



## ML Strategies Update

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## Health Care Update

### **Congressional Negotiators Reach Deal on Veteran Affairs Bill:**

Senator Bernie Sanders (I-VT) and Representative Jeff Miller (R-FL), the respective chairmen of the Senate and House Veterans Affairs Committees, capped off a month and a half worth of negotiations this weekend to bridge competing bills that would reform the Department of Veterans Affairs (VA).

The details of the compromise will be announced this afternoon (July 28) and are expected to focus on increasing access to health care services from outside the VA through agreements and also standardizing telehealth services, increased focus on technology and data-reporting initiatives, and also increasing the number of major medical facility leases the VA can enter into. Additionally, the legislation would focus on alleviating the staffing shortage through graduate medical education (GME) reforms that would increase scholarship and GME slot opportunities.

Stakeholders expect the legislation to be classified as emergency spending with relation to the statutory Pay-As-You-Go Act of 2010 which would shield the bill from negotiations on spending cuts or new revenues to pay for it. Voting is expected to happen in the next few days, setting up a final vote before the start of the August recess on August 2<sup>nd</sup>.

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

**HHS and Harvard Estimate Coverage:** In a [report](#) published in the New England Journal of Medicine, HHS and Harvard University found that 10.3 million uninsured adults gained coverage through private health insurance or Medicaid during the ACA's first open enrollment period.

**CMS Releases Health Premium Savings:** HHS Secretary Burwell [announced](#) that consumers have saved a total of \$9 billion on their health insurance premiums since 2011 thanks to the ACA's Medical Loss Ratio (MLR). The MLR requires insurers to spend at least 80 percent of premium dollars on patient care and quality improvement activities.

**CMS Tutorial on Quality Reporting:** CMS released a web [tutorial](#) on reporting for 2014 Medicare quality reporting programs. The tutorial provides guidance to providers on how to file compliance information for meaningful use and the Physicians Quality Reporting System.

### **Other Federal Regulatory Initiatives**

**HRSA 340B Clarification:** The Health Resources and Services Administration (HRSA) released an [interpretive rule](#) clarifying that the 340B program, intended to lower drug costs for rural providers, will require pharmaceutical companies to discount orphan drugs when they are used at some medically underserved facilities.

**Burwell Appoints New Senior Counselor:** HHS Secretary Burwell announced that Leslie Dach would fill a newly-created Senior Counselor role at the agency. According to a [press release](#), "Dach will work closely with the Department's senior staff on key policy challenges, strategic initiatives, and engagement with external partners."

**HHS OIG Highlights lack of Security Control:** An HHS inspector general [report](#) finds that HHS did not always take appropriate action to limit access to sensitive personally identifiable information that the agency has access to.

**CMS MU Tip Sheet:** CMS released a [tip sheet](#) detailing that clinical decision support (CDS), required by stag 2 of meaningful use, is more than just "pop up" alerts, notifications, or suggestions. CDS must provide a meaningful contribution to improved quality of care and should encompass a variety of tools, such as "computerized alerts and reminders for providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support; and contextually relevant reference information."

**FDA Receives First Biosimilar Application:** Sandoz is the first company to [announce](#) that it has filed for approval with the FDA of a biologic under the biosimilars pathway created in the Biologics Price Competition and Innovation Act of 2009 (BPCIA).

**CDC Calls HPV Vaccination Underutilized:** CDC officials [announced](#) that the number of girls and boys aged 13-17 years receiving human papillomavirus (HPV) vaccine remains unacceptably low. There has been a slight increase in vaccination coverage since 2012.

**CDC Forms External Lab Safety Workgroup:** The CDC is [forming](#) an external laboratory safety workgroup to review the agency's current practices and provide corrective input through guidance and advice on safety procedures.

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

**Lawmakers Urge Secondary-Payer Rule:** Seven bipartisan lawmakers [wrote](#) to CMS requesting the agency craft a regulation implementing the SMART Act, a law that makes it easier to determine how much Medicare will be repaid after it covers medical expenses that are the responsibility of private liability insurance.

**Rep. DeLauro Presses for e-Cig Regulation:** In a [letter](#) to the FDA, Representative Rosa DeLauro (D-CT) called on the FDA to finalize rules to regulate e-cigarettes, cigars, and other unregulated tobacco products by April 2015.

**Senate HELP Approves Public Health Bills:** The Senate Health, Education, Labor, and Pensions Committee [approved](#) seven bipartisan bills, including: the Promoting Physical Activity for Americans Act; the Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education (MD-CARE) Amendments of 2014; the Emergency Medical Services for Children Reauthorization Act of 2014; the Trauma Systems and Regionalization of Emergency Care Reauthorization Act; the Improving Trauma Care Act of 2014; the Traumatic Brain Injury Reauthorization Act of 2014; and a bill to amend the Employee Retirement Income Security Act of 1974.

