



House Passes FY 2013 Reconciliation Bill and Replaces BCA Sequestration Cuts

House Sets Budget Mark for Post-Election Negotiations

After the House Budget Committee wrapped up consideration of the House Republican approach to 2013 sequestration cuts under the Budget Control Act and FY 2013 budget reconciliation, the House voted 218-199, mainly along party lines, to pass the combined measures under H.R. 5652 (the Sequester Replacement Reconciliation Act of 2012). As passed by the committee, H.R. 5652 provides for reconciliation pursuant to section 201 of the concurrent resolution on the budget for FY 2013 (H. Rept. 112-470). However, this portion was modified in the Rules Committee to drop the Energy and Commerce Committee medical malpractice provisions while retaining the similar Judiciary Committee provisions that would cap non-economic and punitive damages at \$250,000.

As adopted under fast-track reconciliation procedures, the bill makes spending reductions in programs under the jurisdiction of six committees totaling about \$315 billion over the ten year budget window. The following are the major health program related 10-year budget savings:

- ◆ \$23.5 billion from Medicaid and SCHIP, including scrapping the PPACA maintenance-of-effort requirements;
- ◆ \$43.9 billion by allowing the recapture of all overpayments of PPACA subsidies;
- ◆ \$14.1 billion by eliminating HHS authority to award PPACA health insurance exchange

grants;

- ◆ \$10.9 billion by eliminating the PPACA Prevention and Public Health Fund;
- ◆ \$300 million by cancelling unobligated balances for the Consumer Operated and Oriented Plan (CO-OPs);
- ◆ \$4.2 billion from hospital disproportionate share payments;
- ◆ \$11.3 billion by lowering from 6% to 5.5% the threshold for state and health care provider hold harmless agreements; and
- ◆ \$6.3 billion by eliminating increased Medicaid payments to territories.

The addition of H.R. 4966 to the combined measure would prevent about \$78 billion of the \$109 billion in across-the-board cuts scheduled for FY 2013 defense and non-defense spending accounts under the BCA. In

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general, this provision would largely protect defense spending but would retain many of the BCA mandated cuts to domestic programs, including Medicare. CBO projects that the net effect of all changes would result in deficit reduction of about \$242 billion over ten years. The bill would also reduce the \$1.047 trillion BCA 10-year discretionary spending limit by \$19.104 billion, thus eliciting the ire of Democrats and the White House.

Senate Majority Leader Harry Reid declared the bill dead on arrival in the Senate. The White House Statement of Administration Policy (SAP) recommended a veto of the legislation, stating “The approach advanced in this bill only addresses a portion of the pending sequester, and does so in a way that imposes far greater cuts than the sequester would entail. The bill would break the agreement on

discretionary spending made in last summer’s budget agreement; advancing the House Budget Resolution’s approach to increase defense spending and reduce non-defense spending relative to the levels agreed to in the BCA....”

With the Senate in gridlock over budget matters until after the November elections, Senate Republicans will nonetheless propose several budget plans as a reminder that the Senate has not passed a budget resolution in three years. The success of negotiations on budget matters after the election will likely ride on the election results. The Senate legislative gridlock over budget and other matters has led **Senate Majority Leader Harry Reid** to threaten changing Senate rules to prevent filibusters. If Congress fails to defer or override the BCA mandated cuts beginning next January 2nd, the cuts for health agencies would be significant--

about \$2.4 billion for NIH; \$445 million for CDC; \$191 million for the FDA; etc.

FY 2013 Appropriations

The House Appropriations Subcommittee on Military Construction and Veterans Affairs released a draft that would provide an overall funding level similar to FY 2012, as follows: military construction: \$10.6 billion, including \$927 for medical facilities; and \$60.7 billion for Veterans Affairs, including \$41.4 billion for medical services. The House also passed the Commerce, Science, Justice appropriations bill, thus setting up the first of the potential spending spats with the Senate. The House Armed Services Committee also approved an FY 2013 defense authorization bill which may further challenge pentagon spending plans.

Republicans Question Loans to CO-OPs

In a letter to HHS, Republican **Senators Coburn, Enzi and Hatch and Reps. Boustany and Rehberg** asked the agency for information on the process used for awarding PPACA loans to Consumer Operated and Oriented Plans (CO-OPs). They expressed their concerns that “Based on the HHS efforts to date, there appears to be little evidence that the CO-OP program will promote greater competition and lower costs in most state insurance markets....”

