

Tom Koutsoumpas, TKoutsoumpas@mlstrategies.com Jeremy Rabinovitz, JRabinovitz@mlstrategies.com Alexander Hecht, AHecht@mlstrategies.com Gary Bacher, GEBacher@mintz.com Kevin M. Kappel, KMKappel@mlstrategies.com Robert C. Skinner, RCSkinner@mlstrategies.com Joshua Booth, JBooth@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

HEALTH CARE REFORM UPDATE April 16, 2012

Implementation of the Affordable Care Act (ACA)

On April 9th the Department of Health and Human Services (HHS) issued a proposed rule implementing many of the administrative simplification provisions of the ACA. The proposed rule would give each health plan a unique, standardized identifier to be used by providers and others transacting with the plan. The rule also pushes back the deadline by which providers will be required to comply with ICD-10, the system of disease and treatment codes published by the World Health Organization (WHO), by one year, to October 1, 2014. Providers had expressed concern that the new system is overly complex and burdensome to implement. The proposed rule can be found here. An HHS fact sheet can be found here.

On April 10th the Centers for Medicare and Medicaid Services (CMS) announced the selection of twenty-seven organizations as Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program. These are the first ACOs to be approved under the program, although 32 "Pioneer ACOs" have been functioning under a separate program since December 2011. CMS is reviewing 150 additional applications for approval by July. A CMS press release describing the program and listing the initial ACOs can be found here.

On April 11th CMMI announced that it had selected seven geographic areas to participate in the Comprehensive Primary Care (CPC) initiative. The CPC is a four-year, multi-payer initiative that will aim at fostering collaboration between public and private health care payers to strengthen primary care. Medicare will work with commercial and State health insurance plans and offer bonus payments to primary care doctors who better coordinate care for their patients. More information and a list of the selected markets can be found here.

On April 12th New York Governor Andrew M. Cuomo signed an executive order to establish a health insurance exchange in the state. The Republican majority in the State Senate has blocked legislation to create an exchange. The order can be found here. A New York Times article can be found here.

Other HHS and Federal Regulatory Initiatives

On April 9th the FDA launched the second phase of its medical device Innovation Pathway, "Innovation Pathway 2.0." The Innovation Pathway is a pilot program launched in 2011 to provide for expedited approval of

innovative medical devices. The second phase includes new tools to encourage collaboration between the FDA and device manufacturers throughout the device development process. More information can be found here.

On April 11th the FDA issued guidance documents for the food industry and pharmaceutical companies on the proper use of antibiotics in farm animals. The guidance documents are intended to encourage industry to voluntarily phase out the use of medically important antibiotics in farm animals, thus reducing antibiotic resistance. An FDA news release can be found here.

Other Health Care News

On April 9th Charles Blahous, a policy analyst for the Mercatus Center at George Mason University and the GOP trustee for Medicare and Social Security, released a study "The Fiscal Consequences of the Affordable Care Act" finding that the ACA will increase the deficit by \$340 billion over the next decade. Blahous asserts that Congressional Budget Office (CBO) estimates finding that the ACA would decrease the deficit double-counted certain savings. The study can be found here. A response from the White House refuting the findings can be found here.

On April 9th Health Affairs published a study finding that, compared to European counterparts, the U.S. spends more on cancer care and also has better survival rates. The authors opine that the study shows that the high spending on cancer treatment "may be worth it," but caution that further research is needed to determine which spending is most cost effective. The study can be found here.

On April 11th several patient advocacy groups sent a letter to HHS Secretary Kathleen Sebelius urging the Department to revise its position on the Essential Health Benefits (EHB) to require more robust drug coverage. The letter states that the standards set out by HHS in a December 2011 bulletin are "wholly inadequate to meet the complex needs of patients with chronic diseases and disabilities." The letter can be found here.

Hearings and Markups Scheduled

Senate

On April 18th the Senate Special Aging Committee will hold a hearing entitled "The Future of Long-Term Care: Saving Money by Serving Seniors." More information can be found here.

On April 19th the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies will hold a hearing on the FY2013 budget for the FDA. More information can be found here.

On April 21st the Senate Veterans' Affairs Committee will hold a field hearing entitled "Improving Access to Quality Healthcare for Rural Veterans." More information can be found here.

House

On April 16th the House Veterans' Affairs Subcommittee on Health will hold a hearing on several bills related to veterans' health. More information can be found here.

On April 17th the House Budget Committee will hold a hearing entitled "Strengthening the Safety Net." More information can be found here.

On April 18th the House Energy and Commerce Subcommittee on Health will hold a hearing entitled "FDA User Fees 2012: How Innovation Helps Patients and Jobs." More information can be found here.