



ML Strategies Update

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Health Care Update

Sovaldi Pricing Lower in Canada: Under pressure from Health Canada, Canada's health system regulator, Gilead is offering the Hepatitis C drug, the pricing of which has drawn the attention of US regulators and lawmakers, to Canadian patients for significantly less than in the United States. The Canadian Hepatitis C Education and Prevention Society announced that a 12-week course of the treatment could be \$55,000. This, compared to the \$84,000 price tag for the same treatment course in the U.S., constitutes approximately a 40 percent discount for Health Canada. This move reflects an effort by Health Canada to lower prices compared to the US market across their health system. In addition to likely continuing to fuel the focus of US lawmakers and regulators on the pricing of Sovaldi, the decision by Gilead could also rekindle discussions of importation of drugs to the US, fake prescription websites, and other controversies. Just last week, Senate Finance Committee Chairman, Ron Wyden (D-OR) was joined by Senator Chuck Grassley (R-IA) [on a letter](#) to the CEO of Gilead, asking for data that justified the high price for the drug. This marked the first time that the new Finance committee chairman has weighed in on the issue and a sign that policymakers will be watching even more closely as utilization and cost data continue to be reported for this next quarter.

Implementation of the Affordable Care Act

Medicare Beneficiaries Have Saved \$11.2 Billion Since ACA's Passage: The Department of Health and Human Services (HHS) [announced](#) that since the passage of the Affordable Care Act (ACA), 8.2 million Medicare beneficiaries have saved, on average, \$1,407 on prescription drugs through donut-hole discounts and rebates.

CMS Predicts Drug Premiums Will Remain Low: In a [release](#), CMS predicted that the average monthly premium for the Medicare prescription drug benefit will be \$32 in 2015. This is a \$1 increase over the previous plan year. CMS Administrator Marilyn Tavenner credited the ACA for the "improved benefits and saving[s]."

Other Federal Regulatory Initiatives

HHS Celebrates Medicare's 49th Anniversary: On July 30th, Marilyn Tavenner, Administrator of CMS, [posted](#) on the HHS website a tribute to Medicare and Medicaid's 49th Anniversary.

FDA Praises New Health Informatics Officer, Data Initiative: On June 2nd, the Food and Drug Administration (FDA) posted a [blog post](#) on its website in which it lauded its new chief health informatics officer, Taha Kass-Hout, M.D. for his commitment to increase the FDA's transparency, innovation, and accountability.

CMS Prolongs Moratorium on Home Health, Ambulance Providers in Several Localities: CMS [announced](#) that it will keep the moratorium on new Medicare home health care and ambulance providers in effect in parts of Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey to combat fraud.

CMS Releases New Guide for Reporting Clinical Quality: CMS released a revised [guide](#) explaining how hospitals and doctors can report electronic clinical quality measures starting next year. The guide includes the QRDA-I, QRDA-III, and updates for the 2015 reporting year.

Sharp Increase in Number of Gaps in Medicare Contractors: HHS' Office of the Inspector-General reported that an annual [IT security audit](#) found a 45-percent increase in the number of gaps at 10 Medicare contractors from FY 2011.

ONC's Fight against Hypertension: The Office of the National Coordinator for Health Information Technology seeks to [obtain](#) better clinical decision support software to spread the use of evidence-based treatments for hypertension. The ONC is offering five prizes, worth a total of \$50,000, to medical professionals who document and promote their use of these treatments.

FDA Lab Test Regulations: The FDA [issued](#) final guidance on the development, review, and approval of companion diagnostics—lab tests used to identify patients who will either benefit or be harmed by treatment of a drug.

FDA Issues Final Draft Medical Device Guidance: The FDA released [final draft guidance](#) to exempt low risk Class II medical devices and 17 certain Class I medical devices from FDA premarket review.

Other Congressional and State Initiatives

Mississippi Senators Sponsor Telehealth Bill: Senators Thad Cochran (R-MS) and Roger Wicker (R-MS) [introduced](#) the Telehealth Enhancement Act (S. 2662) to increase the number of telemedicine services Medicare pays for.

House Small Business Seeks to Expand Telemedicine: The House Small Business Subcommittee on Health and Technology held a [hearing](#) to assess telemedicine's benefits and its limited access nationwide.

Cummings Seeks Reasons for GOP Governors' Differing Views on Medicaid Expansion: Elijah Cummings, the Ranking Member on the House Oversight Committee, has [requested](#) six Republican governors to prepare reports explaining why they chose to either facilitate or forgo Medicaid expansion in their states.

