



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 22, 2012

Leading the News

On October 16th the Food and Drug Administration (FDA) sent agents to the New England Compounding Center (NECC) to investigate the recent outbreak of meningitis caused by a contaminated medicine created by the NECC. Officials acknowledged the investigation but said it would be premature to suggest potential results. An article on the investigation can be read [here](#). On October 17th Chairman Fred Upton (R-MI), Ranking Member Henry Waxman (D-CA) and other members of the House Committee on Energy and Commerce sent a letter to FDA Commissioner Margaret Hamburg requesting all documentation relating to the agency's interactions with the NECC since 2004. The letter from the Committee can be viewed [here](#).

On October 16th Representative Edward Markey (D-MA) wrote to the Department of Justice (DOJ) and requested that the New England Compounding Center (NECC) be investigated for alleged violations in the sale of controlled substances. The letter from Rep. Markey to the DOJ is available [here](#).

On October 18th Senator Richard Blumenthal (D-CT) sent a letter to the Department of Defense (DOD) that requested details on a contract the DOD had with a compounding center linked to the New England Compounding Center (NECC). Ameridose, which has the same owner as NECC, received a sole-source purchase agreement from the Pentagon in July 2012. The letter from Sen. Blumenthal is available [here](#).

On October 18th the FDA confirmed unopened vials found in an investigation at the NECC contained the virus responsible for the meningitis outbreak. An archive of updates is available [here](#). Finally, on October 21st the CDC announced twenty three deaths as a result of the contaminated injections. The full current case count is can be viewed [here](#).

Implementation of the Affordable Care Act

On October 15th the Government Accountability Office (GAO) released a report finding that the ACA's Prevention and Public Health Fund provided support for 43 activities across five governmental agencies. \$500 million was made available through the fund in fiscal year 2010 and went to the Health Resources and Services Administration (HRSA), while most of the \$750 million made available in fiscal year 2011 went to the Centers for Disease Control (CDC). The full report from GAO is available [here](#).

On October 16th the Commonwealth Fund issued a report on the effects of the ACA on Medicare Advantage (MA). The Fund's report finds that \$12.7 billion in MA overpayments will be eliminated under the ACA, and an increased emphasis will be placed on performance by providing \$2.1 billion to plans that perform well. These changes under the ACA are intended to increase incentives for MA plans to be more efficient and to improve the quality of care for their enrollees. The full report can be read [here](#).

On October 16th Massachusetts launched its new Health Information Exchange (HIE) that, according to Governor Deval Patrick, will allow for increased coordination between care providers and will lower health care costs. The governor initiated the HIE by sending his own personal health data from a hospital in Boston to a hospital in Springfield. The press release from the governor's office is available [here](#).

On October 18th the New Jersey Assembly passed a bill that would establish a state-run health insurance exchange. The bill must still be signed by Governor Chris Christie, who has indicated he will not make a decision on the exchange until after November's elections. Coverage of the legislative process can be found [here](#).

On October 18th Pennsylvania Insurance Commissioner Michael Consedine said it appears unlikely that Pennsylvania will have a state-run insurance exchange ready by January of 2014. Consedine said he still seeks answers from HHS on how to best implement the exchange. An article from the Associated Press can be read [here](#).

On October 19th the Urban Institute released a report indicating that the ACA is not a government takeover of healthcare. Instead, the ACA relies on incentives, infrastructure, and information to create an effective private marketplace. The report from the Urban Institute is available [here](#).

On October 19th four scrap metal recycling companies in Missouri filed a lawsuit against the Obama administration's contraceptive mandate. The lawsuit from the Missouri companies is available [here](#). Also on October 19th, Archbishop Thomas Wenski of Miami joined the 50 or so other Catholic dioceses, universities and entities throughout the U.S. filed a lawsuit against the HHS over the administration's contraceptive mandate. Press coverage on the Archbishop's lawsuit is available [here](#).

Other HHS and Federal Regulatory Initiatives

On October 15th Senators Tom Coburn (R-OK) and Orrin Hatch (R-UT) sent a letter to Centers for Medicare and Medicaid Services (CMS) Administrator Marilyn Tavenner expressing concern that CMS missed an October 1st deadline to report on the effectiveness of its fraud prevention system (FPS). The letter sent to CMS can be seen [here](#).

On October 15th Dr. Farzad Mostashari, the National Coordinator for Health Information Technology in the Office of the National Coordinator for Health Information Technology (ONC), launched a review to determine if health care professionals are using electronic health records (EHR) to overbill Medicare. The review is prompted by findings that medical professionals added \$11 billion more to their fees in the last decade. An article on the review process is available [here](#).

