



## ML Strategies Update

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## Health Care Update

**E&C continues to push for bipartisan efforts to improve drug pipeline:** This week, the House Energy and Commerce health subcommittee continues an effort launched in May to find potential common ground that legislators can coalesce around to improve the drug pipeline from discovery to development to delivery. On Wednesday, July 9<sup>th</sup>, the panel will examine opportunities to modernize clinical trials and accelerate the development of new cures and treatments. On Friday, July 11, the committee will solicit feedback from patients on how to expedite the drug discovery, development, and delivery process,

The overarching initiative, entitled Energy and Commerce “[21<sup>st</sup> Century Cures](#)”, is co-led by E&C Chairman, Fred Upton (R-MI) and Ranking Member of the Subcommittee on Oversight and Investigation, Diana DeGette (D-CO). What is notable about the committee’s efforts is that it has been largely divorced from any links to the Affordable Care Act, a rare opportunity for health care stakeholders to advance legislative proposals without the intense political scrutiny that consumes the majority of current health policy.

Additionally, the bipartisan efforts come at an especially important time for health care stakeholders and policymakers who have recently focused on the rising costs of some specialty drugs and the sustainability of the health care system. It is largely believed by most health policy experts that Congress will have to act in the coming months and year to help prepare the health system for an upcoming wave of new targeted therapies and innovative diagnostics that could potentially cost several times that of treatments today, but at the same time represent major breakthroughs in clinical medicine.

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

**Burwell Announces 76 Million Americans with New Services:** Health and Human Services (HHS) Secretary Sylvia Burwell [announced](#) today that about 76 million Americans in private health insurance plans are newly eligible to receive expanded coverage for one or more recommended preventive health care services.

**OIG on Exchange Inconsistencies:** A [report](#) by the HHS Office of Inspector General (OIG) found that Affordable Care Act (ACA) exchange marketplaces were unable to resolve most inconsistencies, which they reported most commonly as problems with citizenship and income.

**OIG Report on Eligibility Controls:** A [report](#) by the HHS OIG examining the controls in place to verify applicants' eligibility to enroll in ACA health plans found that not all internal controls implemented by the Federal, California, and Connecticut marketplaces were effective in ensuring that individuals were enrolled in health plans according to Federal requirements.

**White House Report on Failure to Expand Medicaid:** The White House Council of Economic Advisers released a report, [Missed Opportunities: The Consequences of State Decisions Not to Expand Medicaid](#). The report details the effects of 24 states opting not to expand Medicaid, noting that these states could forgo billions in federal stimulus.

## **Other Federal Regulatory Initiatives**

**CMS Releases CY2015 Medicare Physician Fee Schedule:** CMS released a [proposed rule](#) that would update payment policies and rates for services furnished under the Medicare Physician Fee Schedule. The proposed rule also adds several new billing codes for telemedicine services that providers can bill Medicare for in the coming year

**CMS Proposes Hospital Outpatient Prospective Payment System (OPPS) Updates:** For CY 2015, CMS [proposed](#) its Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System policy changes. The proposed rule updates Medicare payment policies and rates for hospital outpatient department and ASC services, and updates and streamlines programs that encourage high-quality care in these outpatient settings.

**CMS Releases Home Health PPS 2015 Rule:** CMS released [proposed changes](#) to the Medicare home health prospective payment system for CY 2015. The rule projects that Medicare payments to home health agencies in CY 2015 will be reduced by 0.30 percent, a decrease reflecting the impact of the 2.2 percent home health payment update and rebasing.

**CMS Releases End-Stage Renal Payment Rule:** CMS issued a [proposed rule](#) that would update payment policies and rates under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for CY 2015. The proposal also creates new quality and performance measures to improve the quality of care by outpatient dialysis facilities

**CMCS Releases Medicaid/CHIP Fact Sheets:** In an effort to increase outreach and enrollment, the Center for Medicaid and CHIP Services (CMCS) created a set of [Medicaid Fact Sheets](#) aimed at helping consumers understand the basics of eligibility, program benefits, and how to enroll.

**FDA Releases Draft Compounding Guidance:** The Food and Drug Administration (FDA) released [draft guidance](#) setting standards for the manufacturing of drug compounds. The FDA also released [proposed rule](#) updating the list of drugs considered too risky to compound, with penalties for violating these rules.

**ONC and SAMHSA Pilot Behavioral Health Exchange:** A coalition of states, the Office of the National Coordinator for Health Information Technology (ONC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) [announced](#) they have successfully piloted a [project](#) for the interstate exchange of electronic behavioral health data.

**HHS Issues Disaster Preparedness Grants:** HHS [announced](#) that it has awarded more than \$840 million to continue improving emergency preparedness of state and local public health and health care systems.

**NIH Expands Sites in Undiagnosed Disease Network:** The National Institutes of Health (NIH) [announced](#) \$43 million in grants to six medical research centers so that they can focus on difficult-to-solve medical cases and develop effective approaches to diagnose them. The sites include UCLA, Baylor, Duke, Vanderbilt, Stanford, Harvard and NIH itself.

**CDC Report on Opioid Painkiller Use:** The CDC [Vital Signs Report](#) found that the prescription and use of opioid painkillers varies across the country, with most heavy use tending to be in the South. In addition, in 2012, health providers prescribed a total of 259 million bottles of painkiller.

**Federal Patient Protection Panel:** On July 21-22, the Secretary's Advisory Committee on Human Research Protections will meet to discuss [proposals](#) to change the definition of "informed consent" in certain studies involving big data.

### **Other Health Care News**

**Digital Health VC Fundraising Increases:** According to a [report](#) produced by incubator RockHealth, in the first six months of 2014 venture capital funding for digital health has already surpassed 2013 fundraising.

**Consumers Skeptical of Wellness Programs:** A [poll](#) released by Kaiser Health found that, although 76 percent of the public supports workplace wellness programs, 62 percent of consumers oppose wellness programs that would result in higher premiums if they choose to not participate.

**Group Calls for Telemedicine in Managed Care:** In a [letter](#) to the National Association of Insurance Commissioners (NAIC), the American Telemedicine Association (ATA) called for better incorporation of telemedicine in NAIC's definitions of network adequacy.

### **Upcoming Hearings and Markups**

#### *Senate*

On July 9<sup>th</sup>, the Senate Special Aging Committee will hold a roundtable [discussion](#) titled "Improving Audits: How We Can Strengthen the Medicare Program for Future Generations."

#### *House*

On July 9<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "21st Century Cures: Modernizing Clinical Trials."

On July 10<sup>th</sup>, the Energy Policy, Health Care and Entitlements Subcommittee of the House Oversight and Government Reform Committee will hold a hearing titled "Medicare Mismanagement Part II: Exploring Medicare Appeals Reform."

On July 11<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "21st Century Cures: Incorporating the Patient Perspective."

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