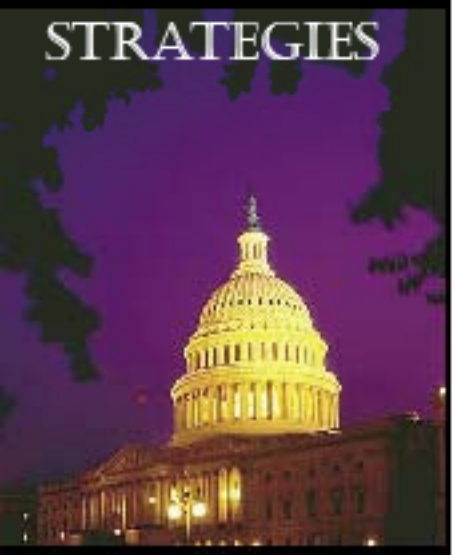
HART HEALTH HH STRATEGIES



Health Policy Briefing

July 25, 2011

Congress Fiddles, Will Rome Burn? Wednesday is Apparent Deadline for Debt-Deal

Budget Deal or "In Your Face" House Action?

Last Friday the **President** and **House Speaker John Boehner** failed to reach an agreement on a $3-4 trillion ten-year "Big Deal" deficit reduction plan. A Saturday White House meeting with congressional leaders also did not appear to move the budget deficit negotiations further to enable a quick agreement to raise the debt ceiling limit, thus avoiding a default on August 2nd. The President blamed House Republican Tea Party sympathizers for the collapse of a long term budget deal while **House Speaker Boehner** said the President was unwilling to agree to meaningful Medicare and Medicaid entitlement reforms and insisted on $1.2 trillion in revenue increases over ten years even though House Republicans were willing to a tax overhaul that would raise $800 billion in revenues.

This Wednesday appears to be the practical deadline for reaching a bicameral agreement or singular action by the House to force Senate Democrats and the President to accept a House spending-reduction/debt ceiling measure. **House Speaker John Boehner** said he would confer with the other congressional leaders to forge an agreement or be forced to come forth with a House Republican solution to the impasse. If so, it is likely that the House Republican leadership will resurrect, for a vote by Wednesday, a revised version of H.R. 2560, the Cut, Cap and Balance Act, which the House passed last week on a 234-190 vote and the Senate tabled on a 51-46 vote. Also, Senate Democrats may offer a counter fall-back proposal that would cut spending about $2.5 billion over ten years without increasing taxes while increasing the debt ceiling sufficient until 2013. It is yet possible that a proposal can be crafted which would increase the debt limit while addressing the long-term deficit problem, even if the mechanism to reduce deficits and reform the tax system is left to a special congressional committee or similar forum. Still on the table is the plan proposed by **Senate Minority Leader Mitch McConnell** which

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would require the President to seek congressional authority to raise the debt ceiling by $2.5 trillion over three installments in the next 18 months and for him to propose spending reductions of an equal amount with Congress debating the reductions under normal appropriations procedures.

If the final legislation to lift the debt ceiling cap includes a special deficit reduction procedure, the $3.7 trillion 10-year deficit reduction proposal offered by the Gang of Six could take on added significance. The plan released by **Senators Chambliss, Coburn, Conrad, Crapo, Durbin and Warner** would provide for a cap on discretionary spending and phasing in a "chained" CPI for Social Security and other government benefits. About $500 billion in "health savings" would be targeted by congressional committees which would be directed to finish details of the plan. The plan would also result in a net of $1 trillion in new revenue by limiting tax breaks for medical costs, charitable donations, mortgage costs and retirement funds in return for lowering individual tax rates to three brackets (the first between 8% and 12%, the second between 14% and 22%, and the third between 23% and 29%) and one corporate tax rate. The plan would eliminate the Alternative Minimum Tax (AMT) while keeping the earned-income tax credit and the child tax credit. Of note, the plan also proposes to pay for reforming the current Medicare physician payment sustainable growth rate (SGR) at a cost of $298 billion. In addition, the plan calls for the repeal of the PPACA CLASS Act long-term care program and for the judiciary committees to obtain savings from some sort of medical malpractice reform. The plan would also require the Senate Budget Committee to report legislation within six months from the plan's date of enactment "to review total federal health care spending starting in 2020 with a target of holding growth to GDP plus one percent per beneficiary." The plan would require the Congress and the President to take appropriate action if the growth rate is exceeded. **Senator Tom Coburn** upped the ante on the Gang of Six plan by releasing details on a ten-year $9 trillion deficit reduction proposal containing: $2.64 trillion in Medicare and Medicaid spending cuts; an increase in the Medicare eligibility age by two months annually until reaching age 67; increasing Part B premiums by 2% annually until reaching 35% of costs; block granting Medicaid; and requiring means testing for Medicare and other federal programs. About $1 trillion in revenue increases would be raised by eliminating several current tax breaks.

