for enrollment data and so far, website visit statistics have not been a reliable measure of actual applications completed. If the numbers are significantly lower than the approximately 500,000 estimated enrollees HHS expected prior to the start of open enrollment, we expect renewed calls from members of Congress for the Administration to consider a variety of policy changes ranging from an extension of the open enrollment period to a wholesale delay of enforceability of the individual mandate – a set of potential options that will be strenuously opposed by the payer community.

Implementation of the Affordable Care Act

On November 1, the Department of Agriculture [submitted](#) a request to the Office of Management and Budget (OMB) to conduct a study to determine if implementation of the Affordable Care Act (ACA) could increase the number of people enrolled in the Supplemental Nutrition Assistance Program (SNAP).

On November 4, the Commonwealth Fund [released](#) the results of their Affordable Care Act Tracking Survey which found that one in five visitors to the online health insurance marketplaces were between the ages of 19 and 29.

On November 4, Centers for Medicare and Medicaid Services (CMS) Communications Director Julie Bataille said during a press briefing that CMS had partially fixed errors on completed applications on the federal health insurance marketplace sent to insurers, known as 834 files, so that they now display the correct information.

On November 5, CMS Administrator Marilyn Tavenner [testified](#) before the Senate Health, Education, Labor, and Pensions that healthcare.gov is slowly improving and should be fully operational by the end of November. She also stated that CMS' enrollment target by the end of November is 800,000 enrollees.

On November 5, the California Department of Insurance [announced](#) it had obtained an agreement from Blue Shield of California that it will allow 115,000 policyholders to keep their health insurance until March 31, 2014, after improperly notifying consumers their policies would be cancelled on December 31, 2013.

On November 5, White House Chief of Staff Denis McDonough [met with](#) some of the nation's largest health insurance companies to update them on progress made to improve healthcare.gov and to encourage them to step up efforts to educate consumers about the health insurance marketplaces.

On November 5, House Oversight and Government Reform Committee Chairman Darrell Issa (R-CA) [released](#) 175 pages of notes taken from an October meeting by the Center for Consumer Information and Insurance (CCIIO) documenting early problems with the launch of healthcare.gov.

On November 5, House Committee on Ways and Means Chairman Dave Camp (R-MI) [subpoenaed](#) CMS for the data it has on the number of individuals who have enrolled for health insurance on the online health insurance marketplaces.

On November 5, the American Academy of Actuaries [sent a letter](#) to members of Congress stating that delaying the individual mandate or extending the open enrollment period could increase premium rates and trigger risk corridor payments that would increase costs to the government.

On November 6, President Obama [spoke](#) in Dallas, Texas, and expressed frustration with the Texas governor and state legislature for refusing the Medicaid expansion and impeding the implementation of the ACA.

On November 6, Department of Health and Human Services (HHS) Secretary Kathleen Sebelius [testified](#) before the Senate Finance Committee, where she rejected calls to delay implantation of the ACA. Chairman Max Baucus (D-MT) urged Secretary Sebelius in his opening statement to fix healthcare.gov as quickly as possible.

On November 6, [President Obama met](#) with sixteen Senate Democrats to discuss ongoing efforts to repair healthcare.gov and to ramp up communication, education, and outreach to consumers about the

implementation of the ACA. President Obama also asked for their input regarding how the ACA is affecting their constituents.

On November 6, the White House [released](#) a map showing the states that have refused to expand Medicaid and the number of Americans that will be uninsured as a result. However, some have criticized the map for misrepresenting states' intentions and political circumstances.

On November 6, Representative Dave Camp (R-MI) [sent a letter](#) to IRS Acting Commissioner Danny Werfel asking him to disclose state-by-state data on the number of applicants for health insurance the IRS has examined to determine premium tax credit eligibility.

On November 6, the Kaiser Family Foundation [released](#) a study which found that 17 million individuals who are currently uninsured or who purchase insurance on their own would be eligible for premium tax credits in 2014 if they purchased insurance on the online health insurance marketplace.

