HHS

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Policy Briefi

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Congress Misses Budget Resolution Deadline

ongress missed the April 15 statutory deadline to approve a budget and begin the process of passing annual spending bills. Conservative Republicans in the House continue to argue in favor of lower spending levels, against those who want to align with the \$1.07 trillion discretionary spending level passed in last year's bipartisan budget agreement. Nevertheless, Speaker of the House Paul Ryan (R-Wis.) maintains that the House will adhere to regular order, and House appropriators continue to make progress on individual spending bills for fiscal year (FY) 2017, despite the slim chances of these bills making it to the floor in the near future. Law allows House appropriations bills to proceed to the floor after May 15 in the absence of a budget resolution. The full House Appropriations Committee advanced funding for the Military Construction-Veterans Affairs (MilCon/VA) last week, using the spending levels outlined in in the 2015 budget deal. The details of the House FY 2017 Agriculture/FDA spending bill were also released. The \$21.3 billion spending bill is \$451 million less than FY 2016 levels and \$281 million below the president's request. The Food and Drug Administration (FDA) would receive a \$33 million increase over FY 2016 levels, and the budget would approve the collection of \$64 million in extra user fees over last year, resulting in a total budget of \$4.478 billion, \$300 million less than requested in the President's budget. The bill provides \$10 million in funding through the FDA for continued Zika and Ebola response activities. The spending bill would require the FDA to begin incorporating post-market patient experience into its review of new drugs, and establish an expedited review process for certain medical devices.

Meanwhile, Majority Leader Mitch McConnell (R-Ky.) announced that he would begin moving appropriations bills to the Senate floor this week, likely starting with Energy-Water. The budget agreement allows the Senate the option of simply naming the budget limits for the individual spending bills between April 15 and May 15, so that the chamber can proceed under regular order while the budget

resolution continues to be negotiated. The Senate could use House-passed FY 2016 appropriations as vehicles for FY 2017 in order to avoid procedural challenges requiring appropriations bills to originate in the House. If floor action begins this week, it would be the earliest consideration of a spending bill in the chamber

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since the modern budget process began in the 1970s. The Senate's first spending bill, for MilCon/VA was advanced out of subcommittee and full Committee last week. The draft bill provides \$177.4 billion in discretionary and mandatory funding for the VA, which includes increases for health care as well as medical and prosthetic research. This funding would be a \$14.7 billion increase above FY 2016 and \$160 million above the President's request. The Senate also disclosed the 12-subcommittee spending allocations, known as 302(b) allocations, in preparation for consideration of spending bills on the floor. The 302(b) spending allocation for the Agriculture/FDA bill is \$21.25 billion, down from \$21.75 billion in FY 2016. The Labor/HHS/Education allocation is \$161.9 billion, down from \$162.1 billion. The remainder of the allocations are as follows:

- Commerce-Justice-Science would receive \$56.285 billion, up from \$55.7 billion.
- Defense would receive \$515.95 billion, up from \$514.1 billion in current base spending, and \$58.6 billion in overseas contingency operations spending, equal to the current level.
- Energy and Water would receive \$37.5 billion, up from \$37.2 billion.
- Financial Services would receive \$22.4 billion, down from \$23.2 billion.
- Homeland Security would receive \$41.2 billion, up from \$40.96 billion.
- Interior-Environment would receive \$32 billion, down slightly from \$32.2 billion.
- Legislative Branch would receive \$4.4 billion, about the same as current levels.
- Military Construction-VA would receive \$83 billion, up from \$79.9 billion.
- State-Foreign Operations would receive \$37.2 billion in base funding and \$14.9 billion in overseas contingency operations funding for a total of \$52.1 billion, down from \$52.7 billion.
- Transportation-HUD would receive \$56.5 billion, down from \$57.3 billion.

The allocations were approved 29-1, with Sen. Jerry Moran (R-Kan.) voting no.

