



FDA User Fee Bill Signed into Law; GOP/HHS Respond to PPACA SCOTUS Decision

President Signs FDA User Fee Legislation

Last Monday the President signed S. 3187 into law (P.L. 112-144). Among other provisions, the law reauthorizes PDUFA; reauthorizes MDUFA; authorizes new generic drug and biosimilars user fee programs; provides new incentives for the development of antibiotics; adds provisions to address drug shortages; adds a new fee program related to rare pediatric diseases; gives an additional five years of market exclusivity to manufacturers that develop new qualified infectious disease products (QIDPs); increases the federal penalties and prison times for persons who knowingly and intentionally commit acts related to trafficking in counterfeit drugs; and adds a requirement for the FDA to issue guidance on the use of the internet and social media to promote FDA regulated medical products. CBO estimates that the law will reduce direct spending by \$307 million and reduce deficits by \$311 million over ten years.

Appropriations Standoff

While the House is scheduled to take up the FY 2013 Defense Appropriations bill this Wednesday, **Senate Majority Leader Harry Reid** is apparently resigned to forego any further scheduling of stand-alone spending bills in the Senate during the remaining 35 or so days left on the legislative calendar before the November elections. Nonetheless, the House is intent on passing at least the DOD, Agriculture/FDA and Financial Services appropriations measures before the August recess. If the Senate

Majority Leader relents, it is possible that the VA/Military Construction spending bill could be approved in the Senate before the end of the fiscal year. The lack of stand-alone action on the outstanding bills will force Congress to pass a continuing resolution to enable federal agency spending past the election, thus setting up a contentious post-election debate on the FY 2013 spending limits for most agencies, including HHS/CMS, etc. As part of the expected lame-duck session, members will have to confront the significant “sequestration” cuts mandated under the Budget Control Act. HHS estimates that beginning next year the cuts to HHS would amount to about a 7.8% spending reduction and lead to, among other things: the elimination of 2,300 new and competing NIH research grants; about 12,150 fewer patients receiving benefits under the AIDS Drug Assistance program; about 169,000 fewer individuals being admitted in substance use disorder treatment programs; and the curtailment of Medicare/Medicaid anti-fraud efforts.

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House Republicans Again Push Through PPACA Repeal Bill

Spurred on by the Supreme Court's decision upholding the PPACA, last week the House voted 244-185 to pass H.R. 6079, legislation to repeal all provisions of the PPACA. Garnering just five Democrat votes, the bill is essential DOA in the Senate. Republicans argued the job-killing aspects of the bill with **House Speaker John Boehner** stating that "This law continues to make our economy worse, and there is even more resolve to repeal this law..." On the other hand, **House Minority Leader Nancy Pelosi** emphasized the benefits of the legislation stating that the Republican initiative would result in the cancellation of coverage for pre-existing medical conditions, remove additional Medicare

prescription drug coverage, cancel coverage for children ages 26 and younger, remove preventive health benefits for women and repeal the end of lifetime insurance coverage limits. Whether or not additional repeal efforts will be made in the House, such as eliminating the Medicaid maintenance of effort rule, remains to be seen. Of note, CBO said it would not have a cost estimate of the effect of the repeal until the end of July. Setting up talking points before the vote, the House Oversight and Government Reform Subcommittee on Health Care heard testimony from a number of physician groups who maintained the law will "destroy the doctor-patient relationship." One witness said that new bureaucracies and financial burdens

will result from the PPACA's provisions on EHR, ACOs and the IPAB. **Subcommittee Chairman Trey Gowdy** said that the law will create a significant doctor shortage. At another hearing by the full committee, **Chairman Darrell Issa** said "We know that Obamacare makes labor more expensive..." and a witness testified that the increased health care costs under the PPACA have directly affected job creation in the restaurant industry. **Rep. Elijah Cummings**, the ranking member, said that Republicans were "continuing the same old scare tactics today, warning about massive job losses and economic ruin should the Affordable Care Act continue."

Multiple Questions Remain About Expansion of Medicaid in 2014

Governors and state Medicaid administrators have raised multiple Medicaid implementation issues connected to the Supreme Court's decision that HHS cannot withhold current Medicaid funding if states refuse to expand coverage as allowed for under the PPACA. In one missive, the Republican Governors Association sent HHS a letter including 25 questions about the expansion and the National Governors Association requested answers to the following: will states that expand Medicaid coverage up to a level below 133% of the FPL receive the enhanced FMAP available for "newly covered" populations; will states be allowed to phase in Medicaid coverage up to 133% FPL in years after 2014 and still receive the enhanced FMAP; if a state opts not to expand Medicaid what other Medicaid provisions of the PPACA will apply; and what options and federal assistance are available for states that do expand Medicaid coverage. HHS responded in part by saying that there will be no deadline for states to decide on expanding Medicaid under the PPACA and that, if a state opts out of the expansion, then the PPACA allows for individual coverage mandate