Other Congressional and State Initiatives

On October 16th the American Hospital Association (AHA) sent a letter to Representatives Sam Graves (R-MO) expressing appreciation and support for his recently introduced *Medicare Audit Improvement Act of 2012*. The legislation would reform the Recovery Audit Contractor (RAC) program. According to the AHA, the current RAC is too complicated and has many conflicting regulations. The full letter from AHA to Rep. Graves is available [here](#).

On October 17th Senators Richard Burr (R-NC), Tom Coburn (R-OK), Pat Roberts (R-KS), and John Thune (R-SD) sent a letter requesting to meet with staff from the CMS and the ONC regarding electronic health records (EHR). The senators questioned if EHRs increase the use of diagnostic testing rather than the intended reduction on testing and cost to taxpayers. The letter from the senators is available [here](#).

On October 18th a Massachusetts state audit indicated there are flaws in the eligibility determination process for healthcare services. The audit found the proposed process lacks effective ways to determine the income and residency of beneficiaries. The full audit can be found [here](#).

On October 18th Virginia Health Commissioner Karen Remley resigned following the passage of several controversial abortion clinic regulations. Remley said her ability to perform her role had been compromised by the General Assembly's decision. An article on the resignation can be read [here](#). The full letter from Remley is available [here](#).

On October 19th Representative Darrell Issa (R-CA) said he will move to subpoena documents from HHS relating to the \$8 Medicare Advantage pilot program. Issa suggested HHS overstepped its legal authority by authorizing the pilot program and said the documents provided to his committee were inadequate. The letter sent to Secretary Sebelius can be seen [here](#).

Other Health Care News

On October 15th the American Medical Association AMA and more than 100 other medical groups sent a letter to Chairman Max Baucus (D-MT) and Ranking Member Orrin Hatch (R-UT) of the Senate Finance Committee. The organizations urged the senators to eliminate the current sustainable growth rate (SGR) model and create a more feasible payment model for the future. The letter sent to the senators can be viewed [here](#).

On October 15th the American Medical Association's (AMA) Council on Medical Service, responsible for policy recommendations, suggested that a form of premium support could work for Medicare. The Council said subsidies should be linked to rising health care costs, and not to GDP or other factors that could force seniors to pay more. The recommendations from the AMA are available [here](#).

On October 16th the Annals of Internal Medicine released a study finding that implantable cardioverter-defibrillators (ICDs) can be used effectively even after they have been removed from the initial patient because of upgrades, infection, or even patient death. The study found that battery life in the ICDs is still useful and could help those who would otherwise be unable to afford an ICD. A summary of the report is available [here](#).

On October 16th advocates for AIDS funding and research said sequestration cuts would severely limit prevention efforts and access to treatment for Americans dealing with AIDS. The advocates issued a release stating the cuts would eliminate 460 AIDS research grants and 15,700 people would lose access to treatment drugs. The release can be read [here](#).

On October 16th the Association of Regional Centers for Health Information Technology (ARCH-IT) responded to certain members of the House Committees on Appropriations, and Energy and Commerce committee who said that HHS should suspend the “meaningful use” electronic health records (EHR) program. ARCH-IT said it is too late to turn back now from developments being made to bring American health care into the 21st century. The statement from ARCH-IT can be read [here](#).

On October 18th Catholic Health East and Trinity Health announced a merger that will create a system with over \$19 billion in assets. The system will have 82 hospitals and 89 care facilities across 21 states. The announcement on the merger can be seen [here](#).

On October 18th AARP released a report finding that over 40% of workers in the United States have cared for an aging friend or relative in the past five years. Caregivers spend the equivalent of a part-time job providing unpaid assistance, and these care commitments can often interfere with full-time work commitments. The report from AARP is available [here](#).

On October 18th the American Academy of Pediatrics (AAP) released a report addressing the negative effects of guns in the home of a child. The AAP said that firearm deaths continue to be a prevalent problem among American youth. The full report is can be seen [here](#).

On October 19th the Partnership for the Future of Medicare (PFM) announced it is beginning bipartisan efforts to promote the sustainability of Medicare. PFM hopes to provide credible, relevant, and thought-provoking research that will help policymakers responsibly address Medicare reform. The announcement from the PFM is available [here](#).

On October 19th the Eldercare Workforce Alliance announced that sequestration would have a dramatic and negative impact on America’s seniors. The Alliance said more practicing doctors are needed to care for the oldest citizens of the country. The report from the Alliance is available [here](#).

Hearings and Mark-Ups Scheduled

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