Appropriations Issues

House Appropriations Committee Chairman Harold Rogers announced that consideration of the FY 2012 Labor/HHS/Education Appropriations legislation will be delayed until after the August congressional recess. The House has approved only six of the nine spending bills to date with the Legislative Branch appropriations bill being the last bill approved. The House voted 252-159 to pass the bill which cuts most legislative branch agencies by about seven percent. The Senate has passed only one appropriations measure, the FY 2012 Military Construction/ Veterans-Affairs bill (H.R. 2055), thus putting into question just how many spending bills will be passed by the beginning of the new fiscal year October 1st. Action on FY 2012 appropriations bills has been severely interrupted due to the debt- ceiling/budget negotiations and the lack of a Senate budget resolution allocating total spending among the several Senate appropriations panels.

IOM Recommendations on "Essential Benefits"

The Institute of Medicine issued recommendations to HHS on certain medical services that should be considered "essential benefits" under PPACA mandated health plans. The IOM recommended that following services be included without participant cost-sharing: FDA-approved contraception; domestic violence screening and counseling services; human papillomavirus testing; counseling for sexually transmitted infections; screening for gestational diabetes; and lactation equipment. **Senate HELP Committee member Richard Burr** said "I'm not sure you could point to any area of health care that I believe should be free. All of health care should have some out-of-pocket cost-sharing. One reason why health care spending is at the level it is is because a lot of people perceive it to be free. That's a utilization nightmare."

PPACA "CO-OP" Regulations Proposed

HHS proposed regulatory requirements that private, nonprofit organizations would have to meet in order to offer PPACA health coverage in 2014 as Consumer Operated and Oriented Plans (CO-OP). The proposal includes information on how such entities can apply for up to $3.8 billion in PPACA loans to develop co-ops. To be approved, co-ops must be newly established, meet state insurance regulations and plow back any profits to benefit plan participants.

PCORI Seeks Comments on Comparative Effectiveness

The Patient-Centered Outcomes Research Institute (PCORI) has requested comments on how the agency should conduct comparative effectiveness research using the $600 million annually provided under the PPACA. Comments are due by September 2nd on patient-centered research that would "help people make informed health care decisions and allow their voice to be heard in assessing the value of health care options."

Senate Hearing on "Reducing Medicare Drug Costs"

At a Senate Aging Committee hearing members suggested that legislation is needed to help reduce the costs of drugs under Medicare. The panel released a report making several recommendations, including requiring: the negotiation of drug prices under Part D; prescription drug manufacturers to provide drug discounts for low-income Medicare recipients; and the negotiation of drug prices under Medicare Part B when it is the majority purchaser.

Insurance Agents Get Support from NCIL

The executive committee of the National Conference of Insurance Legislators adopted a resolution supporting H.R. 1206, the Access to Professional Health Insurance Advisors Act, which would change the PPACA definition of minimum loss ratio to allow for agent and broker commissions to be included as administrative expenses in computing the MLR. The NAIC has refused to make a similar recommendation to HHS for the adjustment.

Proposed Medicare Coverage for Screening of Depression

CMS proposed that Medicare benefits be expanded to include coverage of the annual screening for depression for beneficiaries in primary care settings that have staff-assisted depression care supports in place to assure accurate diagnosis, effective treatment and follow-up. CMS did not place a deadline on requested comments.

