

Washington Boston New York Stamford Los Angeles Palo Alto San Diego London ML Strategies, LLC

701 Pennsylvania Avenue, N.W. Washington, D.C. 20004 USA 202 434 7300 202 434 7400 fax

www.mlstrategies.com

Tom Koutsoumpas
Jeremy Rabinovitz
Kevin Kappel
TKoutsoumpas @mlstrategies.com
JRabinovitz @mlstrategies.com
KMKappel @mlstrategies.com

HEALTH CARE REFORM UPDATE February 6, 2011

Implementation of Health Care Reform Law

The Medicaid and CHIP Payment and Access Commission (MACPAC), established under the CHIP Reauthorization Act of 2009 (CHIPRA) and expanded under the Affordable Care Act (ACA), took a significant step back from its duties on January 28th. Responsible for issuing and voting on recommendations to Congress, HHS, and the states on a range of issues including the implementation of the ACA, MACPAC held a contentious meeting on January 28th after issuing a set of draft recommendations that led many commission members to call for a "do over" due to the complexity and costs of the proposals when states are facing significant budget deficits. It is unclear where the panel will go next, but many members have called for revising the recommendations. More information on MACPAC's public meetings can be found here. On February 3rd, HHS Secretary Kathleen Sebelius issued a press release that can be found here marking the two-year anniversary of CHIPRA.

On January 31st U.S. District Court Judge Roger Vinson ruled in the multi-state lawsuit led by Florida Attorney General Pam Bondi (R) that the ACA is unconstitutional. Although his ruling against the ACA was expected, Vinson's ruling was broader in scope than many thought it would be as he determined that the mandate could not be severed from the law, thus finding the entire law void. He stopped short of ordering the government to cease with its implementation of the law, however, and he also ruled against the states claiming that the Medicaid expansion in the law is coercive. The ruling is the second to find the mandate unconstitutional, while over a dozen federal judges have upheld the provision as constitutional. A copy of Vinson's ruling can be found here.

Following the ruling, on February 1st, despite the judge declining to issue an injunction against the implementation, many state officials declared the law dead. Wisconsin Attorney General J.B. Van Hollen (R) said that Wisconsin was "relieved of any obligations or duties" to implement the ACA, and Florida Governor Rick Scott (R) told reporters that he has no plans to phase in any provisions between now and a potential Supreme Court decision in 2012.

On February 1st, Dr. Don Berwick, administrator of the Centers for Medicare and Medicaid Services (CMS), signaled that an initial proposal outlining the Obama administration's vision for Accountable Care Organizations (ACOs) until the ACA should be out within a month. Dr. Berwick predicted a wide range of questions to be answered including quality care metrics, financial risk to providers, and potential relaxation of anti-trust laws.

In an email to senior staff, HHS Secretary Sebelius announced that she was replacing Jay Angoff with Steve Larsen at the head of the new Center for Consumer Information and Insurance Oversight, an office originally created by the ACA under HHS but that was recently transferred to CMS. Larsen recently served as Angoff's deputy, and his previous career includes six years Maryland insurance commissioner.

On February 2nd the Senate Judiciary Committee held a hearing on the constitutionality of the ACA in the wake of Judge Vinson's ruling that the law is unconstitutional. Assistant Senate Majority Leader Dick Durbin (D-IL) presided over the hearing, and House Judiciary Chairman Lamar Smith (R-TX) announced that he would follow suit later in February. More information on the hearing can be found here.

As he had promised earlier, House Energy & Commerce Chairman Fred Upton (R-MI) launched an investigation on February 2nd into HHS' handling of almost \$1.5 billion for comparative effectiveness research and for administrative expenses to implement the ACA. Calling them "slush funds," Chairman Upton announced the investigation in two separate letters to HHS Secretary Sebelius. The Committee announcement can be found here. On February 3rd the Ranking Democrat on the Committee, Rep. Henry Waxman (D-CA), fired back and accused the Chairman of "fishing expeditions" that are "an abuse of the oversight process."

On February 2nd the Senate voted on two amendments to the Federal Aviation Administration reauthorization touching the ACA. The Senate first voted 81-17 to repeal the new 1099 tax filing requirement. The ACA provision had been universally rejected by businesses and business advocacy groups. Following the bipartisan vote, the Senate voted strictly on party lines, 47-51 (Sens. Joe Lieberman (I-CT) and Mark Warner (D-VA) were absent for the votes), to reject an amendment offered by Senate Republicans to repeal the entire ACA. Some ACA supporters had feared that some Senate Democrats who appear vulnerable in 2012 might cross the aisle and vote for the repeal. However, all 51 Democrats who voted against the repeal on February 2nd, with the exception of newly elected Sen. Joe Manchin (D-WV), originally voted for the legislation.

