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@mintz.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
October 8, 2012

Implementation of the Affordable Care Act (ACA)

On October 1st the Supreme Court asked for input from the federal government on the lawsuit from Liberty University that challenges components of the ACA. Liberty says its concerns were not appropriately addressed in the June decision to uphold the ACA. Liberty contends that employer requirements are unconstitutional and the individual mandate is a violation to freedom of religion. An article on the Liberty lawsuit can be read here.

On October 1st a Missouri federal judge struck down a challenge made by St. Louis CEO Frank O'Brien of O'Brien Industrial Holdings LL, against the contraceptive mandate of the ACA. Judge Carol Jackson ruled requiring employers to cover contraception through their insurance plan does not place a substantial burden on religious exercise. An article on the ruling is available here.

On October 1st Alabama Governor Robert Bentley wrote to Department of Health and Human Services (HHS) Secretary Sebelius indicating his state will not select an essential health benefits (EHB) benchmark. The governor stated not enough information is available from HHS to create an effective EHB plan and that parameters do not allow states to select innovative mechanisms. The letter from Governor Bentley is available here.

On October 1st the North Dakota Insurance Department submitted an EHB plan to HHS. The selection of the Sanford Health Plan was submitted by North Dakota even though a request for a final EHB rule from HHS was not received prior to the recommendation deadline. A letter from the North Dakota Insurance Department can be viewed here.

On October 2nd 57 patient advocacy groups signed a letter to HHS Secretary Sebelius expressing concerns with the EHB bulletin. The groups urged HHS to abandon proposed plans and instead move

to create a plan that will be suitable for the private insurance market and the Medicaid population. An article on the topic and the letter sent by the patient groups can be seen here.

On October 2nd the Urban Institute released a report highlighting the cost savings provided by the ACA. The report indicates that state-based insurance exchanges, Medicare payment reductions, and an excise tax on high-cost employer-sponsored insurance plans will all help reduce costs. The full report is available here.

On October 2nd Avalere Health indicated that 21 states and the District of Columbia have submitted their EHB plans to HHS. The actions taken by each state can be seen here. An article on the can be viewed here.

On October 3rd the HHS Office of Inspector General (OIG) announced reviews that it will make of the ACA. OIG will review the readiness of states to comply with exchange and Medicaid eligibility requirements and will assess the Consumer Operated and Oriented Plan Program (CO-OP). A full list of programs that will be reviewed is available here.

On October 3rd the D.C. Health Benefit Exchange Board voted to accept a plan that requires businesses with 50 members or fewer to purchase insurance through a city-run exchange. The exchange, which would take effect in 2014, is intended to make the purchase of insurance more transparent, accountable and affordable. An article on the Board's vote is available here. A press release from Mayor Vincent Gray's office can be seen here.

On October 4th the New Jersey state senate passed the bill to create a state insurance exchange. The bill will next be considered by the Assembly. To become law it will need to be signed by Governor Chris Christie, who previously vetoed a similar bill and has not expressed support for the legislation. An article on the senate's decision is available here.

Other HHS and Federal Regulatory Initiatives

On October 1st the U.S. Food and Drug Administration (FDA) indicated that a lack of funding is making it difficult to implement new rules regarding food safety. The FDA is required to make some of the biggest changes in food safety since the 1930s. An article on the requirements is available here.

On October 4th the Solicitor General's office asked the Supreme Court to review a challenge from the Federal Trade Commission (FTC) on a patent settlement agreement between brand and generic drugmakers. The brief was filed at the request of the FTC. The brief can be viewed here.

On October 4th the HHS Office of the Inspector General (OIG) released a report highlighting problems with dietary supplements. The OIG found that seven percent of supplements lacked a required disclaimer and 20 percent included prohibited disease claims on labels. The OIG recommends that the FDA improve the notification systems for these claims. The report can be read here.

On October 4th the Medicare Fraud Strike Force charged 91 individuals for their involvement in false billing schemes that resulted in a loss of $429.2 million. HHS Secretary Sebelius said the crackdown puts criminals on notice and that the ACA offers more tools to prevent fraud in the future. An article on the situation can be viewed here. The press release from HHS can be seen here.

