



House Republican Budget Cuts Target Health-Related Programs; PDUFA Markups

Budget Reconciliation Markups Begin

To meet the House Budget Committee's 10-year \$59.2 billion in FY 2013 reconciliation instruction savings allocated to the Ways and Means Committee, the committee adopted several measures which target refundable tax credits and the health-related programs. One provision the Joint Tax Committee estimates would save \$43.9 billion would modify the PPACA health subsidy program by tightening up the recovery of all overpayments that are made in error. A second provision estimated to save \$7.6 billion would require a Social Security number for a family to claim refundable child tax credits. Also, the House Judiciary Committee approved provisions which would save \$41 billion over the years by adopting language similar to the medical malpractice reforms previously passed by the committee and the full House. The provisions reflect those under H.R. 5, the Help Efficient, Accessible, Low-cost, Timely Healthcare Act of 2012, which would, among other things, cap non-economic damages at \$250,000. Other House committees will soon report their budget saving recommendations so as to enable the Budget Committee to package all budget savings into one reconciliation bill which is expected to be taken to the House floor sometime in May.

Senate Budget Committee Balks on Budget Reconciliation

Senate Budget Committee Chairman Kent Conrad convened his committee

and unveiled a committee mark which is reflective of the tax, Medicare, Social Security and other entitlement reforms recommended by the Simpson-Bowles Presidential Commission which would provide \$5.4 trillion in deficit reduction over 10 years. He said that he would take no votes on amendments to the plan before the election. A substitute that **Senator Toomey** said he would like to offer would repeal the PPACA, freeze Medicaid spending until 2018 and convert the program to a state block grant and provide for a federal version of medical malpractice reform. If the committee does not advance a plan, **Senator Toomey** said he would try to force a vote in the Senate on his plan by means of a rule providing for a budget vote if the committee fails to act.

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HHS Cites Two Health Insurers for Unreasonable Rate Increases

Pursuant to the authority given HHS under the PPACA, the Center for Consumer Information and Insurance Oversight determined that the health insurance rate increases proposed by two health insurers are based on “unreasonable assumptions.” The rate increases, as high as 24%, would apply to more than 60,000 residents in seven states. HHS said the insurers should rescind the rates if they are

in effect or to refrain from putting them into effect. The agency also said they should issue refunds to consumers or to publicly explain why they should not. Although the PPACA does not provide authority for HHS to alter rate hikes, the insurers cited must post their response on the HHS website and their own websites.

Dual Eligible Demonstration Project: Unknown Impact On Access to Physicians

CMS is working with states across the country to coordinate the care of dual eligible beneficiaries in a series of state-based demonstrations. CMS explains that the goal of the program is to coordinate care for beneficiaries in both Medicare and Medicaid, resulting in improved health delivery. However, this population includes the frail and elderly and there are many questions yet to be answered. Many are concerned that most states plan to automatically enroll dual eligible beneficiaries in Medicaid managed care – removing

them from the Medicare program. One of the unanswered questions is how or if physicians and patients will be notified before a dual eligible beneficiary is passively enrolled in a Medicaid managed care program. At least 37 states and the District of Columbia are currently planning demonstrations and many states expect to begin enrolling beneficiaries before the end of the year. These proposed demonstrations will be a significant change for Medicare beneficiaries, enrolling up to two million dual eligible beneficiaries in the Medicaid program. **MedPAC**

Chairman Glenn Hackbarth stated recently that he was concerned that the duals initiative could be more focused on the potential savings to the states and health programs than on the patient. “We’re talking about these significant changes, which could limit choices available to dual eligible beneficiaries,” Hackbarth said. “It’s untoward to focus on how everybody else is going to benefit financially from changes in care other than the patient.”

PPACA Physician Value Payments

CMS has sent out so-called resource use reports to 20,000 physicians showing their patients’ average health care costs and quality of care. The reports, part of the Physician Value-Based Payment Modifier program set by the PPACA to start in 2015, also provided cost and quality comparisons with other physicians. Payments made in 2015 are intended to be based on care provided in 2013. By 2017 the program is expected to include most Medicare participating physicians.

