



## ML Strategies Update

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## Health Care Update

- **Congress shifts from SGR permanent repeal to temporary patch:** Lawmakers are meeting early this week to complete negotiations over a temporary patch to the Medicare physician payment formula known as the Sustainable Growth Rate ("SGR"). Although there are two competing bills to fully repeal the SGR in the House and Senate, most Congressional analysts lowered their expectations for a repeal compromise due to continued disagreement over how to pay for the \$138 billion (House) to \$180 billion (Senate) bill. Parameters that still need to be ironed out this week for a temporary SGR patch include:
  - Length of the patch (between 9 and 13 months);
  - Physician payment update (a modest to neutral cut with an outside chance of modest increase);
  - Inclusion of Medicare extenders (e.g. ambulance add-on payments, outpatient therapy caps and low-volume provider adjustments); and,
  - Finding approximately \$15 billion in payfors (minus the \$2.3 billion set aside for SGR patch or repeal passed in February 2014).

With the April 1<sup>st</sup> deadline quickly approaching, lawmakers are hoping to pass a patch by end of this week or early next week to avoid delayed payment for Medicare physician claims. The farthest past a SGR deadline Congress has taken to pass a patch was in 2010, when a patch was not passed until almost one month after the deadline. That year, Congress did provide retroactive relief after claims were held for approximately 2 weeks.

- **Lawmakers Focus Scrutiny on Cost of Innovative Drugs:** Democratic leaders on the House Energy and Commerce Committee, Representatives Henry Waxman (D-CA), Frank Pallone (D-NJ), and Diana DeGette (D-CO), wrote to Gilead Sciences, Inc. to request a briefing to justify the pricing of the company's drug Sovaldi, recently approved to treat Hepatitis C. Lawmaker interest in the drug reflects growing interest on behalf of Congress in the increasing costs of innovative treatments. With the biopharmaceutical industry at a potential crossroads on the future of research and development around the next generation of therapies for the most vexing diseases, the question of affordability continues to dominate the consciousness of policymakers and private sector payers alike. Stakeholders ranging from patient advocacy groups to clinical researchers are contemplating how to negotiate the rising costs of innovative drugs with the overall quality impact to patients and the economic impact both short and long term to the system at-large.

### **Implementation of the Affordable Care Act**

**ACA Enrollment Reaches 5 Million:** Centers for Medicare and Medicaid Services (CMS) Administrator Marilyn Tavenner [announced](#) in a blog post that more than 5 million people have enrolled in a health insurance plan through the federal and state marketplaces.

**Dems Tout ACA Enrollment:** Democratic staff of the Energy and Commerce Committee [released](#) a memo comparing enrollment in the Affordable Care Act (ACA) and Medicare Part D, which found that the rate of enrollment for the ACA is exceeding the rate of enrollment for Medicare Part D.

**House Oversight Questions Mandate Delay Authority:** Republican members of the House Oversight Committee [sent a letter](#) to Treasury Secretary Jack Lew requesting more information about the Treasury Department's legal authority to delay the ACA's employer mandate.

**DOJ Files Dismissal of Johnson Lawsuit:** The Department of Justice (DOJ) [filed a motion to dismiss](#) Senator Ron Johnson's (R-WI) lawsuit against the Office of Personnel Management (OPM) to overturn a regulation giving health insurance subsidies to members of Congress and some staff.

**8 in 10 Asian Americans Eligible Under ACA:** According to a new report [released](#) by the Department of Health and Human Services (HHS), 1.6 million Asian Americans, Native Hawaiians, and Pacific Islanders are eligible for tax credits or for Medicaid or the Children's Health Insurance Program.

**CMS Report on Prescription Drug Savings:** HHS released a [report](#) on the progress the agency has made closing the prescription drug "donut hole." The report finds that 7.9 people on Medicare saved almost \$9.9 billion on drugs since passage of the ACA—close to \$1,265 per person.

