



Jeremy Rabinovitz, JRabinovitz@mlstrategies.com
Alexander Hecht, AHecht@mlstrategies.com
Joseph P. Hammang, PhD, JPHammang@mlstrategies.com
Andrew Shin, AJShin@mlstrategies.com
Abby Matousek, AMatousek@mlstrategies.com
Alyssa Franke, AFranke@mlstrategies.com

ML Strategies, LLC
701 Pennsylvania Avenue, N.W.
Washington, D.C. 20004 USA
202 434 7300
202 434 7400 fax
www.mlstrategies.com

Follow us on Twitter @MLStrategies

HEALTH CARE UPDATE

February 10, 2014

SGR Replacement Bill Introduced: The Chairmen and Ranking Members of the Senate Finance, House Ways and Means, and House Energy and Commerce Committees introduced a bill to repeal and replace the Medicare Sustainable Growth Rate (SGR) formula. The bill would institute a 0.5 percent payment update for five years, consolidate existing quality programs into one value-based performance program, incentivize care coordination for patients who with chronic care needs, introduce clinical care guidelines and the development of quality measures, incentivize physicians to join alternative payment models, and make payment and quality data more available. Notably, the bill does not indicate how it will pay for repealing the SGR formula. While many lawmakers have been discussing a possible 9-month patch to provide more time to negotiate a vast menu of pay-fors, several physician groups have voiced their strong opposition against a delay, instead supporting a vote on the permanent replacement legislation as soon as possible.

- **Data Security in Spotlight Again:** Reports surfaced this weekend detailing data breaches into three of the world's largest medical device companies including Medtronic, Boston Scientific and St. Jude Medical sometime during the first half of 2013. While it is unclear how much, if any, patient health information was compromised, this latest breach will add to already robust activity from lawmakers to bring attention to the issue of security and privacy, especially in the context of health care. House Republicans have made exchange data security a priority for some time, already holding half a dozen hearings this Congress on the issue and on January 10th, the House passed the Health Exchange Security and Transparency Act of 2014 (H.R. 3811), requiring the Health and Human Services (HHS) Secretary to notify individuals within two days should they be impacted by a data breach of the health care exchange. Citing high profile data breaches at Target, Neiman Marcus, and other online outlets, Majority Leader Eric Cantor (R-VA) [outlined in a January memo](#) similar concerns over security of health care data.
- **Drug Shortages Drop in 2013:** In advance of today's House Energy and Commerce Health Subcommittee hearing on drug shortages and means of addressing them, the Food and Drug Administration (FDA) released a report finding the number of drug shortages dropped in 2013. The Center for Drug Evaluation and Research (CDER) reported that it prevented 140 shortages between January and September 2013— with only 38 shortages in the first three quarters of the last year, compared to 117 over that period in 2012. Large pharmaceuticals and generics manufacturers have responded to the Obama Administration's call for more attention to the problem, which, combined with the close scrutiny and media awareness, has had a positive impact for patients and consumers. Still, drug shortages have been a cyclical issue for manufacturers and suppliers and continued vigilance is necessary.

Implementation of the Affordable Care Act

CMS Releases Draft Letter to Issuers: The Centers for Medicare and Medicaid Services (CMS) [released](#) a draft 2015 letter to issuers participating in the federally-facilitated marketplaces. Comments responding to the letter are due on February 25th.

CBO Lowers Enrollment Projections: The Congressional Budget Office has [lowered](#) its projection of individuals who will get healthcare coverage through federal and state exchanges from 7 million to 6 million individuals. This revision was due to “significant technical problems” at the start of open enrollment.

Risk Corridor Program Funds Conflict: In a memo response to the Energy and Commerce Committee, the Congressional Research Service [stated](#) that the Affordable Care Act (ACA) does not specify where payments from the Risk Corridor Program should be made from and that the Department of Health and Human Services (HHS) does not appear to have sufficient statutory language to create a revolving fund.

Dems Introduce Bill To Expand ACA Tax Credits: Democratic Representatives Anna Eshoo (D-CA) and Mike Thompson (D-CA) [introduced](#) the Fair Access to Health Care Act, which would increase the federal poverty level threshold for tax credits under the ACA proportionally with an area’s cost of living, allowing people living in high-cost areas to purchase health insurance through the exchanges.