MLR Update

HHS issued a final rule which requires health insurers to send annual notices to policyholders when the insurers meet the PPACA’s minimum loss ratio rules, thus expanding on a previous rule which required notice only when MLR failures occurred.

Health Care Innovation Challenge Awards

HHS Secretary Kathleen Sebelius announced that CMS has granted \$122.6 million in PPACA Health Care Innovation Challenge awards to 26 collaborations of hospitals, physicians, nurses, pharmacists, technology innovators, community organizations and advocacy groups.

PPACA Grants for School-Based Health Clinics

HHS announced that \$75 million in PPACA grants will be made for the building and renovation of school-based health clinics. In total \$200 million will be granted over three years.

Revised Medicare Physician Payment Suggestions Requested

The Senate Finance Committee held hearings to elicit comments on how the Medicare sustainable growth rate (SGR) formula used to reimburse doctors and other Part B providers should be reformed for the long term. Four former CMS administrators testified that there is no viable alternative to the current physician payment system ready to be implemented. They suggested that in the short-term Congress could direct CMS to change the current system to better reflect physician treatment patterns and to reward doctors for providing quality care. In the long-term, they

said the current SGR system should be replaced by a new system based on capitated and bundled payments and quality of care measures. Chairman Max Baucus asked the witnesses--Gail Wilensky, Tom Scully, Bruce Vladek, and Mark McClellan--to provide the committee a list of possible fixes for the payment system within one month. However, the Chairman indicated that no decision has been made whether to unveil a possible legislative solution. The House Ways and Means Committee has also asked physician and other provider groups for their reform ideas. Responses are due May

25th to the committee on: their use of quality and outcome measures, including utilizing such tools as electronic health records and patient registries; their experiences with alternative methods, such as bundled payments and shared saving models; and their advice about encouraging beneficiaries to seek appropriate care and what regulatory burdens stand in the way of helping beneficiaries. In related news, Reps. Joe Heck and Allyson Schwartz announced they are developing a new bill designed to reform the SGR.

PPACA Boost in Medicaid Physician Payments

CMS announced a proposed rule under which \$11 billion in PPACA funds will be made available to states to implement the law's requirement that Medicaid reimburse family medicine, general internal medicine, pediatric medicine and related subspecialists at Medicare

levels in CY 2013-2014. CMS said the action is designed to help encourage primary care physicians to continue and expand their efforts to provide checkups, preventive screenings, vaccines and other care to Medicaid beneficiaries. Comments are due by June 11th.

Regulatory Burdens Reduced

CMS announced several rules, induced by the President's executive order to review regulations for overburden, that the agency said will help save more than \$1 billion in the first year and \$5 billion over five years. The "Reform of Hospital and Critical Access Hospital Conditions of Participation" rule was said to save \$940 million per year through such changes as allowing one governing body to oversee multiple hospitals and removing the requirement for a single director of outpatient

services and the elimination of the requirement for non-physician personnel to have special training in administering blood transfusions and intravenous medications. A second rule, "Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction" was said to save \$200 million in its first year by eliminating duplicative, overlapping and outdated regulatory requirements for health providers.

FDA Issues

FDA User Fee Reauthorization Passes House E&C Committee

The House Energy and Commerce Committee voted unanimously to pass H.R. 5651, legislation to reauthorize Food and Drug Administration user fee legislation for medical devices and drugs. The reauthorization would extend the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA). The bill would also authorize new user fee programs: the Generic Drug User Fee Act (GDUFA) and the Biosimilars User Fee Act (BSUFA). The bill would require the FDA to meet certain performance goals, fostering more interaction, predictability and certainty between industry and the FDA. A similar Senate HELP Committee bill is expected to be taken up in the Senate this month. Chairman Upton said his intent is to have the bill passed in the House this month and for a final

conference agreement to be enacted by July 4th.

