



Health Policy Briefing

May 19, 2014

House Reconvenes to Focus on Appropriations and Senate Follows Suit

Appropriations Actions

The Senate Appropriations Committee and the Agriculture/Food and Drug Administration (FDA) and Military Construction/Veterans Affairs (VA) subcommittees will be hard at work this week to finalize their fiscal year (FY) 2015 appropriations bills. The full Appropriations Committee will also set FY 2015 302(b) allocations (i.e., spending caps) for all subcommittees on Thursday which are expected to include about \$4 billion in spending reductions to be spread over several of the subcommittees. The Senate will also continue the consideration of the House-passed bill, H.R. 3474, which the body intends to use as a vehicle to pass various tax extensions (the bill would allow employers to disregard employees with TRICARE coverage from being considered in connection with the Patient Protection and Affordable Care Act's (PPACA) employer mandate). It is possible that the repeal of the PPACA medical device tax could be debated in connection with the tax extenders legislation. The House Agriculture/FDA Appropriations Subcommittee will also mark up its FY 2015 appropriations bill.

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PPACA Health Reform Update

Confirmation in Senate of New HHS Secretary Appears to be a Lock

At the second hearing on the President's nomination to succeed Kathleen Sebelius as the Secretary of the U.S. Department of Health and Human Services (HHS), Sylvia Mathews Burwell heard praise from Senate Finance Committee Republicans and Democrats as to her qualifications and "outstanding character". When Chairman Ron Wyden (D-OR) asked the nominee about the pending bipartisan legislation which would replace the current sustainable growth rate (SGR) Medicare physician payment system, she said she is "excited about the opportunity that we can work together to get a permanent solution..." if confirmed, but was noncommittal as to the timing of the legislation this year. At Senator Orrin Hatch's (R-UT) urging, she said she would want to learn about the individual circumstances in the states provided PPACA funding to establish their PPACA state-run exchanges and that she would use the full extent of the law to get back funds that were misused by states or contractors. Senators Barrasso (R-WY) and Hatch (R-UT) have introduced legislation which aims to obtain such refunds from states with failed exchanges and they have also asked the Center for Medicare and Medicaid Services (CMS) to provide them with information about the failed exchanges in Maryland, Massachusetts, Oregon and Nevada and how the agency intends to oversee state-run exchanges in the future.

CMS Issues Final Marketplace Rules

CMS released final PPACA-related regulations, *Exchange and Insurance Market Standards for 2015 and Beyond*, which among other things: standardizes insurer notices to consumers when coverage is renewed or discontinued; requires insurers to provide data to enable the issuance of quality ratings and make coverage determinations within 24 hours on non-covered drugs for enrollees with conditions that jeopardize their life, health or ability to regain maximum function; sets rules when states can forgo providing "employee choice" in their Small Business Health Options Program (SHOP) marketplaces for plan years beginning in 2015 and requires SHOP open enrollment periods to align with individual enrollment periods; increases the ceiling on allowable administrative costs under the insurer risk corridor program; sets allocation rules for PPACA reinsurance payments when there is a shortfall in fee collections under the program; and clarifies the rules for navigators and the interaction with state laws. CMS also released frequently asked questions (FAQs) with respect of other PPACA requirements, including: essential health benefits (EHB); the actuarial value of plan coverage; mental health parity; guaranteed availability; and transitional policy extensions of plans that don't comply with the law for employers with 51-100 employees and for individuals.

Medicare/Medicaid/PHSA Corner

House Republicans Complain to CMS about MA Cuts

In a letter to the CMS Administrator House Energy and Commerce Republicans again expressed their concern that the cuts to Medicare Advantage (MA) pursuant to PPACA will likely result in fewer benefits and choices and higher premium and cost-sharing costs for beneficiaries, particularly minorities, and asked the agency how it will respond to this situation. They released a Congressional Research Service (CRS) report showing that minorities are more likely to be enrolled in an MA plans than fee-for-service (FFS) Medicare.

