



Tom Koutsoumpas, TKoutsoumpas@mlstrategies.com
Jeremy Rabinovitz, JRabinovitz@mlstrategies.com
Alexander Hecht, AHecht@mlstrategies.com
Gary Bacher, GEBacher@mintz.com
Joseph P. Hammang, PhD, JPHammang@mlstrategies.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
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Leading the News: the Regs are Out!

On November 20th HHS released several widely-anticipated rules implementing high-profile provisions of the Affordable Care Act (ACA). These includes rules including making it illegal for health insurance companies to discriminate against people with pre-existing conditions, allowing insurance companies to only vary premiums within limits, and stating that insurers would only be able to vary premiums based on age, tobacco use, family size, and geography. One of the other rules also promotes increased wellness programs to control health care spending, and a third rule identifies services, known as essential health benefits (EHB), that must be covered under core plans. The EHB comment period ends on December 26th, and states have until the end of this comment period to select an EHB package. The new rules from HHS can be found [here](#).

That same day, HHS also clarified certain regulatory mechanisms regarding health plan options in the new health insurance market under the ACA. The Department noted that the National Committee for Quality Assurance and URAC will be responsible for accrediting qualified health care plans under the ACA. In addition, HHS also proposed that insurers will have a 2-point margin of error on actuarial value (AV), meaning that insurers can be within 2 points of a standard and still receive the desired distinction. AVs, which have metal rankings of bronze through platinum, are an indication of what percentage of care payments the consumer is responsible for covering. Additional information on AVs and accreditation standards is available [here](#).

Implementation of the Affordable Care Act

On November 16th Idaho Governor Butch Otter (R) issued a press release saying that he appreciates the extra time provided by HHS to make a decision on the type of health insurance exchange Idaho will build. Gov. Otter said he hopes the extension will provide time for more questions to be answered. The release from Gov. Otter is available [here](#).

On November 19th Utah Governor Gary Herbert (R) said he believes health care reform will be most successfully implemented at the state level, although the governor also said he still has questions for HHS about the new law. Gov. Herbert issued 10 questions to HHS Secretary Sebelius. The questions can be viewed [here](#). The letter from Gov. Herbert to Secretary Sebelius can be viewed [here](#).

On November 19th a U.S. District Court rejected the argument made by the Christian owners of Hobby Lobby, Inc. that its stores should be exempt from the contraceptive mandate of the ACA because of the company's religious beliefs. The ruling from the U.S. District Court for the Western District of Oklahoma is available [here](#).

Other HHS and Federal Regulatory Initiatives

On November 20th the HHS Office of Inspector General (OIG) issued a list of the top ten challenges facing HHS. The number one challenge involves implementation of the ACA. Other challenges include preventing Medicare and Medicaid fraud and avoiding wasted spending. The full list of challenges is available [here](#).

On November 20th the U.S. Preventive Services Task Force issued a recommendation that nearly all persons ages 15 to 64 should be screened for HIV, a shift toward broader testing. An article on the recommendation can be read [here](#).

On November 21st the Centers for Medicare and Medicaid Services (CMS) announced the first three participants of the Medicare Data Sharing for Performance Measurement program, designed to help provide consumers with more health care information. Groups involved in the program will combine Medicare and private insurance data to create comprehensive reports on provider performance. The release from CMS is available [here](#).

Other Congressional and State Initiatives

On November 16th the Republican leaders of the House Energy & Commerce Committee as well as its Health and Oversight Subcommittees sent a joint letter to FDA Commissioner Margaret Hamburg asking for documentation about what the FDA did regarding the New England Compounding Center before the nationwide meningitis outbreak occurred. Republicans on the Committee have set a deadline of November 30th. The letter to Commissioner Hamburg is available [here](#).

On November 19th Chairman Tom Harkin (D-IA) and Ranking Member Mike Enzi (R-WY) of the Senate Health, Education, Labor and Pensions Committee sent letters to all 50 states requesting information about any prior interactions with the New England Compounding Center. The Committee also requests information on how states regulate other compounding centers in their area. The letter and press release are available [here](#).

On November 19th the Government Accountability Office (GAO) issued a report finding that HHS, along with other government agencies, must do more to appropriately evaluate IT investments. Evaluations done by HHS do not address all Office of Management and Budget guidelines, according to the GAO. The full report can be read [here](#).

On November 19th political leaders in Florida indicated the potential for the creation of a state-federal partnership exchange. New Florida State Senate President Don Gaetz (R) called for the creation of a select committee to better understand the ACA. An article on Florida's efforts is available [here](#).

On November 20th the Congressional Budget Office (CBO) indicated that the cost for a one-year doc fix, designed to freeze Medicare payments to doctors and prevent a 26.5% drop in these payments, increased by \$7 billion. Delaying the cut would now cost \$25 billion. An article on the increased cost is available [here](#).

On November 26th a report issued by the GAO indicated that while CMS has developed a Fraud Prevention System (FPS), more work remains to determine if the FPS is effective. The GAO says that quantifiable benefits must be reported and measurable performance targets need to be established by CMS. Highlights and the full report from the GAO are available [here](#).

Other Health Care News

On November 19th the Pew Charitable Trusts released a report indicating that the number of employees at FDA grew by over 31% from 2007 to 2010, although a quarter of the positions are temporary employment. The report states that the FDA is missing out on top talent due to a long hiring process. The report can be read [here](#).

On November 20th the Patient Center Outcomes Research Institute's (PCORI) Board of Governors met and agreed to draft guidelines that direct the formulation of research questions for comparative effectiveness research. The full and revised document can be found [here](#).

On November 20th a study in the journal *Archives of Surgery* reported that nearly 40% of complications following surgery are experienced at home. As hospitals fell an increasing pressure to decrease stays, experts say that doctors must stay attentive to patient needs following a hospital stay. An article on the study is available [here](#).

On November 20th the CEO of the International Academy of Compounding Pharmacists (IACP) sent a letter to Food and Drug Administration Commissioner Margaret Hamburg asking why the agency did not use its current authority to crack down on the New England Compounding Center. IACP CEO David Miller acknowledged that some changes may need to be made, but he questioned why existing authority was not appropriately used. An article on IACP's comments is available [here](#).

Hearings and Mark-Ups Scheduled

House of Representatives

On November 28th the House Energy & Commerce Committee will hold a hearing entitled, "Examining Options to Combat Health Care Waste, Fraud and Abuse." More information can be found [here](#).