



ML Strategies Update

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JULY 21, 2014

Health Care Update

First Guidance following *Hobby Lobby* released: The Department of Labor (DOL) published a notice on Thursday, July 17th that all “closely held” for-profit companies are required to inform their employees if they plan to opt out of providing the coverage in response to the Supreme Court’s *Hobby Lobby* decision. This is the first formal action the Obama Administration has taken, after the failed attempt to pass legislation in the Senate that would have overturned the Supreme Court’s decision. DOL said that as part of “longstanding regulations,” the employer must explain what coverage areas aren’t provided in an insurance plan.

Health care stakeholders and legal experts are also expecting the Obama Administration to release additional regulations soon. These new rules could potentially require nonprofit and for-profit organizations that object to the provision of contraceptives to their employees, to file a form stating-so with the appropriate agencies. In that scenario, for-profit entities would likely have to submit evidence to verify the pre-existence of their religious beliefs.

Implementation of the Affordable Care Act

CMS Awards Delivery Reform Contract: The Centers for Medicare and Medicaid (CMS) announced the [award](#) of a \$7 billion Research, Measurement, Assessment, Design and Analysis contract to 15 companies as part of a “a wide range of analytic support and technical assistance activities that support models and demonstration programs created or derived under the auspices of the Patient Protection & Affordable Care Act (ACA).”

HHS Has \$11 Million for HIV Research: Department of Health and Human Services (HHS) Secretary Burwell [announced](#) the availability of \$11 million in ACA and Minority AIDS Initiative funding to support the integration of HIV services into primary care through innovative partnerships between health centers and state health departments in Florida, Massachusetts, Maryland and New York.

CMS Releases May Report on CHIP: On July 11th, CMS released its monthly report for May, which includes eligibility and enrollment data for states’ Medicaid and Children’s Health Insurance Programs (CHIP). The report examines states’ implementation of the Affordable Care Act, which it concludes bolstered the Medicaid and CHIP programs.

CMS Reports New Enrollment Figures: CMS Deputy Administrator Cindy Mann reported in a blog post on the HHS website that between October and May Medicaid and CHIP added about 6.7 million new enrollees. In states that have expanded Medicaid, enrollment increased, on average, by 17 percent, whereas in states that did not expand, enrollment increased by 3 percent.

The CBO Predicts Advisory Board for ACA Will Stay Untapped: The Congressional Budget Office (CBO) projects that the Independent Payment Advisory Board (IPAB) won’t begin to operate for at least another decade.

CMS Soliciting HealthCare.gov Contractor: CMS released a contract [solicitation](#) detailing the requirements for the next HealthCare.gov contractor. Bids, which are due August 18th, should address testing of hardware, security testing, and redesigning of the online application.

Other Federal Regulatory Initiatives

CMS Guidance on Hospice Drugs: CMS released [guidance](#) to clarify implementation of the final 2014 guidance on Part D payment for beneficiaries enrolled in the Medicare hospice benefit. The guidance states Part D uses prior authorization for hospice only for certain drug categories.

PCAST on Engineering a Better Health System: The President’s Council of Advisors on Science and Technology (PCAST) wrote an [article](#) for the Journal of American Medical Association on how to build a better health care system through systems engineering science.

CDC Publishes First Measure of Sexual Orientation: The Centers for Disease Control’s (CDC) National Health Interview Survey [published](#) the results of their first ever survey of sexual orientation. Among other things, the survey found that 1.6 percent of U.S. adults identifying as gay or lesbian and 0.7 percent identifying as bisexual.

FDA Providing Recall Data: In a [blog post](#), Food and Drug Administration (FDA) Chief Health Informatics Officer Taha Kass-Hout announced that the FDA will release weekly report on recalls and enforcements as part of the openFDA program. The recalls database is the second dataset to be released on openFDA.

ONC Releases Report on Increase in Doctors who E-Prescribe: On July 11th, the Office of the National Coordinator for Health IT (ONC) released a [report](#), which found that 70 percent of U.S. doctors e-prescribe using an EHR on the Surescripts network.

ONC Announces Pilot Program to Improve EHR certification: The ONC [announced](#) the creation of the Open Test Method Development Pilot Program, which seeks to improve the certification of EHR software.

ONC to Hold Listening Sessions around US for Feedback: The ONC [announced](#) that it will hold listening sessions across the U.S. to gain input from people on how to better carry out the agency’s work.

NIH Develops Program to Combat Drug Use: The National Health Institutes (NIH) is developing a [program](#), the National Drug Early Warning System (NDEWS), to help health experts respond quickly in areas where the use of illicit drugs, such as heroin, skyrocketed.

GAO Report on Medicaid Spending: A Government Accountability Office (GAO) [report](#) found that most states spent

between \$6,000 and \$8,999 per Medicaid recipient in 2008. Eight states spent at least \$10,500 per enrollee.