Zika Update

Cenior health officials announced last week that the threat of the Zika virus is wider than originally thought, and that • the mosquitos that carry and transmit the virus are present in as many as 30 states, up from the original 12 predicted. Additionally, it is now believed that the virus can affect women throughout their entire pregnancy, rather than just during their first trimester, according to the Centers for Disease Control and Prevention (CDC). The CDC went on to officially confirm that there is conclusive evidence that the Zika virus increases the risk of the birth defect known as microcephaly. Officials also said that there is a growing link between the virus and neurological conditions as well as premature birth. The Administration continues to reiterate their request for \$1.9 billion in emergency funding to combat the virus, especially in areas like Puerto Rico, where hundreds of thousands of cases are expected. Also last week, the House of Representatives passed by voice vote S. 2512, the Adding Zika Virus to the FDA Priority Review Voucher Program Act. The bill will add the virus to the list of tropical diseases under the program, which awards a voucher to the sponsor of a new drug or biological that is approved to treat or prevent a tropical disease. The voucher can be used to get an expedited review of any drug of the sponsor's choosing, or be sold on the open market. The voucher could get a drug on the market up to three months sooner than it normally would. The legislation passed the Senate by unanimous consent last month. While the White House has said that the President will sign the bill, it was nonetheless criticized by the administration for its lack of actual dollars to combat the virus. Although the House Appropriations Committee rejected a Democratic attempt to attach such emergency supplemental funding to the Military Construction-Veterans Affairs (MilCon/VA) appropriations bill, Chairman Harold Rogers (R-Ky.) noted that staff has begun work on separate Zika legislation, and the panel went on to approve a substitute amendment that would direct the administration to use unobligated Ebola funding in the immediate future for the purpose of fighting Zika.

Changes Possible to Part B Proposed Payment Model

Chief Medical Officer for the Centers for Medicare and Medicaid Services (CMS) Patrick Conway has said that the agency is open to suggestions on the major elements of the Medicare Part B proposal that would change the way doctors are paid to administer drugs in their offices. Concerns about the size and the scope of the Part B plan have been raised by lawmakers, including, Senate Finance Chairman Orrin Hatch (R-Utah), House Ways and Means Committee Chairman Kevin Brady (R-Texas), and House Energy and Commerce Chairman Fred Upton (R-Mich.). CMS is accepting comments on the proposed model through May 9.

HHS Report Indicates Small Premium Increases

A new **report** from the U.S. Department of Health and Human Services (HHS) indicates that insurance premiums on the exchanges will rise by four percent on average for people receiving tax credits under the Affordable Care Act (ACA). For the 15 percent of people not receiving tax credits, premiums will increase by eight percent on average. These are relatively small increases compared to the double-digit premium hikes initially proposed by insurers. The report highlights that 43 percent of consumers returning to HealthCare.gov chose a new plan for 2016 and were able to reduce their premiums.

Director of Precision Medicine Cohort Selected

Eas Director of the Precision Medicine Initiative (PMI) Cohort Program. He will lead the National Institutes of Health's (NIH) work on a longitudinal study of one million volunteers to advance precision medicine. Mr. Dishman was a part of the PMI Working Group that developed the design for this research study. In addition to his experience in the private sector, Mr. Dishman himself has benefited from access to precision medicine during his 23-year battle with a rare form of kidney cancer.

Analysis Shows Rising Out-of-Pocket Costs for Consumers

A new **report** from the Kaiser Family Foundation indicates that out-of-pocket costs are rising for consumers of employer-sponsored health coverage. Employees have seen these costs rise by 77 percent between 2004 and 2014, while the plans' average payment per enrollee only increased by 58 percent. Plans paid for 85.3 percent of covered medical expenses in 2014, a decrease from 86.7 percent in 2004. The increase in workers' deductibles is most responsible for this rise in out of pocket spending, increasing from \$99 in 2004 to \$353 in 2014. Payments towards coinsurance rose 107 percent, while payments for copays decreased by 26 percent.

Conservatives Push for Elimination of Lame Duck Session

Conservative leaders and lawmakers, headed by Sen. Ted Cruz (R-Texas), are seeking to eliminate the lame-duck congressional session that would take place following the November elections. They fear that this time period could be used to confirm Merrick Garland, the President's Supreme Court nominee, or to move legislation supported by President Obama, such as the Trans-Pacific Partnership (TPP) trade deal. A letter is currently being circulated that urges Speaker of the House Paul Ryan (R-Wis.) and Senate Majority Leader Mitch McConnell (R-Ky.) to promise that there will be no legislative session between Election Day and the start of the 115th Congress. When the 2016 congressional calendar was released early this year, it included dates for a lame duck session (Nov. 14 – Dec 16).

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Upcoming Congressional Meetings and Hearings

House Energy and Commerce Health Subcommittee hearing on "Medicare Access and CHIP Reauthorization Act of 2015: Examining Physician Efforts to Prepare for Medicare Payment Reforms;" 10:15 a.m., 2322 Rayburn Bldg.; April 19

House Veterans' Affairs Committee hearing: "A Continued Assessment of Delays in Veterans' Access to Health Care;" 10:30 a.m., 334 Cannon Bldg.; April 19

House Appropriations markup: FY 2017 Agriculture/FDA Bill, Energy and Water Bill, and Revised Report on the Interim Suballocation of Budget Allocations; 10:30 a.m., 2359 Rayburn Bldg.; April 19