In a briefing on February 2nd, officials from the Advanced Medical Technology Association (AdvaMed), the entity representing the medical device industry, laid out the group's legislative and regulatory priorities for 2011, including the repeal of numerous ACA provisions such as the excise tax on device manufacturers and the repeal of the Independent Payment Advisory Board (IPAB). The following day, Sen. Scott Brown (R-MA) introduced a bill to repeal the excise tax on medical device manufacturers.

On February 3rd, despite the ruling of Judge Vinson in Florida dominating the headlines, Virginia Attorney General Ken Cuccinelli (R) said that he would soon file a petition with the Supreme Court to have his case, the only other lawsuit to have deemed the ACA unconstitutional, fast-tracked to the nation's highest court. Supreme Court rules allow circumventing normal appellate procedures in cases of "such imperative public importance." Cuccinelli's announcement comes less than a day after Sen. Bill Nelson (D-FL), a supporter of the ACA up for re-election in 2012, introduced a resolution calling for an expedited review of the ACA by the Supreme Court.

Other HHS and Federal Regulatory Initiatives

On January 31st HHS Secretary Sebelius and Agriculture Secretary Tom Vilsack jointly unveiled the federal government's nutritional guidance that is updated every five years. The guidance and report note the childhood obesity epidemic throughout and break down areas and food groups that could be targeted for a healthier lifestyle. A copy of the HHS press release can be found here.

In a speech before the Council on Foreign Relations in New York on January 31st, FDA Commissioner Margaret Hamburg warned that additional drug and food public health crises could occur unless other countries also took steps to apply more stringent standards. The Commissioners comments come in the wake of Congress passing the most sweeping food safety overhaul in seven decades.

February 6, 2011 Page 3

On February 2nd CMS published a proposed rule that would require Medicare-participating providers and suppliers to provide beneficiaries with written notice about their right to contact a Medicare Quality Improvement Organization (QIO) to report on they care that they receive. In its current form, only Medicare beneficiaries that are admitted to the hospital are required to receive that notice. More information on the rule and QIOs can be found <a href="https://example.com/here-participating-providers and suppliers to provide beneficiaries with written notice about their right to contact a Medicare Quality Improvement Organization (QIO) to report on they care that they receive. In its current form, only Medicare beneficiaries that are admitted to the hospital are required to receive that notice. More information on the rule and QIOs can be found <a href="https://example.com/here-participating-part

HHS announced on February 2nd the launch of the "Direct Project" health information exchange pilots, an 'open government' initiative that encourages greater cooperation between groups in the health care and information technology sectors. The announcement highlighted collaborations between public health agencies and provides in Minnesota and Rhode Island but noted that other programs will be coming soon to others states. The HHS press release can be found here.

On February 3rd the National Coordinator for health IT, Dr. David Blumenthal, announced to the staff of ONC and HHS that he would be stepping down as National Coordinator to return to academia this spring. In his letter, Dr. Blumenthal also listed out some of the most significant highlights for health IT that occurred under his watch since the passage of the HITECH Act as part of the American Recovery and Reinvestment Act. It is not immediately clear who might replace him as National Coordinator.

In response to growing discontent from state executive leaders about the fiscal burdens imposed by Medicaid, HHS Secretary Sebelius sent a letter to governors on February 3rd that sketched out five areas where state leaders could reduce costs and find savings. Meanwhile, the same day the Executive Director of the National Governors Association, Raymond Scheppach, targeted the Medicaid program as an unsustainable program that is a primary reason that states cannot get their fiscal houses in order. A copy of the HHS press release accompanying the Secretary's letter can be found here.

Other Legislative Initiatives

On February 1st the Senate Energy Committee held a hearing on the bipartisan American Medical Isotopes Production Act of 2011. The bill authorizes funding for the Department of Energy to establish a domestic supply of molybdenum-99 to produce medical isotopes. More information on the hearing can be found here.

House Appropriations Committee Chairman Hal Rogers (R-KY) released on February 3rd an overview of his proposed spending cuts for fiscal year 2011. In the release, the Chairman noted a proposed \$13.6 billion cut below the President's request, a 4% cut, for the Labor-HHS budget. A copy of the Committee's release can be found here.

On February 3rd the Senate Judiciary Committee held a business meeting to consider the bipartisan Patent Reform Act of 2011, co-sponsored by Sens. Patrick Leahy (D-VT), Orrin Hatch (R-UT), Chuck Grassley (R-IA), Amy Klobuchar (D-MN), Jeff Sessions (R-AL), Chris Coons (D-DE), Jon Kyl (R-AZ), and Al Franken (D-MN). The House Judiciary Committee is expected to consider similar reform soon. A webcast of the business meeting can be found here.