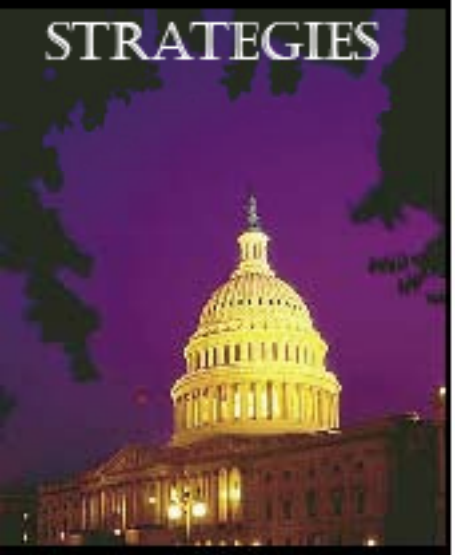
HART HEALTH STRATEGIES



Health Policy Briefing

February 13, 2012

Administration FY 2013 Budget to be Released Monday; Line-Item Veto Passes House

Budget Issues

On Monday, OMB will release **President Obama's** FY 2013 budget recommendations which are expected to only trim the FY 2012 projected federal deficit of $1.33 trillion to about $.9 to $1.2 trillion. The Administration is not expected to recommend major changes to Medicare, Medicaid and Social Security, although the President has previously suggested he would accept higher premiums for high-income Medicare beneficiaries. The President's FY 2013 budget is likely to be DOA as was his FY 2012 budget recommendations. Senate Majority Leader Harry Reid is unlikely to want to bring the new budget to a vote in the Senate, given the Senate's rejection of the President's recommendations for FY 2012. Instead, **Senator Reid** declared that he will not advance a FY 2013 budget resolution during this election year. Last week the House passed two budget-related bills: H.R. 3521, the Expedited Legislative Line-Item Veto and Rescissions Act of 2011, was passed on a vote of 254-173; and H.R. 3581, the Budget and Accounting Transparency Act of 2011, was passed on a vote of 245-180. The line-item veto concept may find some receptivity in the Senate among some Democrats when **Senators John McCain and Tom Carper** attempt to push the concept in the context of other legislation.

Doc-Fix and Payroll Extender Talks Flounder

House Republican conferees on H.R. 3630 offered up spending cuts that would fund about one-half the cost of extending current Medicare physician payment levels, payroll tax reductions and unemployment insurance extensions to the end of this year. The proposal, rejected by Democrats, would raise Medicare Part B and D premiums for higher-income beneficiaries ($31 billion over ten years), require inaccurate PPACA exchange subsidies to be repaid ($13.4 billion over ten years) and extend the current freeze pay for federal employees. In rejecting calls for the use of "war savings" to finance the legislation, **House Speaker John Boehner** suggested that Democrats get "serious" about negotiations. Further discussions on potential payfors are likely to be held this week behind closed doors. **Senate Majority Leader Harry Reid** said his office has begun to draft a Democrat alternative (which he could move separately as a threat to Republicans to reach a compromise on the legislation in conference).

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PPACA Health Reform Update Administration Backtracks on PPACA Contraceptive Coverage Mandate

Reacting to the backlash over interim final HHS regulations requiring all health plans, except certain church and related institutions, to cover women's contraceptives, the White House announced a new policy that would instead allow religious organizations, such as universities and hospitals, to avoid the mandatory coverage requirement but place the burden on health insurers to offer covered individuals the option of such coverage for no cost. The revised policy is unlikely to have cut this Gordian knot, given the contention by self-insured parochial entities that the revision would still require them to offer and pay for such coverage in violation of their religious tenets. **House Speaker John Boehner** has pledged to advance legislation if the new rule is found to be deficient in protecting "religious freedom." **Senators Joe Manchin and Marco Rubio** introduced legislation, S. 2092, which would exempt individuals or entities with a religious or "moral conviction" objection from offering health insurance coverage for contraception or sterilization services and from having to engage in "government-mandated speech" with respect to such services. This latest dustup of a PPACA mandate could also find its way into the various suits challenging the constitutionality of the PPACA's individual mandate.