Medicare DME Bidding Renewed

CMS announced that it will renew bidding for the nine First Round areas of the durable medical equipment competitive bidding program this summer. The bidding will include some new items and there will be new product category groupings of similar items and accessories. The bidding will not include retail diabetic supplies. Round Two and national mail order contracts and prices are scheduled to go into effect July 1, 2013.

FDA Fee Reauthorization Markups Scheduled

The House Energy and Commerce Health Subcommittee announced that, pending further agreement, it intends to mark up legislation this week to reauthorize the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA). The draft bill also includes language from H.R. 4274, Rogers-Eshoo-Markey legislation that would permanently authorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). The omnibus

bill would also create new user fee programs for generic drugs, called the Generic Drug User Fee Act (GDUFA), and for biosimilar drugs, called the Biosimilars User Fee Act (BSUFA). Rep. Henry Waxman said the draft bill includes the proposed Generating Antibiotic Incentives Now (GAIN) Act, H.R. 2182, which would extend the exclusivity period for new prescription antibiotics from 10 years to 15 years and add an additional six-month period of exclusivity if the new antibiotic identifies a companion

diagnostic test. He also said the draft legislation should include a provision to preserve the effectiveness of new antibiotics once they are on the market. The Senate HELP Committee announced it intends to mark up similar legislation on April 25th. The House E&C Committee would like to see the bill passed by the end of June in order to give guidance to the FDA and affected parties before the expiration of the current law on September 30.

HAI National Action Plan

HHS announced an updated National Action plan to help eliminate health care-associated infections (HAIs). The plan was developed by the HHS Partnership for Patients: Better Care, Lower Costs, a public-private initiative

designed to improve the quality, safety and affordability of health care. The plan details specific goals for decreasing the following types of infections in the future: a 50% reduction in bloodstream infections; 100% adherence to central line insertion practices; a

25% percent reduction in urinary tract infections; and a 50% reduction in Methicillin-resistant Staphylococcus aureus (MRSA) invasive infections in the general population. HHS requested comments on the revised plan.

H. RES. 615 (REFORM), expressing the sense of the House of Representatives that members who vote in favor of the establishment of a public, federal government-run health insurance option are urged to forgo their right to participate in the Federal Employees Health Benefits Program (FEHBP) and agree to enroll under that public option; FLEMING; to the Committee on House Administration, April 16.

S. 2295 (DRUGS), to permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so; LEAHY; to the Committee on Health, Education, Labor, and Pensions, April 18.

S. 2297 (DRUGS), to amend the Controlled Substances Act to make any substance containing hydrocodone a Schedule II drug; MANCHIN; to the Committee on the Judiciary, April 18.

H.R. 4378 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for coverage and payment for complex rehabilitation technology items under Medicare; CROWLEY; jointly, to the committees on Energy and Commerce and Ways and Means, April 18.

H.R. 4384 (DRUGS), to permit manufacturers of generic drugs to provide additional warnings with respect to such drugs in the same manner that the Food and Drug Administration allows brand names to do so; VAN HOLLEN;

to the Committee on Energy and Commerce, April 18.

S. 2304 (MEDICARE), to amend Title XVIII of the Social Security Act to allow chiropractors to provide items and services through private contracts under Medicare; MIKULSKI; to the Committee on Finance, April 19.

S. 2321 (TOURETTE SYNDROME), to amend the Public Health Service Act to provide for the expansion, intensification, and coordination of the programs and activities of the National Institutes of Health with respect to Tourette syndrome; MENENDEZ; to the Committee on Health, Education, Labor, and Pensions, April 19.

S. 2323 (APPROPRIATIONS), making appropriations for Departments of Commerce and Justice, and Science, and Related Agencies for the fiscal year ending Sept. 30, 2013, and for other purposes; MIKULSKI; from the Committee on Appropriations; placed on the calendar, April 19.

H.R. 4404 (INSPECTORS GENERAL), to create a centralized website on reports issued by the Inspectors General, and for other purposes; CRAWFORD; to the Committee on Oversight and Government Reform, April 19.

H.R. 4470 (HEALTH CARE COVERAGE), to amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, the Internal Revenue Code of 1986, and

title 5, United States Code, to require individual and group health insurance coverage and group health plans and federal employees health benefit plans to provide coverage for routine HIV screening; WATERS; jointly, to the committees on Energy and Commerce, Ways and Means, Education and the Workforce, and Oversight and Government Reform, April 19.