



Health Policy Briefing

December 8, 2014

Bipartisan Push to Adjourn on Friday Greases Skids for CRomnibus/DoD Authorization

CRomnibus or Another CR?

Reading the tea leaves from Speaker John Boehner’s (R-OH) remarks last week, it appears that his preferred means to extend fiscal year (FY) 2015 federal funding is Rep. Price’s (R-GA) suggestion, a so-called CRomnibus which would provide appropriations for the U.S. Department of Health and Human Services (HHS) and all other agencies, except for the Department of Homeland Security (DHS), through September 30, 2015. House Republicans would fund DHS only for the first few months into 2015 in order to give them leverage next year to defund or scale-back the President’s executive order allowing certain illegal aliens to remain in the United States and become eligible for various benefits, such as Social Security and Medicare. Appropriators are expected to release their draft of the limited omnibus bill on Monday which would allow the House to act by Wednesday and the Senate shortly thereafter in order to avoid a government shutdown which would occur if federal spending authority is not extended by the end of this coming Thursday, December 11th. The CRomnibus approach appears to have enough support from Republican conservatives inasmuch as House Republicans were given the opportunity to vote last week to approve H.R. 5759, the Preventing Executive Overreach on Immigration Act by a vote of 219 - 197. If the content of the CRomnibus is resisted by enough House Republicans or the President and congressional Democrats object, it is likely that Congress will still meet Friday’s deadline for adjournment sine die by passing a simpler short-term continuing resolution (CR). It remains to be seen how much of the President’s request for \$6.2 billion in funds to help fight Ebola will be contained in the legislation.

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House Approves Compromise FY 2015 DoD Authorization

The House passed H.R. 3979, the National Defense Authorization Act (NDAA) for Fiscal Year 2015, which was named after the House and Senate Defense committees' two retiring chairmen, Carl Levin (D-MI) and Howard P. "Buck" McKeon (R-CA). Among the provisions of the \$513.4 billion compromise are those continuing the Defense Health Program and several related to military personnel health cost-savings (i.e. a one-time increase of \$3 for pharmacy co-pays for retail prescriptions and mail-order non-generic prescriptions and a requirement that all non-generic prescription maintenance medications be filled through military treatment facility pharmacies or the national mail-order pharmacy program beginning next October). A military compensation and benefits commission is expected to report early next year on other long-term health and personnel cost-savings measures. The President's pick to be the next Secretary of Defense, Ashton B. Carter, will have much to say about how much of the commission's recommendations on health care and other issues will be promoted by the Administration. In other health-related news, the department said that the military has begun testing an isolation unit to treat and evacuate service members deployed to West Africa who become infected with the Ebola virus.

House Passes ABL Act and Defers on Additional Health Legislation

Last week the House approved and sent to the Senate H.R. 647, the Achieving a Better Life Experience Act of 2013 (or the ABL Act), legislation that would allow state programs to establish tax-exempt ABL accounts to assist individuals with a disability to pay for qualified disability expenses which include those related to health and wellness. The amounts in such accounts would be disregarded in determining eligibility for Medicaid and other means-tested federal programs. Some Democrats objected to the inclusion of Medicare cuts to offset \$1.4 billion of the \$2 billion ten-year cost of the legislation, including: \$444 million for vacuum pumps used to treat erectile dysfunction; \$365 million that would accelerate to 2016 the application of relative value targets for uncorrected (misvalued) overpayments under the Medicare physician fee schedule; and \$380 million that would delay for one year, through December 31, 2024, the inclusion of oral-only drugs in the end-stage renal disease (ESRD) prospective payment bundle. The House also passed H.R. 5771, the Taxpayer Tax Increase Prevention Act of 2014, which would extend only through 2014 certain employer and individual tax breaks, including one that would allow individuals to make tax-free withdrawals from Individual Retirement Accounts (IRAs) to charitable organizations. Members who support the passage of a permanent fix to the current sustainable growth rate (SGR) mechanism under the Medicare physician payment system are resigned to the fact that their efforts will have to begin again early next year in an attempt to pass legislation before the temporary fix ends on March 31, 2015. In other news, the President signed into law H.R. 4067, legislation delaying until next January a Medicare supervision requirement for outpatient therapeutic services in critical access and small, rural hospitals.