Senate Veterans' Affairs Committee Hearing on Alleged VA Abuses

The Senate Veterans' Affairs Committee grilled the VA Secretary, Gen. Eric Shinseki, on the problems plaguing the agency's provision of health care which it is alleged has caused the deaths of 40 patients in Phoenix who were waiting for care to be delivered. Senator John McCain (R-AZ) said that the Administration has not taken appropriate action in connection with the "scandal" that has apparently now expanded to ten states. However, Chairman Bernard Sanders (I-VT) said that there has been a little rush to judgment and that an independent VA Office of Inspector General (OIG) investigation should be completed before action is taken to dismiss any of the VA leadership. Despite Gen. Shinseki's statement that "Any allegations like this make me mad as hell," sixteen House Republicans called for the resignation of the Secretary. Subsequently, the VA's Undersecretary for Health, Dr. Robert Petzel, did have his letter of resignation accepted by Gen. Shinseki.

CMS Coverage Decision on Mitral Valve Device

CMS issued a proposed national coverage decision rule under which Medicare would cover a particular transcatheter mitral valve repair device "for the treatment of significant symptomatic mitral regurgitation" under certain conditions and when it is furnished in accordance with FDA-approved indications.

FDA Issues

House Caucus on Generic Medicine Announced

Reps. Peter Welch (D-VT) and Keith Rothfus (R-PA) registered a new "Congressional Affordable Medicines Caucus" and asked other members to join with the eight bipartisan members of the caucus to "promote the increased use of high-quality, affordable medicines as a way to lower health care costs."

FDA Draft Guidance on Biosimilars

The FDA released draft guidance to aid manufacturers in developing clinical pharmacology programs designed to show that a proposed biosimilar isn't clinically "meaningfully different" from a branded product. The guidance includes a discussion of approaches for developing appropriate clinical pharmacology databases and the utility of modeling and simulation for designing clinical trials. Comments are due by August 12th.

Upcoming Health-Related Hearings and Markups

House Appropriations Agriculture, Rural Development, FDA, and Related Agencies Subcommittee: will mark up the FY 2015 Agriculture Appropriations bill. 10 a.m., 2362-A Rayburn; May 20.

Senate Appropriations Agriculture, Rural Development, FDA, and Related Agencies Subcommittee: will mark up the FY 2015 Agriculture Appropriations bill. 3 p.m., location TBA; May 20.

Senate Appropriations Military Construction, Veterans Affairs and Related Agencies Subcommittee: will mark up the FY 2015 Military Construction and Veterans Affairs Appropriations bill. 11 a.m., 124 Dirksen; May 20.

House Government Operations Subcommittee of House Oversight and Government Reform Committee: will hold a hearing on autism spectrum disorders. 9 a.m., 2247 Rayburn; May 20.

House Energy Policy, Health Care and Entitlements Subcommittee of House Oversight and Government Reform Committee: will hold a hearing on Medicare management. 9:30 a.m., 2154 Rayburn; May 20.

House Ways and Means Health Subcommittee: will hold a hearing on current hospital issues in the Medicare program, including Centers for Medicare and Medicaid Services' two-midnights policy, short inpatient stays, auditing and appeals; 9:30 a.m., 1100 Longworth Bldg.; May 20.

House Energy and Commerce Health Subcommittee: will hold a hearing titled "21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation;" 10:00 a.m., 2322 Rayburn Bldg.; May 20.

House Energy and Commerce Health Subcommittee: will hold a hearing titled "Keeping the Promise: Site of Service Medicare Payment Reforms;" 10:15 a.m., 2123 Rayburn Bldg.; May 21.

Senate Special Aging Committee: will hold a panel discussion titled "Continuing the Conversation: The Role of Health Care Providers in Advance Care Planning;" 10:00 a.m., 106 Dirksen Bldg.; May 21.

Senate Appropriations Committee: will mark up FY 2015 Agriculture, Rural Development, Food and Drug Administration appropriations bill. 10 a.m., 106 Dirksen; May 22.

