



Joseph P. Hammang, PhD, [JPHammang@mlstrategies.com](mailto:JPHammang@mlstrategies.com)  
Alexander Hecht, [AHecht@mlstrategies.com](mailto:AHecht@mlstrategies.com)  
Andrew Shin, [AJShin@mlstrategies.com](mailto:AJShin@mlstrategies.com)  
Abby Matousek, [AMatousek@mlstrategies.com](mailto:AMatousek@mlstrategies.com)

FOLLOW US ON TWITTER: [@MLStrategies](https://twitter.com/MLStrategies)

**ML Strategies, LLC**  
701 Pennsylvania Avenue, N.W.  
Washington, DC 20004 USA  
202 434 7300  
202 434 7400 fax  
[www.mlstrategies.com](http://www.mlstrategies.com)

December 8, 2014

## Health Care Update

- **SGR Replacement Odds Not Likely to Increase Ahead of Upcoming Deadline:**  
Stakeholders have little doubt that efforts to replace the Medicare physician payment formula designed to control spending, known as the Sustainable Growth Rate (SGR), is going to be as hard, or even harder, to accomplish on Congress' next try. The current pay patch expires March 31<sup>st</sup> and Congress must find just under \$119 billion over 10 years to completely pay for a permanent replacement bill.

Although legislators nearly worked out a bipartisan deal before the last deadline in March 2014, subsequent retirements—including then-Senate Finance Chairman Max Baucus, who went on to become Ambassador to China, and soon to-be-retired House Ways and Means Chairman, Dave Camp (R-MI)—means a new cast of characters at the negotiating table. Even more changes are forthcoming as Representative Paul Ryan (R-WI) ascends to the House Ways and Means chairmanship and Senator Orrin Hatch (R-UT) takes over the Senate Finance Committee. Outgoing Senate Finance Chairman Ron Wyden (D-OR) will take the Ranking Member position as the top Democrat on the Committee.

Reports that GOP House leadership have started to rewrite the deal negotiated largely between Senate Finance and House Ways and Means Committees in early to mid-2014 further complicate a delicately laid out deal that offered modest payment increases while pushing providers towards alternative payment models such as medical homes and accountable care organizations.

Moreover, also complicating the outlook for the SGR is the Achieving a Better Life Experience (ABLE) Act—expected to pass as part of the extenders package—which seeks to utilize pay fors previously used to offset the cost of the SGR fixes. The House bill, which passed on December 3<sup>rd</sup>, cuts pay for Medicare services by close to \$1.2 billion, **including** by identifying relative value targets for misvalued services in the Medicare physician fee schedule, delaying implementation of oral-only policy under Medicare end-stage renal disease (ESRD) prospective payment system, and prohibiting Medicare from covering treatment of vacuum erection systems in Medicare Parts B and D. The bill, which creates a new tax-exempt savings account for those with disabilities, is largely supported—though the means of paying for it are not.

### Implementation of the Affordable Care Act

**GAO Report on Pre-ACA Competition:** The Government Accountability Office (GAO) released a [report](#) studying insurer data from 2010 to 2013. The report, required by the ACA, analyzes competition and market concentration in the health insurance market and finds that enrollment was concentrated among the three largest insurers in most states. Specifically, the “three largest insurers had at least 80 percent of the total enrollment in at least 37 states.”

**HHS Report on Exchange Coverage Savings:** A [report](#) released by the Office of the Assistant Secretary for Planning and Evaluation found that sixty-five percent of current Marketplace enrollees can get coverage for \$100 or less in 2015, after tax credits, if they shop for a more affordable plan within their current metal-rating level.

### Other Federal Regulatory Initiatives

**CMS Finds Health Spending Slowed in 2013:** In a [report](#) published in Health Affairs, CMS found that the growth in health spending slowed. Health spending in 2013 grew 2.6 percent compared to 4.1 percent in 2012. Thus, the health spending share of the gross domestic product remained stable at 17.4 percent in 2013.

**Final Rule to Enhance Medicare Provider Oversight:** CMS released a [final rule](#) to “prevent physicians and other providers with unpaid debt from re-entering Medicare, remove providers with patterns or practices of abusive billing, and implement other provisions to help save more than \$327 million annually.”