GAO Director Testifies on Medicaid Costs: Katherine Iritani, the GAO's director of health care, appeared before a House Oversight Subcommittee to [discuss](#) states' increasing dependence on monies from health care providers and local governments to finance Medicaid. The GAO [found](#) that this shifts costs from states to the federal government. Iritani said this shift indicates the need for better data for oversight over Medicaid.

House Passes Bill to Speed up Approval for Sunscreen Ingredients: The House [approved](#) a bill to streamline the FDA's approval process for new sunscreen ingredients. The FDA has not approved new ingredients in 15 years.

E&C Presses for More Facts on Lab Security Lapses: Five Republican leaders on the House Energy and Commerce Committee sent [letters](#) to CDC, FDA, NIH and HHS asking for more information about recent oversights complicating lab safety.

Surgeon General Seeks Skin Cancer Remedy: Surgeon General Boris Lushniak [urged](#) a robust public response to the growing rate of skin cancer. In his Call to Action, the Surgeon General said no one is immune to skin cancer and that everyone must be vigilant in fighting a cancer that is more widespread than all other cancers combined.

House Members Showcase 21st Century Cures Initiative in their Districts: While in their districts during the August recess, members of the House Energy and Commerce Committee plan to [promote](#) the 21st Century Cures Initiative.

Doggett, Young Seek Hospital Transparency: Representatives Lloyd Doggett (D-TX) and Todd Young (R-IN) have [introduced](#) the Notice Act, which would require hospitals to inform seniors if they classify them as "under observation." Unlike patients who are considered "inpatient," those on observation status are not eligible for Medicare reimbursement.

Bipartisan Lawmakers Seek Governors' View on CHIP: Senators Ron Wyden (D-OR) and Orrin Hatch (R-UT) and Representatives Fred Upton (R-MI) and Henry Waxman (D-CA) sent a [letter](#) to all governors asking for their views on what changes, if any, should made

to CHIP.

Waxman, Pallone Introduce CHIP: Representatives Henry Waxman (D-CA) and Frank Pallone (D-NJ) [introduced](#) the CHIP Extension and Improvement Act of 2014 to extend funding of the health insurance program and to accelerate its enrollment process. The legislation, for which there is a companion bill in the Senate sponsored by Sen. Jay Rockefeller (D-WV), intends to extend CHIP's funding before it expires on October 15, 2015.

House Passes Prescription Drug Bill: The House passed the [Ensuring Patient Access and Effective Drug Enforcement Act](#), which would require HHS to report to Congress on its coordination with state governments to mitigate drug abuse.

Senate Republicans Demand Better Subsidy Verification for ACA: Senators Orrin Hatch (R-UT), Chuck Grassley (R-IA), and Rob Portman (R-OH) wrote a [letter](#) to HHS Secretary Sylvia Burwell pressing for a response to last week's GAO report that found some people had attained subsidies through HealthCare.gov using fake identities.

GAO Testifies on Healthcare.gov: CMS Deputy Administrator Andy Slavitt and GAO Director of Acquisition William Woods [testified](#) before the House Energy and Commerce Oversight Subcommittee on ACA implementation and Healthcare.gov. Woods' written testimony outlines added costs associated with managing Healthcare.gov contractors. The full GAO report is [here](#).

House E&C Democrats Show ACA's Success District-By-District: House Energy and Commerce Committee Democrats released [data](#) on the number of beneficiaries of the ACA in each district.

Other Health Care News

Medicare Trustees Report Shows Continued Cost Reductions: The July 28th Medicare Trustees [Report](#) projects that Medicare's hospital insurance coverage will remain solvent until 2030. A number of factors have contributed to the improved outlook, including lower-than-expected spending in 2013, and lower projected utilization in the types of health care needed by Medicare patients.

Institute of Medicine Seeks Changes to Financing for New Doctors: The Institute of Medicine (IOM) released a [report](#) in which it urged the government to reform its financing for the training of new doctors, rather than increasing funding for graduate medical education as some doctors and hospital groups advocate. IOM recommends leveling the funding and dividing it between traditional residency training programs and reforms to the GME system to enable it to pay based on the performance of hospitals.

Study Finds Number of Uninsured Will Remain High: The Urban Institute and Robert Wood Foundation [released](#) a joint study in which they found that two-thirds of the nation's remaining uninsured adults qualify for Medicaid coverage under the ACA.

Upcoming Hearings and Markups

The Senate and House are in Recess.

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