Other Congressional and State Initiatives

On October 1st Senator Charles "Chuck" Grassley (R-IA) sent letters to three North Carolina hospitals asking them to explain their use of a federal discount drug program. Senator Grassley said the program is meant to help the poorest of patients and should not be used to build up hospital surpluses. A statement from Grassley's office can be found here.

On October 2nd a bipartisan group of 13 lawmakers sent a letter of concern to the Drug Enforcement Agency (DEA) indicating that many small pharmacy owners have had difficulty obtaining certain controlled substances because the supply of wholesalers has been severely limited. The lawmakers expressed concern because many of these patients do not have an alternative source of medicine. The letter to the DEA is available here.

On October 4th House Energy and Commerce Committee Chairman Fred Upton (R-MI), Ways and Means Committee Chairman Dave Camp (R-MI), Energy and Commerce Health Subcommittee Chairman Joe Pitts (R-PA), and Ways and Means Health Subcommittee Chairman Wally Herger (R-CA) called on HHS Secretary Sebelius to immediately suspend the distribution of incentive payments related to the Electronic Health Records (EHR) program. The suggested taxpayer dollars have gone to waste under the HER program, as providers face little accountability even while receiving incentive benefits. A press release from the House Energy and Commerce Committee is available here. The joint letter can be seen here.

Other Health Care News

On October 1st the RAND Corporation released a report that the number of Americans who are 100 pounds or more overweight increased by 70 percent from 2000 to 2010, although growth did begin to slow in 2005. The key findings of the report can be found here. A press release from the RAND Corporation can be found here.

On October 1st the Census Bureau released a report indicating that Americans who are of working age are making less doctor visits than 10 years ago. People 18 to 64 years of age made an average of 3.9 visits to the doctor in 2010, down from 4.8 visits in 2001. An article on the decline can be found here. The actual report can be viewed here.

On October 1st the Generic Pharmaceutical Association (GPhA) filed a brief with the Supreme Court urging for a review of how generic and brand name drugmakers handle patent disputes. The GPhA states that the ability of consumers to access life-saving and health-preserving medicines is currently threatened. The brief sent by GPhA can be seen here.

On October 2nd a federal judge ruled that Abbott Laboratories must pay a $500 million criminal fine for misrepresenting uses of the drug Depakote. Against FDA approval, Abbott promoted Depakote as having the ability to treat dementia and schizophrenia. The FDA only approved the drug to treat seizures, mania, and migraines. An article on the case can be read here.

On October 3rd an article in *U.S. News* indicated that many individuals and families who purchase a health care plan on their own could face burdensome costs. According to *U.S. News*, many plans do not appropriately cover consumers for services like prescription drugs, maternity coverage, mental health treatment, and rehabilitation therapy. The article, which provides a link to an interactive tool helping consumers find the best insurance options, is available here.

On October 3rd a survey released by Medicare Today and KRC Research indicated that nine out of ten people approve of Medicare Part D. The program has experience a 12% approval jump since it was first implemented. An article on the survey is available here.

On October 3rd the Bipartisan Policy Center released a report on ways to accelerate electronic health information sharing. The group states that effective sharing of information can reduce the cost and increase the quality of care for patients. The full report can be found here.

On October 3rd Georgetown University's Center on Health Insurance Reforms released a report on the effectiveness of the sale of health insurance across state lines. The report finds that proposals allowing for the purchases of insurance across state lines have been largely unsuccessful. The full report is available here.

On October 4th Modern Physician released an issue brief on a form of primary care that pays special attention to at-risk patients has been effective in a small number of test sites. The high-intensity process, also known as ambulatory intensive care, selects patients identified as needing specialized care. An article on the process is available here. The actual brief can be seen here.

On October 5th the Congressional Budget Office (CBO) released its report for fiscal year 2012. The federal deficit for the year is $1.1 trillion and Medicare's net spending rose by $15 billion. The full report can be seen here.

On October 6th the *New York Times* reported that a medicine contaminated with a fungus may be to blame for recent deaths from meningitis. Relaxed oversight of drug makers is believed to have allowed a compounding pharmacy in New England to produce the drug. The full article from the *Times* is available here.

Hearings and Mark-Ups Scheduled

Both the Senate and the House of Representatives are in recess.