



Health Policy Briefing

February 12, 2018

Lawmakers Reach Budget Cap Agreement, Fund Government Through March 23

Following a brief partial government shutdown, the Senate passed the latest continuing resolution -- *Bipartisan Budget Act of 2018* -- by a vote of 71-28 in the early hours of Friday morning, followed promptly by passage in the House of Representatives by a vote of 240-186, and ultimately signed by the President Friday morning. The bill extends government funding at current levels through March 23, and lawmakers hope to use the interim time to negotiate a complete omnibus spending bill to fund the government through September 30, the remainder of fiscal year (FY) 2018. The *Bipartisan Budget Act of 2018* raises the budgetary spending caps on defense and domestic spending first imposed in 2011, which will increase federal spending by almost \$300 billion. The budget agreement also suspends the debt ceiling for a year (until March 1, 2019). Sen. Rand Paul's (R-Ky.) protest of the spending increases delayed the Senate voting process for several hours causing Congress to miss the midnight funding deadline, which resulted in a short government shutdown.

The bipartisan budget agreement includes a number of important public health and health care priorities:

- **Community Health Centers.** \$7.8 billion is provided to fully fund Community Health Centers (CHC) for two years.
- **CHIP.** The six-year funding extension for the Children's Health Insurance Program (CHIP) that Congress passed last month is extended to a full decade of funding for the program.
- **Medicaid DSH Payments.** Scheduled reductions to Medicaid Disproportionate Share Hospital (DSH) payments will be delayed for two years.
- **Medicare Therapy Caps.** Medicare therapy caps are permanently repealed.
- **Enhanced Medicaid for Puerto Rico/Virgin Islands.** Medicaid caps for Puerto Rico and the U.S. Virgin Islands will be increased by \$4.9 billion for two years as they recover from hurricane damage.
- **IPAB Repeal.** The bill repeals the Independent Payment Advisory Board (IPAB) created in the Affordable Care Act.
- **Physician Update.** The budget agreement cut in half the 2019 Medicare physician fee schedule increase from 0.5 percent to 0.25

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percent. The reduction will cost doctors \$105 million in Medicare reimbursements in 2019 and a total of \$1.85 billion over the next decade. The Medicare Access and CHIP Reauthorization Act (MACRA), which replaced the sustainable growth rate (SGR), specified that physicians would receive an annual increase of 0.5 percent from 2016 through 2019, followed by five years of no annual increases. The budget deal passed by Congress will impact the last year of MACRA's scheduled annual increases.

- **MA Bonus Payments.** The deal limits the ability of Medicare Advantage (MA) plans to artificially boost their star rating bonus payments by consolidating a low star plan with a plan that has received a higher star rating. The Centers for Medicare and Medicaid Services (CMS) will be required to calculate a weighted average across the two plans to determine a more accurate star rating. The change is estimated to reduce insurer payments by \$520 million over the next decade, or 0.3 percent of annual payments to MA plans.
- **MACRA Technical Changes.** The bill grants CMS flexibility in applying the 30 percent resource use performance score for three years, while also providing the agency three additional years to ensure a gradual and incremental transition to the performance threshold. The bill also makes technical corrections to the application of the Merit-based Incentive Payment System (MIPS) to covered professional services. Finally, the agreement updates the ability of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) to further aid the development of physician led alternative payment models.

The bipartisan budget agreement increases the budget caps allowing for additional funds for certain health priorities to be executed as a part of omnibus appropriations for FY 2018 and subsequent appropriations in FY 2019. This includes a total of \$6 billion (\$3 billion for each of the fiscal years 2018 and 2019) to combat the **substance abuse epidemic**. These funds will enhance state grants, public prevention programs, and law enforcement activities related to opioids and mental health care. Congress has also given \$2 billion in budget authority to increase support for the **National Institutes of Health** (NIH) and additional scientific research for fiscal years 2018 and 2019. The bill provides \$4 billion for fiscal years 2018 and 2019 to address the backlog of claims at the Department of **Veterans Affairs** health centers. Language from a number of other health care provisions was included in the final bill, including:

- H.R. 3935, the Bolstering Organizations and Options to Support Training in Primary Care Act (BOOST Primary Care Act), providing FY 2018 and FY 2019 funding for the National Health Service Corps;
- H.R. 3394, the Teaching Health Centers Graduate Medical Education Extension Act, providing FY 2018 and FY 2019 funding for Teaching Health Centers;
- H.R. 3924, to amend the Public Health Service Act to extend funding for the special diabetes program for type I diabetes, providing FY 2018 and FY 2019 funding;
- H.R. 3917, to amend the Public Health Service Act to extend funding for the special diabetes program for Indians, providing FY 2018 and FY 2019 funding;
- H.R. 3900, the Youth Empowerment Act, providing FY 2018 and FY 2019 funding for Title V Sexual Risk Avoidance Education;
- H.R. 938, the Medicaid Third Party Liability Act;
- H.R. 3263, to extend the Medicare Independence at home Medical Practice Demonstration program for two additional years;
- H.R. 1148, the Furthering Access to Stroke Telemedicine Act of 2017;
- H.R. 3163, the Medicare Part B Home Infusion Services Temporary Transitional Payment Act;
- H.R. 3271, the Protecting Access to Diabetes Supplies Act of 2017;
- H.R. 2465, the Steve Gleason Enduring Voices Act of 2017;
- H.R. 3245, the Medicare Civil and Criminal Penalties Act;
- H.R. 3120, to reduce the volume of future electronic health record-related significant hardship requests;
- H.R. 829, the Prioritizing the Most Vulnerable Over Lottery Winners Act of 2017; and
- H.R. 4430, to provide temporary direct hire authority for certain emergency response positions.

