



House Passes FY 2011 CR with \$61 Billion in New Cuts; Obama FY 2012 Budget Slammed

President's FY 2012 Budget Receives Senate Love, House Says DOA

Last Monday the President sent his \$3.73 trillion FY 2012 budget to the Hill which purports to “freeze” spending. OMB says the \$1.12 trillion in discretionary spending would result in a 2.7% reduction in such costs from the levels initially proposed for FY 2011 by the President. However, because the FY 2011 appropriations season is not completed the President’s proposal does not take into account the projected FY 2011 spending once the Congress passes a CR for spending beyond March 4th when the current CR expires. The OMB maintains the budget proposal would reduce the deficit by more than \$1.1 trillion over 10 years while making investments in education, infrastructure and technology. Senate Democrat leaders said they would follow the lead of the President in their budget development. However, **House Speaker John Boehner** said the President’s plan would “destroy jobs by spending too much, taxing too much and borrowing too much....and fuel more economic uncertainty and make it harder to create new jobs.”

Of note, the President’s budget does not include any changes to entitlement programs, including Medicare and Medicaid, notwithstanding the recommendations of the President’s Deficit Reduction Commission. In this connection, **Senate Budget Chairman Kent**

Conrad said a bipartisan “gang of six” senators are working on a long-term deficit reduction plan similar to the commission recommendations. House Republicans say they will address entitlement reform in their upcoming FY 2012 budget plan. The reluctance of the Administration to go “first” on entitlement reform sets up the possibility that the House, Senate, and the President may engage in deficit and entitlement reform discussions later this spring in some sort of budget summit.

The \$1.12 trillion in FY 2012 discretionary spending under the President’s budget includes \$79.9 billion for HHS, an increase of \$95 million from his initial FY 2011 recommendations. The

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president's budget deals the agencies of this department the following appropriations:

- CMS--\$4.4 billion, up \$1 billion;
- FDA--\$2.7 billion (including an increase of \$634 million in industry user fees), up \$382 million;
- NIH--\$32 billion, up \$745 million;
- CDC--\$5.9 billion, down \$581 million;
- SAMHSA--\$3.4 billion, down \$45 million;
HRSA--\$6.8 billion, down \$672 million;
- Indian Health Service--\$4.6 billion, up \$572 million;
- the Administration on Aging--\$2.2 billion, down \$151 million;
- the Administration for Children and Families--\$16.2 billion, down \$1.2 billion;
- Office of the Inspector General--\$366 million, up \$76 million.

Under the budget proposal, Medicare physician reimbursements would be frozen for another two years at current levels at a cost of about \$62 billion which would be raised from various Medicare changes over ten years. At a Senate Finance hearing, both **Chairman Max Baucus** and the ranking Republican, **Orrin Hatch**, called on HHS to work on a permanent fix to the SGR this year. **Secretary Sebelius** said she would.

Of the HHS total, \$465 million would go to implement the PPACA with about \$300 million going to CMS. The IRS would receive \$119 million in additional funds to enforce the tax portions of the PPACA and about \$23 million to educate taxpayers about the new law. Also, community health centers would receive \$3.3 billion, including \$1.2 billion from the PPACA. At the same Finance Committee hearing, Republicans pressed the HHS Secretary for

flexibility to allow states to deal with the PPACA's Medicaid maintenance-of-effort requirements for states. Presaging a likely route Republicans will take in crafting long-term budget reform, **Senator Coburn** said federal Medicaid funds should be rolled into a block grant. Under the budget proposal, federal Medicaid spending would total \$269 billion in FY 2012, a \$7 billion decrease compared with FY 2011 because temporary enhanced federal funding for the program expires at the end of June. The President's budget also would limit state use of provider taxes to finance state Medicaid costs over the next 10 years (estimated to raise \$18 billion). The budget also proposes expanding the Medicare durable medical equipment competitive bidding program to Medicaid (a \$6.4 billion savings). Funding for SCHIP would total \$9.9 billion. The budget proposal also anticipates a congressional change to the PPACA 12-year exclusivity period for branded biologic drugs, reducing the period to seven years, while also prohibiting manufacturer "evergreen" extensions (for an estimated savings of \$2.3 billion over ten years). Within the NIH budget, \$100 million would go to the PPACA's Cures Acceleration Network to provide for grants to biotechnology companies, universities and patient advocacy groups to better bring basic research into play in finding new medical treatments. Medicare Advantage providers would be targeted for \$6.2 billion in erroneous payment recoveries. The proposed budget would also eliminate funding for children's hospital GME.