On November 6, the Robert Wood Johnson Foundation and Breakaway Policy Strategies [released](#) a report examining the out-of-pocket costs of health insurance plans to young adults, finding that half of those predicted to buy insurance will be eligible to receive tax credits.

On November 7, Senators Joe Manchin (D-WV) and Mark Kirk (R-IL) [introduced](#) a bill to delay the implementation of the ACA's individual mandate for one year.

On November 7, Senator Marco Rubio (R-FL) introduced the "Healthcare Privacy and Anti-Fraud Act," which would create additional restrictions in order to prevent convicted felons from becoming ACA navigators, and create other policies intended to counter fraud and abuse in the ACA.

On November 7, HHS [announced](#) that \$150 million in ACA funding had been awarded to 236 new health center sites in 43 states to help them care for approximately 1.25 million additional patients.

On November 7, OMB [released](#) a report titled "Impacts and Costs of the October 2013 Government Shutdown," which found that Federal employees were furloughed for a combined total of 6.6 million days at the cost of \$2 billion dollars and that the shutdown resulted in the loss of 120,000 jobs created.

On November 8, the CCIIO [released](#) the final rules for the Mental Health Parity and Addiction Equity Act.

On November 8, Gallup [released](#) a study which found that only 18% of uninsured Americans have visited an online health insurance marketplace. Only 22% of Americans who say they intend to buy insurance through the marketplaces said they have attempted visiting a website.

Other HHS and Federal Regulatory Initiatives

On November 4, CMS [posted](#) a solicitation for a contractor to provide fingerprinting services as part of the National Fraud Prevention Program to monitor and screen high risk Medicare providers and suppliers.

On November 7, the Food and Drug Administration (FDA) [announced](#) that it had made a preliminary determination that partially hydrogenated oils, the primary source of trans fat, would not be recognized as safe for use in food.

On November 8, the FDA [released](#) a proposed rule which would allow generic drug manufacturers to update product labeling to reflect new information in advance of any FDA review of the change, similar to the way brand name drugs labels are currently regulated.

Other Congressional and State Initiatives

On November 5, Representatives Anna Eshoo (D-CA) and Mike Rogers (R-MI) [celebrated](#) the success of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which has led to 500 pharmaceutical drugs being labeled with pediatric information.

On November 6, the House Energy and Commerce Committee [announced](#) that the School Access to Emergency Epinephrine Act, a bill which would enable greater access to emergency supplies of epinephrine in schools, will now be sent to President Obama for his approval.

Other Health Care News

On November 4, the Department of Justice [announced](#) that Johnson & Johnson will pay more than \$2.2 billion to resolve criminal and civil liability resulting from allegations that it promoted off-label uses of three drugs and provided kickbacks to physicians.

In this month's edition of Health Affairs, the RAND Corporation [published](#) a study which found that patient-centered medical home and nurse-managed health center models could potentially reduce projected physician shortages. In addition, they [published](#) a second study which found that although foreign-educated and foreign-born individuals are a major portion of the US health care workforce, there is no cohesive policy or strategy for incorporating these individuals into the workforce.

Hearings and Mark-Ups Scheduled

House

On Wednesday, November 13, the House Homeland Security and Government Affairs Committee will hold a [hearing](#) titled "Cyber Side-Effects: How Secure is the Personal Information Entered into the Flawed Healthcare.gov?"

On Wednesday, November 13, the House Oversight and Government Reform Committee will hold a [hearing](#) titled "ObamaCare Implementation: The Rollout of HealthCare.gov."

On Thursday, November 14, the House Education and the Workforce Committee will hold a [hearing](#) titled "The Effects of the Patient Protection and Affordable Care Act on Schools, Colleges, and Universities."

On Friday, November 15, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) to review the FDA's implementation of the Food and Drug Administration Safety and Innovation Act.