### **Other Federal Regulatory Initiatives**

**GSA Creates Digital Government Hub:** The General Services Administration (GSA) has [launched](#) a digital government program called 18F to partner public and private sector designers and developers to improve government services and improve IT delivery.

**CMS Drops Uncovered Prescription Drug Plan:** In its final 2015 letter to insurers in the federally facilitated marketplace, CMS [dropped](#) a policy encouraging insurers to temporarily cover prescription drugs outside of their normal formulary for new customers.

**CMS Proposes Changes to Risk Corridors:** CMS [released](#) a proposed rule to increase the limit on allowable administrative costs for risk corridor calculations to 22%, allow issuers to adjust their medical loss ratio, and disburse sequestered reinsurance and risk adjustment funds as soon as possible in 2016.

**FDA Unsure of Food Transportation Rule Benefit:** In a [public meeting](#) on the Food and Drug Administration (FDA) Food Safety and Modernization Act, the FDA stated they do not have a dollar value of the prospective benefits of the new food safety transportation rule because there isn't enough data on foodborne illnesses related to transportation. Nevertheless, they were confident the rule would be beneficial.

### **Other Congressional and State Initiatives**

**Senator Wyden SGR Bill Scored by CBO:** Senator Ron Wyden's (D-OR) bill to repeal and replace the Sustainable Growth Rate will cost \$180.2 billion over 11 years, according to a report [released](#) by the Congressional Budget Office.

**ACP Supports SGR Bill:** The American College of Physicians (ACP) [announced](#) that they support the SGR Repeal

and Medicare Provider Payment Modernization Act of 2014 (H.R. 4015/S. 2000) and asked both parties not to attach provisions which would kill the bill.

**McDermott Raises Alarm on Appeals Backlog:** Ranking Member of the House Ways and Means Subcommittee on Health Jim McDermott (D-WA) [sent a letter](#) to HHS Secretary Kathleen Sebelius expressing concern with the backlog of appeals and calling on HHS to review their administrative procedures and reform the Recovery Audit Contractor program to make contractors more accountable.

**Senators Ask FDA for Clarity on Medical Software:** A bipartisan group of six Senators on the Senate HELP Committee [wrote](#) to the FDA requesting that the agency further clarify rules for medical software application developers to promote innovation and keep consumers safe. Lawmakers also urged the FDA to work with Congress to “identify policies that will serve the best interests of patients and innovators alike.”

**Bicameral Post-Acute Reform Draft Released:** The House Ways and Means Committee and the Senate Finance Committee have [released](#) a bipartisan discussion draft bill to modernize Medicare payments to post-acute care providers and create a quality-driven post-acute care system.

**Senators Ask for Transparency on Mobile Medical Apps:** A bipartisan group of six Senators [sent a letter](#) to FDA Commissioner Margaret Hamburg requesting the FDA provide transparency and clarify rules for medical mobile apps and seeking input into what Congress could do to clarify regulation of medical software.

**Warren Pushes FDA on Antibiotics:** During a Senate Health, Education, Labor and Pensions hearing, Senator Elizabeth Warren (D-MA) [strongly questioned](#) FDA Commissioner Hamburg on the use of antibiotics in animal agriculture, stating that their use is contributing to the rise in antibiotic resistance.

### Other Health Care News

**NIAID Head Warns Against Drug-Resistant Bacteria:** Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), published a [commentary](#) in JAMA warning that the problem of multi-drug resistant bacteria is worsening and calling on a “multifaceted, global solution.”

### Upcoming Hearings and Markups

#### Senate

On March 26, the Senate Special Aging Committee will hold a [hearing](#) titled “Preventing Medicare Fraud: How Can We Best Protect Seniors and Taxpayers?”

#### House

On March 26, the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee will hold a [hearing](#) titled “Where Have All the Patients Gone? Examining the Psychiatric Bed Shortage.”

On March 27, the Agriculture, Rural Development, FDA, and Related Agencies Subcommittee of the House Appropriations Committee will hold a [hearing](#) on proposed fiscal 2015 appropriations for the FDA.

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