Following up on his SOTU remarks, the President would allocate \$250 million in grants to help states revise their medical liability laws, such as by: establishing health courts; creating a legal defense for physicians, hospitals and other providers who follow guidelines for best clinical practices and for the use of electronic health record systems; establishing initiatives requiring hospitals and physicians to disclose mistakes early, offer apologies and compensation and to agree to make changes to protect other patients from being harmed in the same way; and revising rules that result in higher malpractice awards.

House Passes FY 2011 CR Extension

Throughout last week, the House debated numerous amendments to H.R. 1, a continuing resolution crafted by the Republican led House Appropriations Committee to provide appropriations for the remainder of FY 2011. As introduced the bill would cut another \$60.9 billion from the current year's spending levels (and nearly \$100 billion from President Obama's original FY 2011 budget as shown in last week's newsletter). Before adjourning until February 28 for the President's Day recess, the Senate Majority Leader, Harry Reid, said the House bill was unacceptable and President Obama said he would veto it in any event. Lacking an agreement on the House CR terms, both the House and Senate will have to reach agreement on a temporary extension of the current CR which expires on March 4th. However, House Majority Leader John Boehner said he would not agree to a short-term CR unless it cuts spending over the interim period (the House CR would result in about a 12% cut). If the Senate majority does not agree to House demands, the government could face another shutdown which last occurred during the speakership of Newt Gingrich. Senate Majority Whip Dick Durbin hinted that an impasse may result in the sort of

budget summit described above in order to obtain House, Senate and Administration agreement on FY 2011 and FY 2012 spending levels, as well as on an extension of the federal debt limit.

The House bill takes a slap at the implementation of the PPACA as follows:

- cutting funding for the Prevention and Public Health Fund, the National Health Service Corps and community health centers;
- prohibiting funding for the PPACA for FY 2011 under the successful amendment offered by Rep. Dennis Rehberg. The Rehberg amendment specifies that "none of the funds made available by this Act under the Title appropriating funds for Labor, Health and Human Services, and Education may be paid to any employee, officer, contractor, or grantee of any department or agency to implement any provisions of the [PPACA]".
- one amendment offered by Rep. Steve King would bar the use of federal funds to carry out the PPACA;
- another King amendment would prohibit the use of funds to pay the salary of any federal officer or employee to implement the law;

- an amendment offered by Rep. Jo Ann Emerson would prohibit the use of funds by the IRS to implement or enforce the individual mandate provision of the PPACA;

- an amendment by Rep. Tom Price eliminates funding for the implementation of the medical loss ratio restrictions;

- an amendment by Rep. Cory Gardner eliminates funding to regulate or promote state health care exchanges;

- an amendment by Rep. Michael Burgess prohibits paying salaries of any officer or employee at the Center for Consumer Information and Insurance Oversight within HHS;

- an amendment by Rep. Joe Pitts prohibits funding for federal agencies to designate healthcare essential benefits.

All of these adopted amendments will heighten Democrat opposition in the Senate to the House-passed CR. Minority Leader Nancy Pelosi said Democrats would work to stop the House-passed CR.

House W&Ms Committee Votes to Repeal 1099 Reporting

Last week the House Ways and Means Committee passed two legislative versions repealing the PPACA's IRS Form 1099 reporting requirements. The first, H.R. 705, would pay for the \$19.2 billion cost

of the legislation by tightening the PPACA's provision for recapturing the overpayment of federal subsidies under health insurance exchanges. Democrats opposed the payfor in the first bill, but allowed a voice vote to occur on the second

bill, H.R. 4, Lungren legislation which does not contain any cost offset. The bill could be brought to the House floor in March or later this spring.

House Judiciary Passes Med-Mal Legislation

Last week on an 18-15 vote, the House Judiciary Committee passed medical malpractice reform legislation, H.R. 5 (the Help Efficient, Accessible, Low-cost, Timely Healthcare Act) which would place a \$250,000 cap on noneconomic damages and allocate damages based on fault. The committee chairman said the bill would reach the House floor in the next several weeks.

ACO Rules

With accountable care organizations (ACOs) due to start up under the PPACA next January, CMS has sent to OMB proposed rules for their establishment. With considerable differences among insurers, providers and others as to the scope and operations of ACOs, **Senators Mark and Tom Udall** and six others wrote the Department of Justice and the Federal Trade Commission requesting that they coordinate their antitrust guidance for ACOs.

HHS Grants

HHS announced that grants for seven cooperative agreements totaling \$241 million were awarded to "early innovator" states to help design and implement information technology infrastructure needed to operate health insurance exchanges. The program is designed to create various health insurance exchange models that other states can use.