PPACA Health Reform Update

PPACA Administrative Actions

In an effort to increase enrollment under the Patient Protection and Affordable Care Act's (PPACA) exchanges, HHS encouraged individuals currently enrolled in plans to "shop" on the exchanges for new plans that might give them more value and higher tax credit subsidies. The Centers for Medicare and Medicaid Services (CMS) released a proposed rule under which accountable care organizations (ACOs) would be given more flexibility in renewing their participation, including in a new performance two-sided risk model for sharing in any savings or losses. The agency is seeking comment on this model and other changes, including beneficiary assignment, data sharing, eligibility requirements, participation agreement renewals, compliance and monitoring, and financial benchmarking and waivers for program and other payment rules. In related news, the CMS Office of the Actuary reported that U.S. health care costs grew 3.6% to \$2.9 trillion in 2013 which they said was the smallest increase in more than 50 years and one that probably won't be matched soon, as spending accelerates to meet the needs of millions of individuals who are expected to enroll under the PPACA. Also of note, HHS released information showing that hospital-acquired conditions--including falls, infections and adverse drug events--decreased by 17% between 2010 and 2013 which HHS said saved about 50,000 patients and \$12 billion in health-care costs.

PPACA Health Reform Update cont.

Republicans Again Ask Supreme Court to Strike Down IPAB

Rep. Phil Roe (R-TN) and twenty three other Republican members filed an amicus brief with the U.S. Supreme Court which argues that the PPACA's Independent Payment Advisory Board (IPAB) is inconsistent with the Constitution's separation of powers doctrine and should be considered by the court despite a ruling by the U.S. Court of Appeals for the Ninth Circuit that the issue is not yet ripe for judicial review because the Board has not been named and cannot take action before 2019. Rep. Roe previously introduced H.R. 351, legislation seeking to repeal the IPAB has 227 bipartisan cosponsors.

Medicare/Medicaid/PHSA Corner

Final Rule on Denial of Medicare Participation

CMS issued a final rule under which providers and suppliers can be excluded from enrolling in Medicare if they were previously affiliated with any organization having unpaid Medicare debts which was also terminated from the program. Such an entity can still be enrolled if it agrees to repay the debt. In addition, the rule contains additional restrictions allowing CMS to deny or revoke a provider's billing privileges: if a managing employee is found to have been convicted of certain state or federal felonies within the previous 10 years; and if a provider's billing patterns don't meet Medicare requirements.

House Hearing on CHIP Reauthorization

At last week's House Energy and Commerce Health Subcommittee hearing on the status of the Children's Health Insurance Program (CHIP), Republican and Democrat members expressed a desire to reauthorize CHIP beyond FY 2015. They cited the need by states to set their budgets early next year for the next fiscal year. The executive director of the Medicaid and CHIP Payment and Access Commission (MACPAC) testified that the program should be reauthorized for a transitional period of two years. Rep. Frank Pallone Jr. (D-NJ) said the program should be reauthorized for four years as his bill, H.R. 5364, would provide. Chairman Joe Pitts (R-PA) said "I believe we need to extend funding for this program in some fashion....If we don't, current enrollees will lose their CHIP coverage and many will wind up in Medicaid and on the exchanges, programs which may offer poorer access to care or higher cost-sharing for lower income families. Some will lose access to their insurance altogether." Some members indicated they would like to see other changes made to the program before Congress acts. Among the suggested changes would be to: increase the cap on out-of-pocket costs; restrict eligibility to only lower-income households; and better complement CHIP coverage with private health insurance. A letter from 39 governors also asked Congress to act soon on an extension.

CMS Advises on Part-D Prescription Coverage Eligibility

CMS alerted Medicare Advantage (MA) and Part D plans that the agency will not enforce until December 1, 2015 certain prescription drug prohibitions. At such time CMS will require physicians and eligible professionals who write prescriptions for covered plans to be enrolled in Medicare or have a valid record of opting out of Medicare.