hardship exemptions for persons below the poverty level who lack affordable coverage options. In addition, HHS said that a state can receive extra federal funding for Medicaid information technology costs and state insurance exchange implementation costs even if the state has not decided whether to expand Medicaid eligibility or to run its exchange. HHS is scheduling a number of meetings with states to discuss the above issues. A number of Republican governors continue to resist committing to Medicaid expansion with **Texas Governor Rick Perry** alerting HHS that his state will not conform to the Medicaid expansion option. Also, a number of Republican-led states have served notice they will not establish state-based exchanges, although 15 states recently notified HHS that they will do so (i.e. California, Colorado, Connecticut, Hawaii, Kentucky, Maryland, Massachusetts, Minnesota, Nevada, New York, Oregon, Rhode Island, Vermont, and West Virginia). Three states--Washington, Utah and Massachusetts--already have exchanges.

GAO Pronounces HHS MA Demo Off-Base

In a letter released by **Senator Orrin Hatch**, the GAO said it found that HHS has failed to demonstrate that the agency has the legal authority to authorize and implement the \$8.3 billion Medicare Advantage Quality Bonus Payment Demonstration

project which the administration has used to quell Republican angst over Democrats' move under the PPACA to reduce Medicare Advantage payments from previous levels. The GAO recommended in April 2011 that the basis for the program was flawed and

should be scrapped. Another HHS demonstration project has come under attack by both MedPAC and **Senator John D. Rockefeller** who has asked HHS to immediately abandon the upcoming Medicare/Medicaid dual-eligible demonstration project.

Calls for New Medicare Physician Payment System

The Senate Finance Committee held the third in a series of hearings seeking answers on how to replace the current Medicare physician payment "sustainable growth rate" system. Representatives from several notable physician groups testified that a new payment system should include incentives for better quality of care through payment bundling, value-based compensation and medical homes. The AMA also recommended that physicians who want to participate in new Medicare payment and delivery reform pilot projects be given the option to do so on a rolling basis to better manage short turnaround times. To avoid the 27% cut in 2013 Medicare Part B physician payments, **Chairman Max Baucus** said the committee will have to act one way or another, regardless that "improving the physician payment system is no easy task."

ACOs on the Rise

CMS announced that eighty-nine new accountable care organizations have been selected to participate in the second wave of the Medicare Shared Savings Program (MSSP), thus bringing the total number of participants to 154. About one-half of the new ACOs are physician-led organizations serving fewer than 10,000 patients. New applications will be accepted annually and, for 2013, the application period is from August 1 through September 6.

Final EFT Standards Announced

CMS announced that the interim final rule adopting health care electronic funds transfer standards will stand as a final rule. All health plans covered under HIPAA must comply by January 1, 2014.

S. 3368 (MEDICAL

MARIJUANA), to amend the Food and Nutrition Act to prohibit the provision of funds made available to carry out that act in any state that allows income deductions for controlled substances, including medical marijuana; ROBERTS; to the Committee on Agriculture, Nutrition, and Forestry, July 10.

H.R. 6079 (REFORM), to repeal the Patient Protection and Affordable Care Act and health care-related provisions in the Health Care and Education Reconciliation Act of 2010; CANTOR; jointly, to the committees on Energy and Commerce, Ways and Means, Education and the Workforce, Natural Resources, the Judiciary, House Administration, Rules, Appropriations, and the Budget, July 9.

H.R. 6097 (TAXATION), to exempt employers from any excise tax and certain suits and penalties in the case of a failure of a group health plan to provide coverage to which an employer objects on the basis of religious belief or moral conviction; SENSENBRENNER; jointly, to the committees on Energy and Commerce, Ways and Means, and Education and the Workforce, July 10.

S. 3376 (OVER-THE-COUNTER DRUGS), to amend the Federal

Food, Drug, and Cosmetic Act to prevent the abuse of dextromethorphan, and for other purposes; CASEY; to the Committee on Health, Education, Labor, and Pensions, July 11.

H.R. 6103 (MEDICARE), to amend Title XI of the Social Security Act to increase fines and penalties for Medicare fraud to augment Medicare fraud enforcement activities, such as the Health Care Fraud and Enforcement Action Team (HEAT) program; HOCHUL; jointly, to the committees on Ways and Means and Energy and Commerce, July 11.

H.R. 6107 (VETERANS' HEALTH), to amend Title 38, U.S. Code, to improve the ability of health care professionals to treat veterans via telemedicine; RANGEL; to the Committee on Veterans' Affairs, July 12.

H.R. 6118 (LABORATORIES), to amend Section 353 of the Public Health Service Act with respect to suspension, revocation, and limitation of laboratory certification; GRIMM; to the Committee on Energy and Commerce, July 12.