Hearings on PPACA and President's Budget

Last week the National Academy for State Health Policy issued a briefing paper on PPACA requirements for state health insurance exchanges. A major issue for states is whether to establish separate exchanges for individuals and families and separate exchanges for small businesses. The exchanges have to provide minimum coverage according to the PPACA beginning in 2014. In this connection, at last week's House Energy and Commerce Subcommittee on Health hearing on the PPACA, the Chairman, **Cliff Stearns**, said the PPACA has resulted in "lost coverage, higher premiums, and higher costs. And when the damaging effects of the Administration's health care plan got so bad that people were starting to notice, then it was time for waivers..." However, **Rep. Henry Waxman** stuck up for the Administration waiver process maintaining that HHS did not act with bias in granting the waivers for union and other mini-med plans effective during the period before the exchange rules take effect. Last week the Administration went further and granted waivers to health insurers covering 900 plans in four states, exempting them from the minimum \$750,000 essential benefits requirement. At a Ways and Means Committee hearing, **Chairman Dave Camp** grilled **HHS Secretary Kathleen Sebelius** on the President's budget proposals, stating that the PPACA "is a mess, and so is the budget that is meant to finance its implementation..." He also said the Medicare physician payment two year extension is "absent of any policy details..." He also called attention to the lack of long-term reform proposals for Medicare under the budget.

State Challenges to PPACA

Last week the Virginia AG, **Ken Cuccinelli**, testified before the House Judiciary Committee regarding the state's suit and the PPACA individual mandate. He said that by passing the PPACA, Congress asserted an unprecedented use of the commerce clause by compelling citizens to purchase insurance from private vendors or pay a penalty to the government. He said his lawsuit is about liberty and not health care. Other witnesses said the individual mandate is constitutional

and fits within the application of the commerce clause. In other news, the Department of Justice has asked the U.S. District Court for the Northern District of Florida to clarify the effect of its ruling declaring the PPACA individual mandate unconstitutional. The judge also said the entire law invalid, due to the lack of a severability clause and the inability to unwind the various provisions, but refused to agree to a declaratory judgment order asked for by the 26 state plaintiffs. He said that such

an order is unnecessary because of a "long-standing presumption that the federal government will comply" with such judicial rulings. Some states maintain that they do not have to go forward with implementing provisions of the PPACA, thus DOJ is seeking a ruling to clarify the matter. Judge Vinson gives plaintiffs three days to given their comments on the DOJ request.

SCHIP Quality Improvements/ Allotments

Last week CMS wrote states providing them with an update on requirements of CHIPRA to improve health care quality for children under SCHIP. States are expected to submit data by the end of 2013 on the quality of health care and consumer satisfaction measures through the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Child Medicaid Survey. CMS also released final SCHIP rules explaining the methodology for determining FY 2009-2015 state CHIP allotments.

Medicaid Issues

Last week CMS issued proposed regulations under the PPACA which would deny federal funding to state Medicaid programs for provider payments in cases in which care was given for preventable conditions, such as treatment of a catheter-associated infection. States must give notice to CMS about plan amendments that modify their current policy or implement nonpayment for the first time by September 30th.

Nursing Home Closure Rules

CMS issued an interim final rule providing new closure procedures for long-term care facilities that participate in Medicare and Medicaid. As required under the PPACA, Medicare skilled nursing facilities and Medicaid nursing facilities that are closing must submit written notification of the closure to HHS, the state's LTC ombudsman and residents of the facility and their legal representatives. The interim final rule takes effect March 23.

HHS Ten-Year Vaccine Plan

HHS announced a new 10-year vaccine plan called the 2010 National Vaccine Plan: Protecting the Nation's Health through Immunization. The goals of the plan are to: develop new and better vaccines; enhance the safety of vaccines and vaccine practices; support better vaccine understanding and decision making by the public, providers and policymakers; ensure a stable supply of, access to and better use of vaccines recommended in the U.S.; and increase global prevention of death and disease through safe use of vaccinations.

FDA Issues

House E&C Committee Hearing on FDA Approvals--At last week's House Energy and Commerce Subcommittee on Health hearing on FDA medical device approval rules, committee Republicans criticized the agency on its delays in approving medical devices, especially in comparison with the approval process in Europe. However, the Center for Devices and Radiological Health Director said adopting the European system would result in greater harm to patients. He also asked for greater funding to help speed up the process, but was rebuffed by Republicans who said the budget crisis would not permit increased funding.

