



ML Strategies Update

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Health Care Update

- **Administration Releases Updated Contraception Coverage Rules:** On August 22nd, the Obama Administration proposed to extend a religious exemption to providing contraception coverage to closely held for-profit corporations. As we noted in an [earlier update](#), the interim final rule, a result of the Supreme Court's recent decision involving Wheaton College and Hobby Lobby, allows eligible organizations to notify the Department of Health and Human Services (HHS) of an objection to contraception coverage. In turn, HHS and the Department of Labor will work with insurers and third-party administrators. Under the rule, female employees may still receive contraception, but without cost sharing.

Closely held for-profit entities will be defined in two ways: 1) the entity could not be publicly traded, and ownership of the entity would be limited to a certain number of owners; or 2) the entity could not be publicly traded, and a minimum percentage of ownership would be concentrated among a certain number of owners. A Centers for Medicare & Medicaid Services (CMS) fact sheet on the changes can be found [here](#).

CMS is taking comments on the proposal, including solicitation feedback on how to define "closely held," alternative approaches to the rule, and on documentation, and disclosure of for-profits. Comments will be open for 60 days.

Federal Regulatory Initiatives

FDA to Hold Public Meeting on Generic Drug Policies: The Food and Drug Administration (FDA) will hold a public meeting in September to answer questions about the agency's new Generic Drug User Fee Act policies. The policies have received criticism from some people who worry that the FDA could ignore applications submitted before and during the time the agency changes its review metrics for applications.

FDA Opens Up Incident Reports: As part of the openFDA project, the FDA provided [details](#) on Application Programming Interface (API) for the for Manufacturer and User Facility Device Experience (MAUDE) database. This will allow developers and researchers to easily access reports on medical devices.

DEA Issues Hydrocodone Rule: The Drug Enforcement Administration (DEA) released a [final rule](#) reclassifying hydrocodone painkillers to Schedule II substances. This more restrictive classification will require patients to obtain a new prescription for a refill and impose other new safety measures.

FDA Seeks to Improve Clinical Trial Data: The FDA announced [plans](#) to improve the collection and availability of clinical trial data based on demographics such as gender, race, ethnicity, or age. The action plan includes 27 deliverables toward "improving the completeness and quality of demographic subgroup data collection, reporting and analysis (quality); identifying barriers to subgroup enrollment in clinical trials and employing strategies to encourage greater participation (participation); and, making demographic subgroup data more available and transparent (transparency)."

FQHCS, Top EHR Users Report Benefits: The Health Resources and Services Administration posted [data](#) this week showing that 95.8 percent of federally qualified health centers (FQHCS) use an electronic health record at one or more of their sites. On Friday, officials from the ONC and CDC [reported](#) that 84.5 percent of FQHCS received meaningful use payments.

CDC Spends \$6 Million to Rein in Drug Overdose: CDC awarded \$6 million to Kentucky, Oklahoma, Tennessee, Utah and West Virginia to combat prescription drug overdose. The states plan to use the funding to increase access to overdose reversal drugs, bolster prescription drug monitoring programs, and enact "Good Samaritan" laws, which seek to encourage people to report drug overdose.

Inspector General Unearths Abuse in Nursing Facilities: According to an investigation into nursing facilities conducted by the HHS Office of the Inspector General, 85 percent of nursing facilities reported at least one charge of abuse or neglect in 2012. In addition, the OIG [found](#) that 47 percent of these allegations were not reported, in violation of federal regulations.

Research Casts Doubt on CMS' Assessment of Meaningful Use Programs: According to new [research](#) from the University of Michigan School of Public Health, CMS may want to cease tracking the number of patients who receive their lab results. CMS uses this data to assess the effectiveness of its meaningful use program.

ONC Seeks Input for Roadmap through New Website: The Office of the National Coordinator for Health IT (ONC) announced Wednesday it has a [website](#) through which it will gather input as it begins creating a roadmap to interoperability.

FDA to Convene Cybersecurity Public Forum: The FDA intends to hold a public forum on cybersecurity for medical devices and the healthcare and public health sector in 2014, according to an FDA regulatory policy adviser. The agency will formally [announce](#) the details for the forum, which will be held in the DC area, in a Federal Register notice in the coming week.

Other Congressional and State Initiatives

House Republicans Press on Transparency: Chairman of the House Energy and Commerce Committee Fred Upton (R-MI) and Oversight Subcommittee Chairman Tim Murphy (R-PA) [wrote](#) to CMS Administrator Marilyn Tavenner asking about a document instructing a CMS employee to delete an email exchange between CMS, the HHS, and the White House.

21st Century Cures on the Road: the House Energy and Commerce Committee's 21st Century Cures Initiative is being continued over August recess in Members' districts. Representative Gus Bilirakis (R-FL) has held [two](#) roundtables; Representative Michael Burgess (R-TX) is participating in a [discussion](#) hosted by the Manhattan Institute and the Tufts Center for the Study of Drug Development; Representatives Bob Latta (R-OH) and Bill Johnson (R-OH) are hosting a [roundtable](#); and Health Subcommittee Chairman Pitts (R-PA) is hosting a [roundtable](#) with FDA participants.

CDC Warns on Child Sunscreen Use: The Centers for Disease Control (CDC) released a [study](#) showing that the percentage of kids using sunscreen has fallen from 67.7 percent in 2001 to 56.1 in 2011. From 2001 to 2010, incidence of

melanoma increased annually by 1.6 percent among men and by 1.4 percent among women.

Other Health Care News

Chinese Hackers Collect Data on Millions of US Patients: According to Community Health Systems, Chinese hackers stole non-medical patient ID data on approximately 4.5 million people. The hackers, who launched the cyber-attack sometime between April and June of this year, gathered patient names, addresses, birthdates, phone numbers, and Social Security numbers. The suspected culprit is an “Advanced Persistent Threat” group from China, which likely secured the data through state-of-the-art malware. Community Health Systems reported this and other information regarding the attack in a [filing](#) with the United States Securities and Exchange Commission.

JAMA Praises Licensure Proposal: The Journal of the American Medical Association published an [article](#) praising the Federation of State Medical Boards (FSMB) draft Interstate Medical Licensure Compact, calling the compact a “major reform in medical licensing.”

BPC White Paper Promotes Organized Systems of Care: The Bipartisan Policy Center’s Health Project released a [white paper](#) August 19th that outlines steps towards and obstacles to creating more organized systems of health care. One of the paper’s recommendations was to repeal the sustainable growth rate payment system for doctors and to transition Medicare to a payment and delivery system that rewards doctors for efficiency and quality of care.

Upcoming Congressional Hearings and Markups

The Senate and House are in Recess.

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