Challenges to PPACA Constitutionality

The Department of Justice asked the Supreme Court to expand from 60 to 90 minutes the oral arguments on whether or not the Anti-Injunction Act (AIA) precludes the court's consideration of other arguments, that the individual mandate and Medicaid expansions are unconstitutional, until 2014 when the individual mandate penalties kick in under the PPACA. The court will hear at least five and one-half hours of oral argument between March 26 and March 28, including whether or not the mandate penalties constitute a "tax" for AIA purposes. In the appeal from the Eleventh Circuit, the plaintiffs (26 states, the NFIB and individuals) filed their briefs arguing that the individual mandate is "unprecedented and unbounded" under the Commerce Clause and which question why Congress would wait 220 years to exercise such authority. All of the above parties also said that any decision relating to the AIA should not delay the court's decision on the constitutionality of the individual mandate and Medicaid expansions. In addition, the American Center for Law and Justice, on behalf of 119 House Republicans, filed a brief arguing that the individual mandate is unconstitutional. House Democrats Question

HHS Decision on Essential Benefits

The ranking members of the three House committees of jurisdiction over the PPACA wrote to HHS Secretary Kathleen Sebelius expressing their serious concerns over the delegation to states of the decision as to what constitutes "essential benefits" for individual and small group plans. Republicans previously said that, by issuing a "bulletin" rather than a regulation, the bulletin was a misapplication of the law's rulemaking requirements.

IRS Guidance on CO-OPs

The IRS issued proposed and temporary guidance to would be sponsors of Consumer Operated and Oriented Plans (CO-OPs) on the conditions for such organizations to be deemed tax-exempt. The IRS said that qualified nonprofit health insurers must apply to the IRS for tax-exempt status with an effective date on either the date of formation or March 23, 2010 (the DOE of the PPACA). Although the IRS will generally rely on the criteria set by CMS as to CO-OP requirements, a revenue ruling providing additional guidance will be issued later.

Tri-Agency Final Regulations on Benefit Disclosure

HHS/CMS, DOL/EBSA and Treasury/IRS issued a final rule defining the PPACA's "standardized, easy-to-understand" summary description of plan benefits that health insurers must provide plan participants before they enroll. The 8-page summary must provide information on plan deductibles, out-of-pocket expenses, covered services and providers, exclusions, etc. A 4-page glossary of health coverage and medical terms explained in plain English must accompany the plan summary. The rule applies even to large self-insured group health plans that are already subject to ERISA plan summary and disclosure rules. The regulations go into effect this August.

House W&Ms Hearing on SGR

The House Ways and Means Health Subcommittee held hearings last week to explore avenues to reform the Medicare physician payment "sustainable growth rate" in an affordable way. **Chairman Wally Herger** said that, if a long-term solution cannot be found, the program will go bankrupt. Witnesses described several ways to improve quality through medical homes, data-driven performance programs, incentives to form physician groups and other payment models.

CMS Makes CED Coverage Decisions

CMS said it used its Medicare "coverage with evidence development" (CED) authority to conditionally cover transcatheter aortic valve replacement (TAVR), a new technology for treating aortic stenosis, provided the beneficiary is enrolled in a national registry that tracks health outcomes. In like manner, CMS said it will allow Medicare coverage for extracorporeal photopheresis (ECP), a procedure in which a patient's white blood cells are exposed first to a drug and then to ultraviolet light, if the beneficiary is in a clinical trial. Permanent coverage will be determined after further evidence is obtained in the trials.

