



ML Strategies Update

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AUGUST 10, 2015

Health Care Update

Major Medicaid Drug Payment Rule Under OMB Review: Last week a highly anticipated rule that could set the standards for the Medicaid Drug Rebate program arrived at the White House for final review. The Medicaid Outpatient Drug Rule could include significant changes to what is included (and what is not) in the Average Manufacturer Price (AMP) calculation and how “best price” would be calculated for rebate purposes versus strictly discounts. Stakeholders beyond drug manufacturers that have engaged policymakers on this upcoming rule range from Pharmacy Benefit Managers (PBMs) to chain pharmacies and even insurance carriers, among others.

Lawmakers in Congress have also expressed an interest in modifying the AMP calculations for the Medicaid program such as the recent [21st Century Cures Act](#) that was passed in the House. That legislation would have excluded generics from the AMP calculation.

Federal Court Victory for Prescription Off-Label Use Proponents: At the end of last week, a federal district court judge ruled that a drug manufacturer could market off-label uses for a prescription drug to health care professionals, so long as its statements are truthful and non-misleading. The case, [Amarin Pharma, Inc v. FDA](#), represents a significant win for the drug industry which would allow Amarin Pharma Inc. to make off-label statements akin to dietary supplement manufacturers.

This case follows on the heels of a previous victory for proponents of off-label use and marketing in a 2012 case, [United States v. Caronia](#), in which the court ruled that drug manufactures should be allowed to share and discuss with health care providers, journal articles, and other materials that help support off-label claims.

Stakeholders will now wait to see how FDA takes this recent court decision into account and whether it will apply the narrow holding in the Amarin case in its future off-label oversight framework. [Check our blog soon](#) to read more on this case and the future for off-label use and promotion.

Implementation of the Affordable Care Act

Actuaries: Affordable Care Act marketplace changes will influence premiums for 2016: Premium increases for 2016 Affordable Care Act (ACA) plans will be driven by the phasing out of programs designed to shield insurers from risk, more in-depth knowledge about the fledgling customers base and the growing cost of prescription drugs, according to a [report](#) issued by the American Academy of Actuaries.

Federal Regulatory Initiatives

FCC seeks to protect hospital monitoring systems in new rule: The Federal Communications Commission (FCC) approved [regulations](#) that will allow unlicensed wireless devices to operate on the same frequencies as hospitals' remote monitoring systems. However, the commission also added protections for providers using those systems.

Hospitals, Lawmakers object to FCC order on unlicensed spectrum: The American Hospital Association (AHA) and some members of Congress have objected to the above-mentioned spectrum order, saying it will compromise patient safety. The AHA last week [called](#) for a three-month postponement to work on a compromise. Sixteen members of Congress followed suit. "We urge you not to rush any of the highly technical decisions that must be made before considering all of the facts, particularly when patient safety is at issue and when a short delay to enable continued stakeholder discussions will in no way delay the start date of the auction," states a [letter](#) to the FCC, initiated by Representative Bob Latta (R-OH).

ICD-10 preparedness lags: According to a Workgroup for Electronic Data Interchange (WEDI) [survey](#), approximately one quarter of physician practices say they won't be ready to move to the ICD-10 coding system when it takes effect October 1. In contrast, nearly 90 percent of hospitals and nearly all health plans said they are ready or will be ready when the switch to the more complex coding system occurs.

HHS proposes faster drug studies during public health emergencies: The Department of Health and Human Services (HHS) officials outlined a plan to accelerate the study of investigational medicines during public health emergencies so that new drugs can reach patients faster. Their proposal is modeled off a clinical trial design developed earlier this year to test Ebola treatments.

Hospitals Urge DOJ Antitrust Probe of Anthem-Cigna Deal: The American Hospital Association urged antitrust regulators this week to consider whether health insurer Anthem Inc's planned acquisition of rival Cigna Corp would boost healthcare costs. In a [letter](#) to the Department of Justice (DOJ), the AHA said combining the major health insurers threatens to reduce competition.

HHS OIG: Terminated Medicaid providers continue to participate in other states' programs: The Department of Health and Human Services' Office of the Inspector General (OIG) found that over 10 percent of Medicaid providers who were terminated from one state's program in 2011 continued to participate in other states despite new ACA rules cracking down on fraud, a new HHS Inspector General report finds. The [report](#) states that state agencies reported that 295 of 2,539 providers "terminated for cause" in one state were still participating in other states' Medicaid programs as of January 2012. The report says 172 of those 295 providers were still participating in Medicaid as late as January 2014.

Congressional Updates

Bill to require meaningful use changes for ambulatory surgery heads to President: Before leaving on its August recess, the Senate approved S.1347, The Electronic Health Fairness [Act](#). It was approved by unanimous consent, and will exempt patient encounters in ambulatory surgery centers from meaningful use requirements.

GOP lawmakers: Health and Human Services too vulnerable to hacks: The House Energy and Commerce Committee released a [report](#) outlining how hackers have repeatedly attacked HHS, and that the department remains vulnerable. They recommend HHS be reorganized.

Bill introduced to expand broadband program to nursing homes: Sen. John Thune (R-SD) introduced S. 1916, the Rural Health Care Connectivity [Act](#) of 2015, that would allow skilled nursing facilities to apply for financial help to purchase broadband Internet under the FCC's Rural Health Care Program, a \$400 million fund that helps health care providers adopt broadband. Nursing homes are currently ineligible for the program.

Senate HELP clears DeSalvo nomination: The Senate HELP Committee gave unanimous consent to the [nomination](#) of Karen DeSalvo as Assistant Secretary of Health. The nomination now heads to the Senate floor for consideration.

Other Updates

Physicians react to JAMA article on medical scribes: The Journal of the American Medical Association (JAMA) published [letters](#) covering a range of physician reaction to a [viewpoint](#) that appeared in the journal in April that said using medical scribes creates more barriers to developing usable EHRs.

Report calls for changes in California telemedicine policies: According to a [report](#) released by telehealth and children's health advocates, telemedicine is underused in California to treat children with special needs and complex medical conditions. They recommend policymakers expand the locations eligible for telemedicine services such as a patient's home and the number of codes eligible for Medicaid reimbursement.

Data needed for health systems thinking: A [report](#) from the National Quality Forum argues that systems thinking will be required to drive improved performance in healthcare. The authors argue that healthcare systems need to gain access to other types of data, like administrative data or patient surveys.

Study Casts Doubt On assumptions about hospital 'Super-Utilizers': Super-utilizers are the frequent users of the health care system, whose serious illnesses send them to the hospital multiple times every year and cost the system hundreds of thousands of dollars annually. Now a new [study](#) from Health Affairs has found that, in contrast to the notion that super-utilizers revisit the hospital frequently over a long period of time, many patients who use health care services intensely do so for a relatively brief period of time.

Upcoming Hearings

The House and Senate are in recess.

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