



ML Strategies Update

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

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

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

APRIL 21, 2014

Health Care Update

- **Biopharma under the reimbursement microscope:** The high cost of drugs, especially innovative biologics and breakthrough targeted therapies, are once again in the spotlight. This time, a prominent physician professional society, the American Society of Clinical Oncology (ASCO), convened a task force of physicians, payers, and others to develop an algorithm that could be used to determine the clinical effectiveness and known side effects associated with a treatment and integrate those factors with the costs. Ultimately, this algorithm could yield a value that would be used to recommend certain drugs over others and simultaneously exert pressure on the biopharmaceutical industry to lower the cost of oncology drugs. Separately, a pair of NIH researchers [recently published a perspective](#) article in the New England Journal of Medicine claiming that the prices of some cancer drugs were so high, that they preclude trials comparing their effectiveness - as much as \$70 million in drug costs alone. This article comes amidst an increase in activity at the Congressional level, where leading Democrats on the House Energy and Commerce Committee have recently called for justification for Gilead Sciences pricing of the company's new chronic Hepatitis C virus treatment, Sovaldi™, citing the apparent high cost of the drug as a significant concern. ***Biopharmaceutical manufacturers are at an apparent crossroads*** as they navigate pressures from stakeholders and policymakers to lower the cost of their drugs. At the same time, the cost to develop breakthrough therapies combined with significantly smaller markets with fewer patients – especially in oncology, remains a challenge.
- **CBO estimates ACA will cost less:** The Congressional Budget Office (CBO) [released an updated estimate](#) of the budget impact of the Affordable Care Act (ACA) which found that the health insurance coverage provisions will cost \$5 billion less than their previous estimate. The law also is projected to cover more individuals than previously believed: 12 million more non-elderly people will have health insurance in 2014 than if Obamacare had not become law. This latest report will add fodder to the ongoing debate over what is causing and how to constrain the high cost of health care.

Implementation of the Affordable Care Act

8 Million Insured: President Barack Obama [announced](#) that 8 million people signed up for private insurance through the health insurance marketplace. Thirty-five percent of those who signed up are under the age of 35 and 28% are between the ages of 18 and 34.

Inappropriate Antibiotic Use May Rise: A study [published](#) in the Centers for Disease Control and Prevention (CDC) journal *Emerging Infectious Diseases* found that inappropriate antibiotic use may rise in Medicaid patients with short-term respiratory tract infections when Medicaid is expanded under the ACA.

Insurance Commissioners Meet Obama: Members of the National Association of Insurance Commissioners [met with](#) President Obama and Vice President Biden to discuss the 2014 ACA open enrollment period and preparations for the 2015 open enrollment period.

Demand for Healthcare Consultants High in Boston: The Federal Reserve's monthly beige book [reported](#) that there is strong demand for healthcare consultants in Boston as a result of the changes imposed by the ACA. In other districts there was some uncertainty about the ACA's requirements and rising health care costs.

Republican Senators Question Census Changes: Senators Lamar Alexander (R-TN), John Thune (R-SD), and Orrin Hatch (R-UT) [wrote](#) a letter to Census Bureau Director John Thompson requesting the agency maintain its current survey questions so as to better study the impact of the ACA.

Other Federal Regulatory Initiatives

SGR Fix More Expensive: In an updated budget baseline, the Congressional Budget Office (CBO) [indicated](#) it expects higher spending on Medicare Parts A and B between 2015 and 2017, increasing the cost of repealing the Sustainable Growth Rate (SGR) by \$9 billion to \$124 billion.

CMS Proposes Updated Life Safety Code: The Centers for Medicare and Medicaid Services (CMS) [proposed](#) a rule to adopt the National Fire Protection Association's 2012 Life Safety Code and Health Care Facilities Code, setting out new fire safety requirements for health care facilities.

AHA Files Lawsuit Over Two Midnight Rule: The American Hospital Association, along with four other hospital associations and multiple hospitals, [filed](#) two related lawsuits against the U.S. Department of Health and Human Services (HHS) challenging the two-midnight rule.

Psychiatric Facility Data Made Public: CMS [released](#) quality measures from 1,753 inpatient psychiatric facilities. The data measures the hours of physical restraint used, the hours of seclusion use, the number of post discharge continuing plans created, and how many of those plans were transmitted upon discharge.

DOJ Settles Claims Against Cancer Treatment Facility: The Department of Justice (DOJ) [announced](#) that the Hope Cancer Institute and its owner have agreed to pay \$2.9 million to settle allegations they violated the False Claims Act by submitting claims to Medicare, Medicaid, and the Federal Employee Health Benefits Programs for drugs and services that were not provided to beneficiaries.

FDA Cautions Against Uterine Surgery Tool: The FDA has [warned](#) against using laparoscopic power morcellation devices, used to treat uterine fibroids, due to concerns they could spread cancerous uterine sarcoma tissues.

CDC Reports Limited Progress on Preventing Foodborne Illness: The CDC Food Safety Progress Report finds that foodborne infections remain an important public health issue. The report finds there were 19,000 infections, 4,200 hospitalizations, and 80 deaths from the nine germs the agency tracks.

CDC Outlines Efforts to Decrease Health Disparities: The CDC's Morbidity and Mortality Weekly [Report](#) highlighted steps the agency is taking to reduce disparities in health care, including offering free vaccines to children, STD group education for black males, and motor vehicle safety classes for American Indian and Native Alaskan populations.

Other Congressional and State Initiatives

Governors Criticize Medicare Advantage Rates: Governors Rick Scott, Bobby Jindal, and Rick Perry [sent a letter](#) to President Obama criticizing CMS' announcement that Medicare Advantage payment rate will rise as "political theater" and claiming that rates will drop instead.

NY MRT Receives Final Approval: New York Governor Andrew Cuomo [announced](#) that New York has received final approval for its Medicaid Redesign Team (MRT) waiver from HHS. The \$8 billion reinvestment includes \$6.42 billion for Delivery System Reform Incentive Payments and a \$500 million fund for safety net providers.

Republican Senators Question HHS Workforce Programs: Senators Tom Coburn (R-OK), Michael Enzi (R-WY) and Richard Burr (R-NC) [wrote](#) to Secretary Sebelius asking for a justification for HHS' plan to set aside additional funding for new and existing health care workforce programs.

Other Health Care News

Poll Shows Support for Democrats on Health Care: A Reuters/Ipsos poll [found](#) that 32% of respondents prefer Democrats' plan, policy, or approach to healthcare, compared to 18% who support Republicans. This increase was attributed to Democrats who were previously ambivalent returning their support to the party.

Report Demands Price Transparency: The Healthcare Financial Management Association, a task force composed of health plans, providers, consumers, and employer and physician groups, [released](#) a report detailing guiding principles and recommendations for improving price transparency in health care.

Medication Spending Rises: IMS Health [released](#) a report which found that total spending on medications rose 1% on a real per capita basis in 2013 and that utilization of health care services rose for the first time in three years.

Upcoming Hearings and Markups

The Senate and House are in Recess.

* * *

Boston · Washington www.mlstrategies.com