Senate Finance Investigates Growing Painkiller Prescription Abuse

Senators Max Baucus and Charles Grassley

sent letters to the Federation of State Medical Boards, major drug companies and academic experts requesting records documenting financial and other ties within the drug industry as part of a Senate Finance Committee investigation into whether drug companies might be contributing to the “epidemic of accidental deaths and addiction [to prescription painkillers] by promoting misleading information about the drugs’ safety and effectiveness....” The senators said their intent is to ensure that physicians and patients receive accurate information about the risks and benefits of the drugs that is not affected by financial interests.

Recently Introduced Health Legislation

S. 2516 (USER FEES), to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; HARKIN; from the Committee on Health, Education, Labor, and Pensions; placed on the calendar, May 7.

S. 2620 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for an extension of the Medicare-dependent hospital (MDH) program and increased payments under the Medicare low-volume hospital program; SCHUMER; to the Committee on Finance, May 7.

H.R. 5334 (MEDICAL THERAPIES), to amend Chapter V of the Federal Food, Drug,

and Cosmetic Act to expedite development and review of breakthrough therapies; BILBRAY; to the Committee on Energy and Commerce, May 7.

H.R. 5341 (MEDICAL DEVICES), to improve postmarket risk identification and analysis with respect to devices, and for other purposes; CAPPS; to the Committee on Energy and Commerce, May 7.

H.R. 5357 (DRUGS), to suspend temporarily the duty on placebos to be used in clinical trials for the drug ASP2408; DOLD; to the Committee on Ways and Means, May 7.

H.R. 5358 (DRUGS), to suspend temporarily the duty on placebos to be used in clinical trials for the drug ASP0777; DOLD; to the Committee on Ways and Means,

May 7.

H.R. 5364 (DRUGS), to suspend temporarily the duty on placebos to be used in clinical trials for the drug ASKP1240; DOLD; to the Committee on Ways and Means, May 7.

H.R. 5566 (MEDICAID), amend Title XIX of the Social Security Act to increase the federal medical assistance percentage for the territories; CHRISTENSEN; to the Committee on Energy and Commerce, May 8.

H.R. 5624 (MEDICARE/ PUBLIC HEALTH), to amend Title XVIII of the Social Security Act to protect and preserve access of Medicare beneficiaries in rural areas to health care providers under Medicare, to amend Title III of the Public Health Service Act to extend discounts under the 340B

program, and for other purposes; MCMORRIS RODGERS; jointly, to the committees on Energy and Commerce and Ways and Means, May 8.

H.R. 5646 (ABORTION), to prohibit funds appropriated for the Department of Homeland Security from being used to pay for an abortion, and for other purposes; HUIZENGA of Michigan; jointly, to the committees on Energy and Commerce and the Judiciary, May 8.

H.R. 5647 (WOMEN'S HEALTH), to eliminate discrimination and promote women's health and economic security by ensuring reasonable workplace accommodations for workers whose ability to perform the functions of a job are limited by pregnancy, childbirth, or a related medical condition; NADLER; jointly, to the committees on Education and the Workforce, House Administration, Oversight and Government Reform, and the

Judiciary, May 8.

H. RES. 644 (NURSES), recognizing National Nurses Week May 6-12, 2012; EDDIE BERNICE JOHNSON of Texas; to the Committee on Energy and Commerce, May 7.

H.R. 5650 (ABORTION), to amend Title X of the Public Health Service Act to provide for no discrimination under the family planning program under such title on the basis of separate provision of abortion; DOLD; to the Committee on Energy and Commerce, May 9.

H.R. 5651 (USER FEE PROGRAMS), to amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes; UPTON; to the Committee on Energy and Commerce, May 9.

H.R. 5690 (FIRST RESPONDERS), to amend the Public Health Service Act to authorize the secretary of health and human services to make grants to eligible entities to train elementary and secondary school nurses on how to respond to a biological or chemical attack or an outbreak of pandemic influenza in a school building or on school grounds; ISRAEL; to the Committee on Energy and Commerce, May 9.

H.R. 5707 (MEDICARE), to amend Part B of Title XVIII of the Social Security Act to reform Medicare payment for physicians' services by eliminating the sustainable growth rate system and providing incentives for the adoption of innovative payment and delivery models to improve quality and efficiency; SCHWARTZ; jointly, to the committees on Energy and Commerce, Ways and Means, and the Budget, May 9.