Medicare Payment Bundling Model

The White House announced that CMS will soon begin the first of several models under which providers will receive Medicare payments for bundled services. Under the model, CMS will negotiate payments with doctors, hospitals, and other providers for a set of health care services constituting an "episode of care." A second bundled payment program will be initiated in 2013.

FDA Issues

House Hearing on FDA Approval of Medical Devices

At a House Energy and Commerce Committee hearing on the FDA approval process for medical devices, Republican members expressed concerns that the FDA process is slower than in Europe and inconsistent. However, **Rep. Henry Waxman** said the FDA process remains the gold standard. An agency spokesman said the FDA could use more funding in order to have a sufficient number of staff to perform their duties. **Chairman Cliff Stearns** said that the problems at the FDA are not a matter of funding.

Senate Judiciary Committee Passes "Pay for Delay" Prohibition

On a 10-8 vote, the Senate Judiciary Committee approved S. 27, **Senator Herb Kohl's** legislation that would make illegal any "pay for delay" settlements that allow brand name drug companies from paying generic drug companies to delay a generic drug's entry into the market. **Senator Orrin Hatch** said that the bill would create expensive delays, discourage innovation and hurt the very people it was intended to help. The Chairman of the FTC praised the bill.

Guidelines for Mobile Medical Apps

The FDA released proposed guidelines under which certain mobile medical applications that pose risks to patients would be regulated. Apps that would have to meet the new guidelines include: accessories to devices that the FDA already regulates; apps that turn a mobile communications platform into a medical device; and apps that offer suggestions about a patient's diagnosis or treatment. Comments are due by October 19th.

H.R. 2557 (TICK-BORNE DISEASES), to provide for the establishment of the Tick-Borne Diseases Advisory Committee; SMITH of New Jersey; to the Committee on Energy and Commerce, July 15.

H.R. 2558 (HOSPITALS), to modify the definition of children's hospital for purposes of making payments to children's hospitals that operate graduate medical education programs; CICILLINE; to the Committee on Energy and Commerce, July 15.

S. 1376 (MEDICAID), to conform income calculations for purposes of eligibility for the refundable credit for coverage under a qualified health plan and for Medicaid to existing federal low-income assistance programs; ENZI; to the Committee on Finance, July 18.

S. 1378 (MEDICAID), to ensure that Social Security and Tier 1 Railroad Retirement benefits are properly taken into account for purposes of determining eligibility for Medicaid and for the refundable credit for coverage under a qualified health plan; NELSON of Nebraska; to the Committee on Finance, July 18.

S. 1381 (TICK-BORNE DISEASES), to provide for the expansion of federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne disease, including the establishment of a Tick-Borne Diseases Advisory Committee; BLUMENTHAL; to the Committee on Health, Education, Labor, and Pensions, July 18.

H.R. 2576 (TAXATION), to amend the Internal Revenue Code of 1986 to modify the calculation of modified adjusted gross income for purposes of determining eligibility for certain health care-related programs; BLACK; to the Committee on Ways and Means, July 18.

S. 1391 (VETERANS' HEALTH), to amend Title 38, United States Code, to improve the disability compensation evaluation procedure of the secretary of veterans affairs for veterans with post-traumatic stress disorder or mental health conditions related to military sexual trauma, and for other purposes; TESTER; to the Committee on Veterans' Affairs, July 20.

H.R. 2595 (NEUROLOGICAL DISEASES AND DISORDERS), to amend the Public Health Service Act to provide for the establishment of permanent national surveillance systems for multiple sclerosis, Parkinson's disease, and other neurological diseases and disorders; VAN HOLLEN; to the Committee on Energy and Commerce, July 20.

H.R. 2600 (CHILDREN'S HEALTH), to provide for implementation of the National Pediatric Acquired Brain Injury Plan; LANCE; to the Committee on Energy and Commerce, July 20.

H. RES. 360 (HIV/AIDS), expressing support for the sixth IAS Conference on HIV Pathogenesis, Treatment, and Prevention and the sense of the House of Representatives that continued commitment by the United States to HIV/AIDS research, prevention, and treatment programs is crucial to protecting global health; HASTINGS of Florida; jointly, to the committees on Foreign Affairs and Energy and Commerce, July 20.