Emergency Responders Bill Passes Committee: The Protecting Volunteer Firefighters and Emergency Responders Act ([H.R. 3685](#)), which would prevent emergency services volunteers from being counted as full-time employees under the ACA’s employer mandate, [passed](#) the House Ways and Means Committee unanimously.

E&C Letter on Healthcare.gov Appeals: Republican members of the House Energy and Commerce Committee [sent a letter](#) to HHS Secretary Kathleen Sebelius asking her to explain how appeals of mistakes or inconsistencies in applications received through healthcare.gov are being handled by HHS.

Senators Question ACA Enrollment Appeals Process: Four Republican Senators [wrote a letter](#) to CMS Administrator Marilyn Tavenner asking her to explain how the agency will process appeals if applications through healthcare.gov are denied due to technical errors.

House Oversight Targets Co-ops: The House Oversight and Government Reform Committee [held a hearing](#) examining the ACA co-op loan guarantee program. Democrats walked out of the hearing and refused to participate. Republican members heard testimony strongly criticizing the long term viability of co-ops.

Other Federal Regulatory Initiatives

CMS Delays “Two Midnight” Rule: CMS has [extended](#) its review of the “Two Midnight” rule through September 30th. The rule would presume that patients are in-patients if they have stayed two midnights in a hospital.

CMS Increases Patients’ Access to Test Reports: CMS, HHS, and the Centers for Disease Control and Prevention (CDC) [released](#) a final rule amending the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to allow laboratories to provide a patient or their designated representative completed test reports.

NIH Launches Partnership for Diagnostics and Development: The National Institutes of Health (NIH) [announced](#) that they would be working with 10 biopharmaceutical companies and several nonprofit organizations to create the Accelerating Medicines Partnership, which will identify and validate the most promising biomarkers for diagnostics and drug development.

OPM Seeks to Expand MSPs: In its Multi-State Plan (MSP) Issue Letter, the Office of Personnel Management (OPM) [stated](#) that their goal in 2015 is to expand MSP coverage to five additional states and add on or more new MSP issuers or groups of issuers.

OIG to Examine Oversight of Drug Compounding: In its recently released work plan, the HHS Inspector General [stated](#) that it plans to conduct two analyses of drug compounding. The first will examine Medicare's oversight of drug compounding in acute care hospitals. The second will examine Medicare Administrative Contractors' review of Part B claims for compounded drugs.

Other Congressional and State Initiatives

Boxer Discusses Medical Errors: Senator Barbara Boxer (D-CA) [wrote letters](#) to all 238 of California's hospitals asking them to share their strategies for preventing medical errors and reducing the transmission of infection within their facilities.

DeLauro Questions Accelerated Drug Approval: Representative Rosa DeLauro (D-CT) [wrote a letter](#) to Food and Drug Administration (FDA) Commissioner Margaret Hamburg listing a number of concerns she has over accelerated drug approvals and device safety.

Senate Finance Urges No Changes to Protected Classes: Every member of the Senate Finance Committee signed a letter to CMS Administrator Tavenner urging her not to reduce the number of "protected classes" in the Medicare Part D program.

Other Health News:

CVS To Stop Selling Tobacco: CVS Caremark [announced](#) that it will stop selling cigarettes and other tobacco products at its CVS pharmacy stores by October 1st, calling the sale of tobacco products inconsistent with their purpose of improving customers' health. The move was praised by [President Obama](#) and [HHS Secretary Sebelius](#).

Hearings and Mark-Ups Scheduled

Senate

On February 12th, the Senate Small Business and Entrepreneurship Committee and the Senate Special Aging Committee will hold a joint hearing on entrepreneurship in the senior-citizen population.

House

On February 10th, the Health Subcommittee of House Energy and Commerce Committee will hold a [hearing](#) titled "Examining Drug Shortages and Recent Efforts to Address Them."

On February 11th, the Higher Education and Workforce Training Subcommittee of House Education and the Workforce Committee will hold a [hearing](#) titled "Serving Seniors Through the Older Americans Act."