AHRQ Publishes Premium Study: According to the Agency for Healthcare Research and Quality's (AHRQ) Medical Expenditure Panel [Survey](#), premiums for employer-sponsored insurance increased by 3.5 percent in 2013.

NIH Will Use Social Media to Monitor Drug Trends: NIH is [developing](#) a National Drug Early Warning System (NDEWS) to monitor emerging trends on social media and the web that will help health experts respond quickly to potential outbreaks of illicit drugs.

Other Congressional and State Initiatives

Joint Subcommittee Hearing on Tech for Cures: The House Energy and Commerce Subcommittees on Communications and Technology and Health met for a [hearing](#), part of the Committee's 21st Century Cures, to discuss disruptive technologies that are currently transforming the health sector and the companies that are working to improve patient outcomes through technology.

House Grills CDC on Anthrax Scare: The House Energy and Commerce Subcommittee on Oversight and Investigations [heard](#) testimony from CDC Director Tom Frieden on steps the CDC has taken to increase safety and security following the potential exposure of workers to anthrax. Frieden told the Committee the agency will take "every step possible to prevent any future incident that could put our laboratory scientists, others in the CDC workforce and the broader community, or the public at risk."

Senate HELP Presses Burwell on CDC Safety: Bipartisan Members of the Senate Health, Education, Labor, and Pensions Committee [wrote](#) to Secretary Burwell, asking for information on agency safety protocols following the discovery of small pox and other dangerous vials at NIH and anthrax at the CDC.

House E&C Passes Public Health Bills: The House Energy and Commerce Committee [passed](#) 7 bills aimed at improving public health. The bills include: H.R. 4771, the Designer Anabolic Steroid Control Act; H.R. 669, the Sudden Unexpected Death and Data Enhancement and Awareness Act; H.R. 4290, the Wakefield Act of 2014; H.R. 4450, the Travel Promotion, Enhancement, and Modernization Act of 2014; H.R. 4250, the Sunscreen Innovation Act; H.R. 594, the Paul D. Wellstone Muscular Dystrophy Community Assistance and Education Amendments of 2014; and H.R. 5057, the EPS Service Parts Act of 2014.

House E&C Examines ACA Eligibility: The House Energy and Commerce Subcommittee on Health held a [hearing](#) to examine the state of the ACA's eligibility determinations. The hearing centered on an HHS OIG report that identified 2.9 million inconsistencies between applicants' information and data received through the Data Hub.

CBO Sees Deficit Rising: The [CBO 2014 Long-Term Budget Outlook](#) shows deficits will begin to grow in coming years because of Social Security and Medicare costs to support an aging population, increasing health care costs, and ACA subsidies.

Pathologists Request EMC Exemption: The College of American Pathologists asked in a [letter](#) to CMS Administrator Marilyn Tavenner, signed and supported by 89 House members, to be exempted from penalties on diagnostic labs that don't use electronic medical records. The letter endorses the Health Information Technology Reform Act ([H.R. 1309](#)).

King, Fischer Seek Tax Credit to Incent Paid Leave: Senators Deb Fischer (R-NE) and Angus King (I-ME) introduced [The Strong Families Act](#), which would provide a tax credit to employers who give their employees paid parental or medical leave.

Other Health Care News

PhRMA Defends Sovaldi Price: In a press [release](#), PhRMA defended the cost of the \$84,000 hepatitis C drug, Sovaldi. PhRMA writes that, without new treatments and cures, the disease would more than double from \$30 billion to over \$85 billion over the next 20 years.

Uninsured Tend to Be in Non-expansion States: A health reform monitoring [survey](#) conducted by the Urban Institute found that more than 60 percent of the nation's uninsured live in states that have not expanded Medicaid.

Rand Report on the Safety Risks of EHR Systems: According to a Rand Corporation [report](#) commissioned by the ONC, safety concerns about electronic health records system too often go undetected because staffs in hospitals and doctors' offices are too busy implementing the system.

Kaiser Survey on Navigators' Role in ACA: A Kaiser [study](#) finds navigators helped over 10 million people understand their insurance options under the new law.

Upcoming Hearings and Markups

Senate

On July 23rd, the Senate Health, Education, Labor and Pensions Committee [hearing](#) on health and income security bills.

House

On July 22nd, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "21st Century Cures: Examining Barriers to Ongoing Evidence Development and Communication."

On July 23rd, the House Energy and Commerce Committee will hold a 21st Century Cures [Roundtable](#) on Personalized Medicine.

On July 23rd, the Oversight Subcommittee of the House Ways and Means Committee [hearing](#) on waste, fraud, and abuse and the ACA's premium tax credit.

On July 24th, the Health Subcommittee of the House Ways and Means Committee [hearing](#) on the status of Medicare advantage under the ACA.

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