**Markey Introduces Opioid Bill:** Senator Ed Markey (D-MA) introduced The Recovery Enhancement for Addiction Treatment ([TREAT](#)) Act, which would increase the number of patients for whom doctors can prescribe addiction medications per year. The bill would also allow certain nurse practitioners and physician assistants to prescribe these medications.

**21<sup>st</sup> Century Cures Roundtable on Personalized Medicine:** The House Energy and Commerce Committee held a [roundtable](#) to hear from representatives of the FDA, Leukemia and Lymphoma Society, Mayo Clinic, and others on personalized medicine. The purpose of this event was to discuss the medical community's use of personalized medicine and ways in which Congress can enhance such usage.

**House E&C Hearing on Communication in Development:** The House Energy and Commerce Subcommittee on Health held a [hearing](#) to discuss the importance of transparent collaboration in the discovery, development, and delivery cycle. Witnesses touched on the benefits of and the barriers to information sharing in the medical industry.

**Tennessee Sued Over Medicaid:** The Southern Poverty Law Center is [suing](#) Tennessee, alleging the state shifted Medicaid enrollment to the federal exchange, knowing that this cannot adequately accommodate low income residents in the state run health care program.

**Senate Approps Releases FY2015 LHHS Report:** The Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies [released](#) the FY2015 Labor-HHS reported bill and draft subcommittee report. The [report](#) requests the ONC inform Congress on if subsidized EHR systems are inhibiting the exchange of patient health information.

**Breast Cancer Education Bill:** Senators Amy Klobuchar (D-MN) and David Vitter (R-LA) and Representatives Debbie Wasserman Schultz (D-FL) and Renee Ellmers (R-NC) have [introduced](#) the Breast Health Education and Awareness Requires Learning Young (EARLY) Act. The bill would create an education and outreach campaign to highlight breast cancer risk.

**Reps Introduce Value Based Bill:** Representatives Diane Black (R-TN) and Earl Blumenauer (D-OR) introduced the Value-Based Insurance Design (VBID) for Better Care Act of 2014 ([H.R. 5183](#)). The bill would establish a regional demonstration program for high-quality Medicare Advantage plans to utilize V-BID to reduce the copayments or coinsurance for beneficiaries with specific chronic conditions.

### Other Health Care News

**FSMB Working on Licensing Agreement:** During a Center for Telehealth & e-Health [webinar](#), Federation of State Medical Board (FSMB) President Humayun Chaudhry said that the federation is hoping to finalize a draft of its interstate medical licensing compact in the coming months.

**Medicare Drug Rebate Report:** The Medicare Rights Center released a [report](#) calling for reforms that would lower the cost of prescription drugs for seniors and the government. Ranking Member of the House Energy and Commerce Committee Henry Waxman (D-CA) praised the report.

**Gilead Reports Sovaldi Sales:** As part of its second quarter 2014 financial [results](#), Gilead reported that it has sold \$3.48 billion in sales of Sovaldi. Combined with sales from the first quarter, the drug has now sold \$5.75 billion so far in 2014.

**CNN Poll ACA Approval:** According to a CNN [poll](#), 18 percent of Americans reported that they or their family is better off under the ACA. An additional 35 percent said, while they may not be better off, the lives of others have been improved by the health care law.

### Upcoming Hearings and Markups

#### *Senate*

On July 30<sup>th</sup>, the Senate Health, Education, Labor, and Pensions Subcommittee on Children and Families will hold a [hearing](#) titled "Paid Family Leave: The Benefits for Businesses and Working Families."

On July 30<sup>th</sup>, the Senate Special Aging Committee will hold a [hearing](#) titled "Admitted or Not? The Impact of Medicare Observation Status on Seniors."

#### *House*

On July 28<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled “Protecting Americans from Illegal Bailouts and Plan Cancellations Under the President’s Health Care Law.”

On July 29<sup>th</sup>, the House Oversight and Government Reform Subcommittee on Energy Policy, Health, and Entitlements will hold a hearing titled “Examining the Federal Government’s Failure to Curb Wasteful State Medicaid Financing Schemes.”

On July 29<sup>th</sup> and July 30<sup>th</sup>, the House Energy and Commerce Committee will [mark up](#) a series of health and commerce bills.

On July 31<sup>st</sup>, the House Energy and Commerce Subcommittee on Oversight and Investigations will hold a [hearing](#) titled “PPACA Implementation: Updates from CMS and GAO.”

On July 31<sup>st</sup>, the House Small Business Subcommittee on Health and Technology will hold a [hearing](#) titled “Telemedicine: A Prescription for Small Medical Practices?”

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