FDA Issues

Revisions Made to Drug-Labeling Rules for Certain Women

The Food and Drug Administration (FDA) said that pharmaceutical companies, in connection with all new prescriptions and biologics, will have to provide additional information about the risks of taking medications during pregnancy, while breastfeeding or which might affect fertility. The risk information would have to be provided in detailed summaries rather than the current letter system.

NIH Issues

NIH Issue Draft Policy on Use of IRBs

The National Institutes of Health (NIH) said it is seeking comments by January 29, 2015 on proposed new policies that would allow for the use of a single institutional review board (IRB) for studies funded by NIH grants. The NIH director said that using single IRBs in multi-site studies would help to reduce duplication of effort, speed the initiation of important research and save time and taxpayer funds. Exceptions would be allowed in cases in which a local IRB review is needed to address the needs of certain participants or in cases where required by specific federal, state or tribal laws or regulations.

Upcoming Health-Related Hearings

House Energy and Commerce Health Subcommittee: hearing to be held titled “Setting Fiscal Priorities;” 10:30 a.m., 2123 Rayburn Bldg.; Dec. 9.

House Oversight and Government Reform Committee: hearing to be held titled “Examining ObamaCare Transparency Failures;” 9:30 a.m., 2154 Rayburn; Dec. 9.

House Energy and Commerce Health Subcommittee: hearing to be held titled “Examining FDA’s Role in the Regulation of Genetically Modified Food Ingredients;” 10:15 a.m., 2123 Rayburn Bldg.; Dec. 10.

Senate Foreign Relations African Affairs Subcommittee: hearing to be held titled “The Ebola Epidemic: The Keys to Success for the International Response;” 10:30 a.m., 419 Dirksen Bldg.; Dec. 10

Health Legislation Recently Introduced

H.R. 5780 (MEDICARE), to amend Title XVIII of the Social Security Act to improve the integrity of Medicare, and for other purposes; **BRADY** of Texas; jointly, to the committees on Ways and Means and Energy and Commerce, Dec. 2.

H.RES. 769 (SYSTEMS INFRASTRUCTURE SECURITY), expressing the sense of the House of Representatives that the health-care, energy, telecommunications and other sectors of the U.S. economy should continue their sector-specific efforts to protect critical infrastructure, to prevent information security breaches and to prevent cybersecurity breaches; **TERRY**; to the Committee on Energy and Commerce, Dec. 2.

H.R. 5790 (OUTCOMES), to authorize the director of the National Institutes of Health to design and enter into agreements for the implementation of prize competitions with the goal of improving health outcomes and thereby reducing federal expenditures; **YOUNG** of Indiana; jointly, to the committees on Energy and Commerce and Ways and Means, Dec. 3.

S. 2975 (MEDICARE), to amend Title XVIII of the Social Security Act to require state licensure and bid surety bonds for entities submitting bids under the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive acquisition program, and for other purposes; **PORTMAN**; to the Committee on Finance, Dec. 4.

S. 2977 (INFORMATION TECHNOLOGY), to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of patient records and certain decision support software; **BENNET**; to the Committee on Health, Education, Labor and Pensions, Dec. 4.

S. 2979 (VETERANS' HEALTH), to extend eligibility for hospital care, medical services and nursing home and domiciliary care for certain veterans who served in a theater of combat operations; **WALSH**; to the Committee on Veterans' Affairs, Dec. 4.

S. 2980 (MEDICARE), to amend Title XVIII of the Social Security Act to modify payment under Medicare for outpatient department procedures that utilize drugs as supplies, and for other purposes; **MENENDEZ**; to the Committee on Finance, Dec. 4.

H.R. 5797 (APPROPRIATIONS), to make a supplemental appropriation for the Public Health Emergency Fund, and for other purposes; **DELAURO**; jointly, to the committees on Appropriations and the Budget, Dec. 4.