**HHS Report on Hospital-Acquired Conditions:** HHS released a [report](#) showing an estimated 50,000 fewer patients died in hospitals and approximately \$12 billion in health care costs were saved as a result of a reduction in hospital-acquired conditions from 2010 to 2013. The [announcement](#) states that this translates to a 17 percent reduction in hospital-acquired conditions over the three-year period.

**FDA Approves New Diabetes Management System:** The FDA [announced](#) it approved a new means of managing diabetes that enables patients to view glucose data and administer insulin through continuous glucose monitors (CGMs) coupled with insulin pumps that are wearable for 7 days.

**FDA Generic Drug Guidance:** The FDA released draft [guidance](#) to better enable generic drug manufacturers to demonstrate safety of generic drugs. The guidance lays out the process for asking the FDA for a letter determining that the study protocol protections are “comparable” to the precautions used in Risk Evaluation and Mitigation Strategies (REMS).

### Congressional Initiatives

**Republicans Write CMS on Deferred-Action Immigrants:** In a [letter](#) to CMS Administrator Marilyn Tavenner, Representative Fred Upton (R-MI) and Senators Orrin Hatch (R-UT) and Lamar Alexander (R-TN), requested information on what steps CMS is taking to reduce the possibility that “illegal immigrants may have unlawfully enrolled in Medicaid because of the Healthcare.gov failure to properly screen applicant eligibility.”

**House E&C Releases Subcommittee Rosters:** The House Energy and Commerce Committee majority released Subcommittee Rosters for the 114<sup>th</sup> Congress. The Subcommittee on Health roster can be viewed [here](#).

**House E&C Weight CHIP Funding:** The House Energy and Commerce Subcommittee on Health held a [hearing](#) to discuss the Children’s Health Insurance Program (CHIP) in a post-ACA environment. The Subcommittee focused on the need to fund the program as, although the ACA authorized CHIP through 2019, it was only funded through 2015.

**Republicans File *Coons v. Lew* Amicus Brief:** Twenty-five Republican Members of Congress filed an [amicus brief](#) with the Supreme Court in the *Coons v. Lew* case, which addressed the constitutionality of the Independent Payment Advisory Board (IPAB).

### Ongoing Ebola Response

**CDC Designated Ebola Treatment Centers:** The CDC [announced](#) 35 new hospitals that will be officially designated Ebola treatment centers and which have the capacity to treat Ebola. The CDC will also be selecting additional facilities in coming weeks.

**President Speaks at NIH on Ebola:** on December 2<sup>nd</sup>, President Obama [visited](#) NIH to meet with a team of scientists working on developing an Ebola vaccine. Speaking on the Ebola response, the President reinforced the need for

Congress to authorize the \$6.2 billion in emergency funding to combat the disease outbreak.

**Congress Passes FDA Priority Review Bill:** The Senate and House [passed](#) S. 2917, a bill that would expand the FDA priority review program to encourage treatments for tropical diseases, including filoviruses (a family of viruses which includes Ebola).

**DeLauro Public Health Emergency Fund Bill:** Representative Rosa DeLauro (D-CT) introduced [legislation](#) to provide \$5 billion for the Public Health Emergency Fund in order to improve the U.S.' ability to response to health crises such as Ebola.

#### Other Health Care News

**AMA Presses CMS on RAC Overhaul:** In a [letter](#) to CMS Administrator Tavenner, the American Medical Association (AMA) requested CMS overhaul its recovery audit contractor program and provide a means to clear the backlog of appeals of rejected Medicare payments.

#### Upcoming Congressional Hearings

##### *House*

On Tuesday, December 9<sup>th</sup>, the House Oversight and Government Reform Committee will hold a [hearing](#) titled "Examining ObamaCare Transparency Failures."

On Tuesday, December 9<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) on setting fiscal priorities and steps to curb government health spending.

On Wednesday, December 10<sup>th</sup>, the House Energy and Commerce Subcommittee on Health will hold a [hearing](#) titled "Examining FDA's Role in the Regulation of Genetically Modified Food Ingredients."

On Wednesday, December 10<sup>th</sup>, the Senate Foreign Relations Committee Africa Affairs Subcommittee will hold a [hearing](#) on the Ebola response.

\* \* \*

Boston · Washington [www.mlstrategies.com](http://www.mlstrategies.com)