



## ML Strategies Update

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## Health Care Update

- **ACA Open Enrollment Closes, Stakeholders Hoping Opportunity Emerges for “Fixes”:** The first open enrollment period of the Affordable Care Act (ACA) ended on March 31<sup>st</sup>. In spite of the technical glitches, the White House [announced](#) 7.1 million Americans had signed up for health insurance through the private exchanges. The Administration also [announced](#) following the deadline that limited enrollment for those who began the process but were unable to fully enroll will continue through April 15<sup>th</sup>. With an [estimated](#) 3 million additional Americans gaining coverage through the optional Medicaid expansion provision in the ACA, supporters of the health law can boast approximately 10 million individuals gaining health coverage as part of the health reform law. Although Congressional hearings from House GOP led committees are likely to continue, Democrats are hoping that the robust signups will change the narrative that the ACA first year exchange implementation was a failure after months of website and other technical problems. Other health care stakeholders will now increase the pressure on moderate Republicans and Democrats to enact smaller “fixes” to the ACA with the mindset that ACA legislative activity can go beyond the standard 50+ “repeal” bills thus far.
- **Obama Administration Recommends “light touch” Approach for HIT Regulation:** Last week, The Department of Health and Human Services' Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC) joined the Food and Drug Administration (FDA) in releasing their [Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework](#) (the “Report”) The report sets out the federal agencies proposed framework to regulate health IT, which was mandated under the Food and Drug Administration Safety Innovation Act (FDASIA) of 2012. While the report generally does not call for significant amounts of regulatory oversight, which is especially important for mHealth product stakeholders, it also lacked clarity on important issues facing health IT stakeholders such as the specific definition of “clinical decision support software” and the difference between wellness and disease. Congress will now review the report and the agencies intend to convene a public meeting on the proposed strategy within 90 days and to finalize the Report based on public input. For more information on the report, please see the [Mintz Levin blog post](#) here.

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

**ACA Could Cost Big Businesses:** The American Health Policy Institute [released](#) a study which found that direct costs to large US employers due to the ACA, above projected health care cost trends, will be between \$163 million and \$200 million per employer. The report looked only at costs, not potential savings.

**House Advances 40 Hour Work Week Bill:** The House of Representatives passed in a 236 to 186 vote the Save American Workers Act ([H.R. 2575](#)). The bill adjusts the ACA definition of full time work from 30-hours to 40-hours.

**Insurers Question Treatment of Off-Exchange Plans:** In a [letter](#) to CMS, America's Health Insurance Plans writes that the Administration's focus on the exchanges has eclipses equally important options outside of the ACA marketplace.

### **Other Federal Regulatory Initiatives**

**President Obama Signs SGR Patch:** President Obama [signed](#) a 12 month patch to the Sustainable Growth Rate (SGR) Medicare formula, avoiding a cut to Medicare physician payments.

**CMS to Release Physician Payment Data:** The Centers for Medicare and Medicaid Services (CMS) announced that it will [release](#) data on payments made to individual physicians in the Medicare program in response to multiple Freedom of Information Act requests.

**HHS to Process Same-Sex Enrollment in Medicare:** HHS [announced](#) that Social Security is now processing some Medicare enrollments for same-sex spouses, requests for Special Enrollment Periods, and requests for reductions in late-enrollment penalties.

**Kidney Damage Not Covered by 9/11 Fund:** The Centers for Disease Control and Prevention (CDC) [denied](#) a petition to add kidney damage to the list of conditions related to the response to the September 11<sup>th</sup> terrorist attacks, citing a lack of sufficient scientific evidence.

**NIH Opens Neuroscience Center:** The National Institutes of Health (NIH) [opened](#) the John Edward Porter Neuroscience Research Center, which will bring neuroscientists from 10 institutes and centers across the NIH to research the nervous system in health and disease.

**Agency Report on Health IT Regulation:** HHS, in conjunction with the FDA, FCC, and ONC, released a [report](#) on the regulation of health IT, recommending that the FDA expand its authority on medical devices.