Senate Appropriations Committee: will mark up the FY 2015 Military Construction and Veterans Affairs bill. 10 a.m., 106 Dirksen; May 22.

Senate Appropriations Committee: will mark up the FY 2015 302(b) allocations. 10 a.m., 106 Dirksen; May 22.

Health Legislation Recently Introduced

H.R. 4625 (MEDICARE), to amend Title XVIII of the Social Security Act to suspend the application of the rebasing of Medicare home health prospective payment amounts, and for other purposes; HALL; jointly, to the committees on Ways and Means and Energy and Commerce, May 9.

H.R. 4627 (MEDICARE), to amend Title XVIII of the Social Security Act to authorize coverage of post-mastectomy, water-resistant coverings if they are determined to be consistent with clinical protocol or medically necessary to reduce the risk of infection, and for other purposes; POSEY; jointly, to the committees on Energy and Commerce and Ways and Means, May 9.

H.R. 4630 (TRICARE), to amend Title 10, U.S. Code, to provide for certain behavioral health treatment under TRICARE for children and adults with developmental disabilities, and for other purposes; LARSON of Connecticut; to the Committee on Armed Services, May 9.

H.R. 4631 (AUTISM), to reauthorize certain provisions of the Public Health Service Act relating to autism, and for other purposes; SMITH of New Jersey; to the Committee on Energy and Commerce, May 9.

H.R. 4633 (HEALTH INSURANCE PREMIUMS), to amend Title XXVII of the Public Health Service Act to require certain health insurance premium increase information submitted to the secretary of health and human services be disclosed to Congress; GRIFFITH of Virginia; to the Committee on Energy and Commerce, May 9.

H.R. 4639 (INFANT MORTALITY), to authorize funding for the creation and implementation of infant mortality pilot programs in standard metropolitan statistical areas with high rates of infant mortality, and for other purposes; COHEN; to the Committee on Energy and Commerce, May 9.

S. 2316 (VETERANS' HEALTH), to require the inspector general of the Department of Veterans Affairs to submit a report on wait times for veterans seeking medical appointments and treatment from the Department of Veterans Affairs, to prohibit closure of medical facilities of the Department and for other purposes; THUNE; to the Committee on Veterans' Affairs, May 12.

H.R. 4656 (TRICARE), to amend Title 10, U.S. Code, to improve access to mental health services under the TRICARE program; GARDNER; to the Committee on Armed Services, May 13.

H.R. 4658 (CIVIL MONEY PENALTIES), to amend Title XI of the Social Security Act to eliminate civil money penalties for inducements to physicians to limit services that are not medically necessary, and for other purposes; MCDERMOTT; jointly, to the committees on Ways and Means and Energy and Commerce, May 13.

H.RES. 584 (FOOD ALLERGIES), expressing support for the designation of May 11 through May 17 as Food Allergy Awareness Week; ISRAEL; to the Committee on Energy and Commerce, May 13.

S. 2333 (TRICARE), to amend Title 10, U.S. Code, to provide for certain behavioral health treatment under TRICARE for children and adults with developmental disabilities; MURRAY; to the Committee on Armed Services, May 14.

S. 2339 (REFORM), to amend the PPACA to require states with failed American Health Benefit Exchanges to reimburse the federal government for amounts provided under grants for the establishment and operation of such exchanges; BARRASSO; to the Committee on Finance, May 14.

S. 2348 (MEDICARE), to amend Title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening; BROWN; to the Committee on Finance, May 15.

Health Legislation Recently Introduced cont.

S. 2353 (MEDICARE), to amend Title XVIII of the Social Security Act to provide for patient protection by establishing safe nurse staffing levels at certain Medicare providers, and for other purposes; MERKLEY; to the Committee on Finance, May 15.

H.R. 4663 (MEDICARE), to amend Title XVIII of the Social Security Act to permit certain nurse practitioners, clinical nurse specialists, physician assistants and certified nurse-midwives to provide certain certifications with respect to inpatient hospital services under Medicare; BLACK; to the Committee on Ways and Means, May 15.