Certain Device Items Exempted from FDA Premarket Review--Last week the FDA issued a final rule that reclassifies certain hardware and software medical device data systems (MDDSs) from class III (highest risk, needing premarket approval) into class I (general controls), thus exempting them from premarket review. The rule is effective April 18.

Recently Introduced Health Legislation

H.R. 663 (REFORM), to delay the implementation of the health reform law until the Supreme Court determines the constitutionality of the individual mandate; BRADY of Texas; jointly, to the committees on Energy and Commerce, Ways and Means, Education and the Workforce, Natural Resources, the Judiciary, Rules, Appropriations, and House Administration, Feb. 11.

H.R. 664 (CHIROPRACTORS), to amend the Public Health Service Act to authorize appointment of Doctors of Chiropractic to regular and reserve corps of the Public Health Service Commissioned Corps, and for other purposes; GENE GREEN of Texas; to the Committee on Energy and Commerce, Feb. 11.

H.R. 666 (PUBLIC HEALTH), to amend the Public Health Service Act to direct the secretary of health and human services, acting through the Center for Health Statistics,

to allocate such sums as may be necessary for the collection of statistics from the most recent versions of the standard certificates of live birth and death and the standard report of fetal death; COHEN; to the Committee on Energy and Commerce, Feb. 11.

H.R. 669 (MEDICAID), to amend Title XIX of the Social Security Act to require 12-month continuous coverage for children under Medicaid; GENE GREEN of Texas; to the Committee on Energy and Commerce, Feb. 11.

H.R. 671 (STATE CHILDREN'S HEALTH INSURANCE PROGRAM), to amend Title XXI of the Social Security Act to require 12-month continuous coverage under the State Children's Health Insurance Program; GENE GREEN of Texas; to the Committee on Energy and Commerce, Feb. 11.

H.R. 675 (PROGRAM EXCLUSIONS), to amend Title XI of the Social Security Act to expand the permissive exclusion from participation in federal health care programs to individuals and entities affiliated with sanctioned entities; HERGER; jointly, to the committees on Energy and Commerce, Ways and Means, and the Budget, Feb. 11.

H.R. 676 (HEALTH INSURANCE COVERAGE), to provide for comprehensive health insurance coverage for all United States residents, improved health care delivery, and for other purposes; CONYERS; jointly, to the committees on Energy and Commerce, Ways and Means, and Natural Resources, Feb. 11.

H.R. 698 (REFORM), to deauthorize and rescind funding for the Patient Protection and Affordable Care Act and health-care-related provisions of the

Health Care and Education Reconciliation Act of 2010; SCOTT of South Carolina; jointly, to the committees on Energy and Commerce, Ways and Means, Education and the Workforce, the Judiciary, Natural Resources, House Administration, and Appropriations, Feb. 14.

H.J. RES. 30 (HEALTH CARE COVERAGE), proposing an amendment to the Constitution of the United States regarding the right of citizens of the United States to health care of equal high quality; JACKSON of Illinois; to the Committee on the Judiciary, Feb. 14.

H.R. 718 (MEDICARE), to require the commissioner of Social Security to revise the medical and evaluation criteria for determining disability in a person diagnosed with Huntington's Disease and to waive the 24-month waiting period for Medicare eligibility for individuals disabled by Huntington's Disease; FILNER; to the Committee on Ways and Means, Feb. 15.

H.R. 722 (PRESCRIPTION DRUGS), to amend the Internal Revenue Code of 1986 to deny any deduction for direct-to-consumer advertisements of prescription drugs; NADLER; to the Committee on Ways and Means, Feb. 15.

S. 362 (PANCREATIC CANCER INITIATIVE), to amend the Public Health Service Act to provide for a Pancreatic Cancer Initiative, and for other purposes; WHITEHOUSE; to the Committee on Health, Education, Labor, and Pensions, Feb. 16.

S. 373 (DRUGS), to amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs; ROCKEFELLER; to the Committee on Health, Education, Labor, and Pensions, Feb. 16.

H.R. 733 (PANCREATIC CANCER INITIATIVE), to amend the Public Health Service Act to provide for a Pancreatic Cancer Initiative, and for other purposes; ESHOO; to the Committee on Energy and

Commerce, Feb. 16.

H.R. 734 (TAXATION), to amend the Internal Revenue Code of 1986 to repeal the medical device tax, and for other purposes; BILBRAY; jointly, to the committees on Ways and Means and Appropriations, Feb. 16.

H.R. 741 (DRUGS), to amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs; EMERSON; to the Committee on Energy and Commerce, Feb. 16.