**Participation in Medicare Physician Quality Reporting Rises:** CMS [released](#) the 2012 Physician Quality Reporting System and Electronic Prescribing (eRx) Experience Report, finding an increase in participation in two programs that allow eligible professionals to earn incentive payments through voluntary participation.

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

**Republican Budget Released:** Budget Committee Chairman Paul Ryan (R-WI) [released](#) the Republican Fiscal Year 2015 Budget. His budget would repeal the ACA, require higher-income seniors to pay more for health insurance, and subsidize private health insurance for those younger than 55.

**CBO Scores Wyden Bill:** The Congressional Budget Office (CBO) [scored](#) Senator Ron Wyden's (D-OR) bill to repeal and replace the SGR, finding it would require \$197 billion from the Overseas Contingency Operations (OCO) fund.

**Representatives Question Zohydro Approval:** Representatives Rosa DeLauro (D-CT), Harold Rogers (R-KY),

and Stephen Lynch (D-MA) [sent a letter](#) to HHS Inspector General Daniel Levinson asking him to investigate the relationship between industry and the Food and Drug Administration in facilitating the approval of the opioid Zohydro ER, which they describe as powerful and potentially dangerous.

**Republicans Express Concerns With Part D Changes:** Republican members of the House Energy and Commerce Committee [sent a letter](#) to CMS administrator Marilyn Tavenner, expressing concerns with the proposed changes to Medicare Part D and asking whether parts of the rule will be finalized in the 2015 call letter.

**Committee Advances Public Health Bills:** The House Energy and Commerce Committee approved four bills to help newborns, trauma patients, and veterinarians, including [H.R. 1281](#), "The Newborn Screening Saves Lives Reauthorization Act," [H.R. 3548](#), "The Improving Trauma Care Act," [H.R. 4080](#), "The Trauma Systems and Regionalization of Emergency Care Reauthorization Act," and [H.R. 1528](#), "The Veterinary Medicine Mobility Act."

**Senate Finance Debates Tax Extenders:** The Senate Finance Committee debated a package of expiring tax provisions, including one amendment to delay the medical device tax. While some Committee Democrats said they support the delay, they said it was not germane to the legislation and the amendment did not receive a vote.

**Eshoo Introduces American HEALS Act:** Representative Anna Eshoo (D-CA) has [introduced](#) the American Helping Encourage Advancements in Lifesaving Science (HEALS) Act. The bill, also introduced by Senator Dick Durbin (D-IL), would expand support for future research at the National Institutes of Health (NIH), the Centers for Disease Control (CDC), the Department of Defense Health Program (DHP), and the Veterans Medical & Prosthetics Research Program.

### Other Health Care News

**Report on Patient Safety and Nurses:** The Robert Wood Johnson Foundation [published](#) a new report which made numerous recommendations for improving patient safety by transforming nurses' work environments. The report found that 44% of harmful events that occurred to hospitalized Medicare beneficiaries were preventable.

### Upcoming Hearings and Markups

#### Senate

On April 9, the Primary Health and Aging Subcommittee of the Senate Health, Education, Labor and Pensions Committee will hold a [hearing](#) titled "Addressing Primary Care Access and Workforce Challenges: Voices from the Field."

On April 10, the Senate Finance Committee will hold a hearing with HHS Secretary Sebelius on the President's FY2015 budget.

#### House

On April 7, the Health Subcommittee of the House Energy and Commerce Committee will hold a [hearing](#) titled "Improving Predictability and Transparency in DEA and FDA Regulation."

On April 8, the Health Subcommittee of the House Ways and Means Committee will hold a [hearing](#) on Department of the Treasury's final employer mandate and employer reporting requirements regulations related to the 2010 health care law.

On April 9, the Health Subcommittee of the House Veterans' Affairs Committee will [mark up](#) pending legislation.

On April 9, the House Veterans' Affairs Committee will hold a [hearing](#) titled "A Continued Assessment of Delays in VA Medical Care and Preventable Veteran Deaths."

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