



Appropriations “Minibus” Vote Delayed Until November

Appropriations Minibus Vote Set for November 1st in Senate

The Senate, on an 82-16 vote, invoked cloture on the appropriations “minibus” legislation which includes the Agriculture/FDA bill, H.R. 2112, the Commerce/Justice/Science bill, H.R. 2596 and the Transportation/ HUD bill, S. 1596. The vote on further amendments and a final vote will occur on November 1st when the Senate returns from a week-long recess. An amendment to the FDA portion of the bill, offered by **Senator David Vitter**, failed on a 45-55 vote. The provision would have allowed U.S. citizens to buy FDA-approved prescription drugs from Canada either in person or over the internet and ship or bring them back into the United States. The minibus could also serve as a vehicle if the House decides to attach another FY 2012 continuing resolution to the measure which would extend federal agency funding from November 18 until December 23. When it returns, the Senate will also try again to take up portions of the Administration’s JOBS Act inasmuch as efforts to pass the entire bill and a smaller measure to fund state jobs failed cloture votes. In related action, the Joint Select Committee on Deficit Reduction continued to take suggestions from the “Gang of Six” and other groups, but without making public comment on any progress that may or may not have been made to meet their fast-approaching deadline. In this connection, the Medicare Payment Advisory Committee sent a letter to several

committees urging them to take action to reform the Medicare physician payment system in order to avoid the scheduled 30% cut in payments next year. The chairman said that “Our concern is that repealing the SGR will become increasingly difficult unless the Congress acts soon...” The Super Committee is scheduled to hold a public hearing this Wednesday on security and non-security discretionary spending.

TAA Health Tax Credits Extended

President Obama signed H.R. 2832 into law (P.L. 112-40). This trade legislation includes an extension of the Trade Adjustment Assistance Act health program which now will provide a tax credit of 72.5% of health insurance premiums for qualified individuals who are adversely affected by unfair trade practices. The effective date applies to coverage periods ending on or after November 20, 2011.

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ACO Rules Released

The Administration released several rules relating to the formation and tax status of accountable care organizations (ACOs). CMS released a final rule which makes the formation of ACOs more likely with fewer qualifications: e.g. the beneficiary assignment process is made prospective, the number of quality measures that providers are required to report

was reduced, a rolling admissions process was established and the one sided-model was allowed to be completely risk-free for the entire length of the agreement. CMS and the HHS OIG also released an interim final rule establishing waivers under the Stark law and civil monetary penalty law for ACOs that participate in the Medicare Shared Savings Program. In addition, the Federal Trade

Commission and Department of Justice issued a final statement on antitrust enforcement that will benefit ACOs. Among the policies is the elimination of a mandatory antitrust review requirement under a proposed rule. The IRS also gave ACOs some relief in that distributions from ACOs do not necessarily need to be proportional to capital investment.

Supreme Court Review of PPACA

The Department of Justice filed a consolidated response brief with the high court which agrees with the state plaintiffs (NFIB, Florida, et al) that the ruling in the Eleventh Circuit, that the PPACA individual mandate is unconstitutional under the commerce clause, should be taken up and that the issue of severability should be reviewed if the court

finds for the plaintiffs. DOJ argued that, if the individual mandate is held invalid, so should the PPACA provisions requiring coverage for preexisting conditions and allowing higher premiums for high risk individuals. DOJ also said it agreed with the Eleventh Circuit finding that the PPACA Medicaid provisions are constitutional and should, therefore, not be reviewed.

In another case, *Liberty University v. Geithner*, DOJ said the court should refrain from granting review of the Fourth Circuit ruling that the Anti-injunction Act barred the court from considering the constitutionality of the individual mandate (because the provision does not go into effect until 2014).

Reduced Regulations?

In accordance with an executive order for agencies to reduce regulatory burdens, CMS announced proposed delivery system regulatory revisions for hospitals and other providers that CMS said would save hospitals and health care providers nearly \$1.1 billion each year and over \$5 billion over five years. The “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction” would affect various health care facilities, including end-stage renal disease (ESRD) facilities, organ procurement and ambulatory surgical centers (ASCs). In a related action, CMS issued additional guidance for hospitals on “meaningful use” requirements which allows clinical data to be considered complete and accurate when generated from certified EHR technology.

CLASS Act Redo

Although the HHS Secretary said the PPACA long-term care program would not be implemented at this time, the White House said the plug has not been pulled on the program. Republicans, spurred on by the U.S. Chamber of Commerce, continues to push narrow legislation that would repeal only the CLASS Act under the health reform law. Senator John Thune said he may offer such an amendment to the FY 2012 minibus.