House Veterans' Affairs Health Subcommittee hearing on: H.R. 2460; H.R. 3956; H.R. 3974; H.R. 3989; draft legislation to ensure that each VA medical facility complies with requirements relating to scheduling veterans for health care appointments and to improve the uniform application of directives; and, draft legislation to direct VA to establish a list of drugs that require an increased level of informed consent"; 10:00 a.m., 334 Cannon Bldg.; April 20

Senate Special Aging Committee hearing on the committee's investigation into the sudden, aggressive price spikes of decades-old prescription drugs; time and place TBA; April 27

Recently Introduced Health Legislation

H.R. 4916 (introduced by Rep. Poliquin): A bill to reauthorize the program of the Department of Veterans Affairs under which the Secretary of Veterans Affairs provides health services to veterans through qualifying non-Department health care providers; to the Committee on Veterans' Affairs; April 12

H.R. 4918 (introduced by Rep. Slaughter): A bill to direct the Secretary of Health and Human Services to issue guidance for the safe prescribing of opioids for the treatment of acute pain; to the Committee on Energy and Commerce; April 12

H.R. 4931 (introduced by Rep. Slaughter): A bill to direct the Attorney General to establish a national pharmaceutical stewardship program to facilitate the collection and disposal of prescription medications; to the Committee on Energy and Commerce; April 13

H. Res. 679 (introduced by Rep. Quigley): A resolution expressing support for designation of May 2016 as ``National Brain Tumor Awareness Month`'; to the Committee on Energy and Commerce; April 13

H. Res. 680 (introduced by Rep. Roybal-Allard): A resolution supporting the goals and ideals of National Public Health Week; to the Committee on Energy and Commerce; April 14

H.R. 4959 (introduced by Rep. Bucshon): A bill to direct the Secretary of Health and Human Services to conduct a study on the designation of surgical health professional shortage areas; to the Committee on Energy and Commerce; April 15

H.R. 4965 (introduced by Rep. Ted Lieu of California): A bill to amend the Federal Food, Drug, and Cosmetic Act to enhance medical device communications and ensure device cleanliness; to the Committee on Energy and Commerce; April 15

H.R. 4966 (introduced by Rep. Ted Lieu of California): A bill to establish requirements for reusable medical devices relating to cleaning instructions and validation data, and for other purposes; to the Committee on Energy and Commerce; April 15

- H.R. 4969 (introduced by Rep. Meehan): A bill to amend the Public Health Service Act to direct the Centers for Disease Control and Prevention to provide for informational materials to educate and prevent addiction in teenagers and adolescents who are injured playing youth sports and subsequently prescribed an opioid; to the Committee on Energy and Commerce; April 15
- S.2771 (introduced by Sen. James M. Inhofe): A bill to amend title 38, United States Code, to expand the qualifications for licensed mental health counselors of the Department of Veterans Affairs; to the Committee on Veterans' Affairs; April 11
- S.2772 (introduced by Sen. Tammy Baldwin): A bill to eliminate the requirement that veterans pay a copayment to the Department of Veterans Affairs to receive opioid antagonists or education on the use of opioid antagonists; to the Committee on Veterans' Affairs; April 11
- S.2777 (introduced by Sen. Bill Cassidy): A bill to modernize the prescription verification process for contact lenses, to clarify consumer protections regarding false advertising of contact lenses, and for other purposes; to the Committee on Commerce, Science, and Transportation; April 11
- S. 2782 (introduced by Sen. Blunt): A bill to amend the Public Health Service Act to provide for the participation of pediatric subspecialists in the National Health Service Corps program, and for other purposes; to the Committee on Health, Education, Labor, and Pensions; April 12
- S. 2786 (introduced by Sen. Capito): A bill to amend title XVIII of the Social Security Act to provide for payments for certain rural health clinic and Federally qualified health center services furnished to hospice patients under the Medicare program; to the Committee on Finance; April 13
- S. 2787 (introduced by Sen. Warner): A bill to amend title XIX of the Social Security Act to provide the same level of Federal matching assistance for every State that chooses to expand Medicaid coverage to newly eligible individuals, regardless of when such expansion takes place; to the Committee on Finance; April 13
- S. 2799 (introduced by Sen. Menendez): A bill to require the Secretary of Health and Human Services to develop a voluntary patient registry to collect data on cancer incidence among firefighters; to the Committee on Health, Education, Labor, and Pensions; April 14
- S. 2803 (introduced by Sen. Sasse): A bill to require the Secretary of Health and Human Services to deposit certain funds into the general fund of the Treasury in accordance with provisions of Federal law with regard to the Patient Protection and Affordable Care Act's Transitional Reinsurance Program; to the Committee on Health, Education, Labor, and Pensions; April 14