



ML Strategies Update

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Health Care Update

Brady Unveils Medicare/Medicaid Fraud Bill: House Ways and Means Subcommittee on Health Chairman Kevin Brady (R-TX) released a [discussion draft](#) of the Protecting Integrity Medicare Act of 2014—the Committee’s expansive bill to address fraud in the Medicare and Medicaid systems. The draft, which is open for comment from stakeholders, includes a number of bipartisan priorities such as removing Social Security numbers from Medicare cards, increasing education for providers to address fraud through the Medicare Administrative Contractors, and changing durable medical equipment (DME) face-to-face requirements. Reigning in fraud and abuse in public programs continues to be a bipartisan area of agreement as lawmakers strive to introduce legislation focusing on reigning in health care spending.

Possible Litigation Threat Adds to Considerations in Containing Drug Costs: As the fight over high spending for the landmark hepatitis C drug, Sovaldi, continues to escalate, especially among state Medicaid programs, stakeholders are now concerned that lawsuits may be an emerging tactic for patients seeking access to the \$84,000 per treatment drug. For example, citing a recent case in Arkansas over the cystic fibrosis drug, Kalydeco, which costs \$300,000 over the course of a treatment, the Global Liver Institute is supporting the plaintiffs and indicated that more lawsuits could be on the way. The difference between the two types of drugs may be in the size of the intended population. While there are 3.2 million Americans with hepatitis C and clinicians continue to argue about the effectiveness of Sovaldi for a large subset of the group, the entire cystic fibrosis population numbers around 30,000 in the U.S. For many policymakers in the states and at the federal level, the debate continues around the likelihood for which any innovative therapy is likely to reduce costs/improve quality for a patient and whether that can justify the up-front price of a particular drug.

Implementation of the Affordable Care Act

HHS Awards State Home Visiting Grants: Health and Human Services (HHS) Secretary Burwell [announced](#) \$106.7 million in FY 2014 grants, awarded to 46 states and jurisdictions. The awards, part of the Maternal, Infant, and Early Childhood Home Visiting Program (Home Visiting Program) established by the ACA, help states expand home visiting services.

Stage 2 Outlook Improving: According to an [update](#) from Centers for Medicare & Medicaid Services (CMS), Stage 2 meaningful use attestations were up through August. As of the end of July, 78 hospitals and 1,898 professionals have met Stage 2 requirements.

HHS Lacks Emails Subpoenaed by Oversight Committee: HHS sent House Oversight Committee Chairman Darrell Issa (R-CA) and Ranking Member Elijah Cumming (D-MD) a [letter](#) notifying them that the agency may not be able to provide all the emails regarding the Healthcare.gov rollout that the Chairman subpoenaed.

CMS' Open Payment System Goes Offline to Undergo Fixes: CMS announced that it will temporarily take down its Open Payment system to complete needed repairs. The news is a win for drug and medical equipment manufacturers. They had earlier requested CMS to extend the deadline so that they can comply with the system's mandate for manufacturers to report information to CMS regarding payments made to doctors and teaching hospitals.

Other Federal Regulatory Initiatives

HHS Holding Telehealth Committee Meeting: The National Advisory Committee on Rural Health and Human Services published a [notice](#) stating that it would be meeting on September 24th in Sioux Falls to discuss telehealth coverage opportunities created by the ACA.

CDC Moved to Emergency Ops: Director Tom Frieden [announced](#) that the CDC's Emergency Operations Center has elevated to Level 1 activity—the agency's highest response level—in response to the Ebola outbreak.

CMS Announces EHR Use Up: CMS [released](#) CDC data showing that EHR adoption among health care providers is up from previous years. Citing studies published in *Health Affairs*, CMS states that in 2013 78 percent of office-based physicians reported they use some sort of EHR system.

New Region II HHS Director Appointed: Secretary Burwell [announced](#) the appointment of Jackie Cornell-Bechelli as Region II Director of HHS. The Region II office is based in New York City, and works with officials in New York, New Jersey, Puerto Rico, and the U.S. Virgin Islands.

ONC Announces New Policy Committees: The Office of the National Coordinator for Health IT (ONC) [announced](#) the efforts of a realignment across health IT. The streamlining resulted in the creation of a new Health IT Policy and Standards Committees.

ONC Outlines Interoperability Plan: In a [blog post](#), the ONC outlined its 10 year vision for interoperability. The agency plans to develop a version 1.0 of a nationwide interoperability map over the next year. The roadmap will outline how to achieve the 3, 6, and 10 year interoperability milestones described in the paper.

CMS Restarting RAC Program: CMS announced that it will restart the [Recovery Audit Program](#). Recovery Audit Contractors will resume work in August to review improper payment claims in the Medicare program.

FDA Releases Biologic Exclusivity Guidance: The FDA released [guidance](#) for biologic sponsors to help the agency determine when exclusivity starts for products. Reference biologics receive 12 years of exclusivity.

Community Health Systems Settles with DOJ: Community Health Systems, Inc., the largest acute care hospital operator, [settled](#) with the Department of Justice for \$98.15 million to resolve allegations that the company's hospitals billed Medicare for inpatient services improperly.

Other Congressional and State Initiatives

Senators Write Burwell on Biosimilars: Senators Lamar Alexander (R-TN) and Orrin Hatch (R-UT) [wrote](#) to Secretary Burwell requesting HHS "immediately release" guidance on biosimilars. The lawmakers argue that, although the FDA has already accepted a biosimilars application for review, it has not released any guidance.

Lawmakers Prod FCC on Rural Broadband: Nine Members of the House wrote to FCC Chairman Tom Wheeler expressing concern over eligibility for the [Healthcare Connect Fund](#) program, which subsidizes broadband for rural health providers.

Democrats Push for E-Cig Protections: Thirteen Senate and House Democrats [wrote](#) to FDA Commissioner Margaret Hamburg asking the agency to use existing authority to protect children from predatory e-cig marketing and tactics.

Rep. Bilirakis Hosting 21st Century Roundtable: As part of the House Energy and Commerce's 21st Century Cures Initiative, Representative Gus Bilirakis (R-FL) will hold [two roundtables](#) in Florida. The first roundtable on August 19th will focus on Patients and the Patient Perspectives and the second on August 22nd will focus on Spurring Innovation, Advancing Treatments, and Incentivizing Investment.

House Subcommittee Convenes for Ebola Hearing: The House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations met for an August [hearing](#) to examine the international response to the Ebola outbreak.

Upcoming Congressional Hearings and Markups

The Senate and House are in Recess.

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