Innovation Advisors Program

CMS announced it is accepting applications for a new Innovation Advisors program for up to 200 health professionals “to test new models of care delivery in their own organizations and communities...and create partnerships to find new ideas that work and share them regionally and across the United States.”

S. 1700 (MEDICAL DEVICES), to amend the Federal Food, Drug, and Cosmetic Act with respect to device review determinations and conflicts of interest, and for other purposes; KLOBUCHAR; to the Committee on Health, Education, Labor, and Pensions, Oct. 13.

S. 1718 (MEDICARE), to amend Title XVIII of the Social Security Act with respect to the application of Medicare secondary payer rules for certain claims; WYDEN; to the Committee on Finance, Oct. 17.

H.R. 3183 (MEDICAL LOSS RATIO), to amend Title XXVII of the Public Health Service Act to exempt licensed independent insurance producer remuneration from the medical loss ratio; YARMUTH; to the Committee on Energy and Commerce, Oct. 13.

H.R. 3189 (CHILDREN'S HEALTH), to direct the secretary of education to establish a program to provide grants for cardiopulmonary resuscitation and automated external defibrillator training in public elementary and secondary schools; CAPPs; jointly, to the committees on Education and the Workforce and Energy and Commerce, Oct. 13.

H.R. 3198 (CANCER SCREENING), to amend Title XVIII of the Social Security Act and Title XXVII of the Public Health Service Act to improve coverage for colorectal screening tests under Medicare and private health insurance coverage, and for other purposes; NEAL; jointly, to the committees on Energy and Commerce and Ways and Means,

Oct. 13.

H.R. 3203 (MEDICAL DEVICES), amend Section 513 of the Federal Food, Drug, and Cosmetic Act to expedite the process for requesting de novo classification of a device; BILBRAY; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3204 (FDA GUIDANCE), to amend the Federal Food, Drug, and Cosmetic Act to ensure public participation in the drafting and issuance of Level 1 guidance documents, and for other purposes; GUTHRIE; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3205 (MEDICAL DEVICES), to amend the Federal Food, Drug, and Cosmetic Act with respect to persons who, with respect to devices, are accredited to perform certain reviews or inspections; PAULSEN; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3206 (FDA ADVISORY COMMITTEES), to amend the Federal Food, Drug, and Cosmetic Act with respect to appointments to advisory committees and conflicts of interest; BURGESS; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3207 (LABORATORY TESTS), to amend the Public Health Service Act to create a pathway for premarket notification and review of laboratory-developed tests, and for other purposes; BURGESS; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3208 (MEDICAL DEVICES), to reaffirm the Safe Medical Devices Act of 1990 by requiring that the secretary of Health and Human Services establish a schedule and issue regulations as required under Section 515(i) of the Federal Food, Drug, and Cosmetic Act, and for other purposes; SHIMKUS; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3209 (FDA PREMARKET REVIEW), to amend the Federal Food, Drug, and Cosmetic Act to provide predictability, consistency, and transparency to the premarket review process; SHIMKUS; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3211 (MEDICAL DEVICES), to amend the Federal Food, Drug, and Cosmetic Act to improve humanitarian device regulation; BASS of New Hampshire; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3212 (MEDICARE), to amend Title XVIII of the Social Security Act to restore state authority to waive for certain facilities the 35-mile rule for designating critical access hospitals under Medicare; THORNBERRY; to the Committee on Ways and Means, Oct. 14.

H.R. 3214 (FDA), to amend the Food and Drug Administration's mission; ROGERS of Michigan; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3216 (VETERANS' HEALTH), to amend Title 38,

United States Code, to establish an ophthalmologic service and director of ophthalmologic services in the Veterans Health Administration of the Department of Veterans Affairs; BENISHEK; to the Committee on Veterans' Affairs, Oct. 14.

H.R. 3218 (PATIENT PRIVACY), to amend PPACA to ensure the privacy of individually identifiable health information in

connection with risk adjustment; BUCSHON; to the Committee on Energy and Commerce, Oct. 14.

H.R. 3230 (MEDICAL DEVICES), to direct the Food and Drug Administration, with respect to devices, to enter into agreements with certain countries regarding methods and approaches to harmonizing certain regulatory requirements; MCMORRIS RODGERS; to the Committee on

Energy and Commerce, Oct. 14.

S. 1734 (INFECTIOUS DISEASES), to provide incentives for the development of qualified infectious disease products; BLUMENTHAL; to the Committee on Health, Education, Labor, and Pensions, Oct. 19.