HHS/CMS Regulatory Agenda

Comments are due by February 17th on the PPACA's Physician Payments Sunshine Act which requires drug and device manufacturers to disclose payments made to physicians and hospitals (a final rule is expected in December 2014). HHS will also release this month a proposed rule on requirements for Stage 2 of the Medicare and Medicaid meaningful use electronic health records (EHR) incentive program. OMB is also reviewing the following: a proposed rule to revise the Medicare hospital outpatient prospective payment system (OOPS) for calendar year 2013 and to make changes to the ambulatory surgical center payment system list of services and rates (for June release and finalized November1); an annual proposed rule to revise payment policies under the physician fee schedule and make changes to payments under Medicare Part B for 2013 (for June release and finalized November 1); and an annual proposed rule to revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for 2013 (for release April 1 and finalized August 1).

Increase on Tax-Delinquent Medicare Providers

At a Senate Finance Committee markup of S. 1813, The Highway Investment, Job Creation and Economic Growth Act of 2012, a payfor was adopted which would increase the levy on tax-delinquent Medicare providers from the current 15% of such payments to 100%.

Guidance on Biosimilar Product Development

The FDA issued three guidance documents required under the PPACA to implement the approval pathway for biosimilar products. The draft guidance on Scientific Considerations describes a risk-based "totality-of-the-evidence" approach that the FDA intends to use to evaluate the data and information submitted in support of a determination of biosimilarity of a proposed product to the reference product. The Quality Considerations draft guidance provides an overview of the analytical factors that are to be considered when assessing biosimilarity between a proposed therapeutic protein product and the reference product for the purpose of submitting a 351(k) application. A Question and Answers document provides answers to common questions that may arise in the early stages of product development. The House Energy and Commerce Health Subcommittee also held FDA hearings focusing on the biosimilar issue and the shortage of certain prescription drugs.

H.R. 3897 (PUBLIC HEALTH), to amend Title XXVII of the Public Health Service Act to provide religious conscience protections for individuals and organizations; CHABOT; to the Committee on Energy and Commerce, Feb. 3.

H. RES. 538 (CANCER PREVENTION), expressing support for designation of Feb. 4, 2012, as National Cancer Prevention Day; ISRAEL; to the Committee on Energy and Commerce, Feb. 3.

H.R. 3975 (MEDICAL DEVICES), to amend Title V of the Federal Food, Drug, and Cosmetic Act to extend the provisions of the Pediatric Medical Device Safety and Improvement Act; ROGERS of Michigan; to the Committee on Energy and Commerce, Feb. 8.

H.R. 3982 (HEALTH INSURANCE COVERAGE), to prohibit the secretary of health and human services from implementing certain rules relating to the health insurance coverage of sterilization and contraceptives approved by the Food and Drug Administration; LUETKEMEYER; to the Committee on Energy and Commerce, Feb. 8.

H.R. 3988 (FDA USER FEES), to amend the Federal Food, Drug, and Cosmetic Act to establish user-fee programs for generic drugs and biosimilars; MURPHY of Pennsylvania; to the Committee on Energy and Commerce, Feb. 8.

S. 2082 (DISEASE AWARENESS), to establish the Cavernous Angioma CARE Center (Clinical Care, Awareness, Research and Education) of Excellence, and for other purposes; UDALL of New Mexico; to the Committee on Health, Education, Labor, and Pensions, Feb. 9.

S. 2092 (PUBLIC HEALTH), to amend Title XXVII of the Public Health Service Act to provide conscience protections for individuals and organizations; MANCHIN; to the Committee on Health, Education, Labor, and Pensions, Feb. 9.

S. 2097 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for coverage of comprehensive cancer care planning under Medicare and to improve the care furnished to individuals diagnosed with cancer by establishing grant programs for provider education, and related research; LANDRIEU; to the Committee on Finance, Feb. 9.

H.R. 3995 (DRUGS), to prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market, and for other purposes; RUSH; jointly, to the committees on Energy and Commerce and the Judiciary, Feb. 9.

H.R. 4008 (DISEASE AWARENESS), to establish the Cavernous Angioma CARE Center (Clinical Care, Awareness, Research and Education) of Excellence, and for other purposes; HEINRICH; to the Committee on Energy and Commerce, Feb. 9.