The final legislation dropped a provision opposed by the medical provider community that would have extended Medicare's misvalued code initiative from 2018 to 2019. The deal does not include any measures to stabilize the individual health insurance market, but supporters are hopeful that such provisions will be included as a part of a long-term spending bill.

WH Budget to be Released Today, Expected to Include Drug Pricing Provisions

The fiscal year (FY) 2019 budget process is set to begin today, when the President is scheduled to release the White House budget. According to some reports, the budget will take into account the recent changes to the overall discretionary caps, per the recent passage of the *Bipartisan Budget Act of 2018*. The President's budget request is expected to include a number of proposals aimed at lowering prescription drug costs for Medicare and Medicaid beneficiaries. The measure would reportedly allow seniors enrolled in Medicare Part D to share in rebates that drug companies pay to insurers and pharmacy benefit managers for the individual drugs that they purchase at the pharmacy and would also expand Medicare's catastrophic drug benefit. In Medicare Part B, U.S. Department of Health and Human Services (HHS) Secretary Alex Azar wants to modify the payment rate for newly launched, physician-administered drugs. He is also looking at potential changes to the 340B drug discount program and to the 180-day exclusivity period for the first generic manufacturer to challenge a particular brand patent. Additionally, the budget will request that Congress grant HHS authority to allow five state Medicaid programs to try and negotiate lower drug costs, including through formulary utilization. It will also ask for a revision of Medicaid's definition of generic and over-the-counter (OTC) drugs.

February 21 Event: Thought Leaders, Experts Converge on Washington to Address Unsustainable Rise in Health Care Costs

On February 21 leaders from every sector of health care will convene at the West Health Healthcare Costs Innovation Summit to generate new ideas, innovations and practical policy prescriptions that will change the trajectory of the cost of healthcare in America. "*Taking Bold Action and Creating Accountability to Solve Our Nation's Healthcare Costs Crisis*," will include keynotes Steve Forbes, Chairman and Editor-in-Chief of Forbes Media; Sanjay Gupta, MD, Chief Medical Correspondent, CNN; and Andy Slavitt, Former Acting Administrator for the Centers for Medicare and Medicaid Services. Andy Slavitt will focus on the urgent need to solve the cost crisis so that health care can become more accessible and more affordable for all Americans. For more information and to register for this free public event, visit hcidc.org.

Sanders Requests Opioid Hearing with Pharma CEOs

Sen. Bernie Sanders (I-Vt.) sent a **letter** this week to the Chairman of the Health, Education, Labor, and Pensions (HELP) Committee Sen. Lamar Alexander (R-Tenn.) requesting that the committee hold a hearing to examine the role of pharmaceutical companies in exacerbating the nation's opioid epidemic. Citing the precedent of a 1994 hearing in the House of Representatives that consisted of witnesses from the country's largest tobacco companies, Sanders argued that the hearing would shine a light on the pharmaceutical industry that could lead to similar improvements in public health oversight. Sanders also notes that he plans to introduce legislation "to prohibit marketing and illegal distribution practices with respect to opioids, create public accountability for these companies and the CEOs, and require companies to reimburse the economic impact of their products."

President Picks White House Staffer for Drug Czar Job

This week, the Trump Administration announced their intention to nominate current White House Deputy Chief of Staff Jim Carroll to be the Director of the Office of National Drug Control Policy (ONDCP), a position commonly referred to as the "Drug Czar." Carroll has served in his current role in the West Wing for three months, and previously worked in the U.S. Treasury and Justice Departments, and as a private-sector attorney. The Administration's first nominee for the Drug Czar position, Pennsylvania Congressman Tom Marino, withdrew himself from consideration after it was reported that he sponsored legislation making it easier for drug companies to distribute opioids throughout the country. The Administration officially named Carroll as the deputy director of the drug office on Friday, where he will serve as Acting Director during his confirmation process in the Senate.

NIH/Opioid Research Legislation Introduced

On Thursday, a bipartisan group of Senators from the Health, Education, Labor, and Pensions (HELP) Committee jointly introduced legislation that would provide more flexible authority at the National Institutes of Health (NIH) to advance research needed to combat the nation's opioid epidemic. The Advancing Cutting-Edge (ACE) Research Act (S. 2406) was introduced by committee Chairman Lamar Alexander (R-Tenn.), Ranking Member Patty Murray (D-Wash.), Sen. Todd Young (R-Ind.), and Sen. Maggie Hassan (D-N.H.). The bill gives the Director of the NIH, Dr. Francis Collins, authority to approve projects using other transaction authority for cutting-edge research, with the goal of increasing scientific understanding and leading to ways to prevent, treat, diagnose and cure disease. This authority includes support for research that is urgently required to respond to public health threats such as the opioid crisis, including the science to develop a non-addictive opioid painkiller. The legislation builds on investments in NIH research from the 21st Century Cures Act (P.L. 114-225) and the Comprehensive Addiction and Recovery Act (P.L. 114-198).

Right-to-Try Gains Traction, Hits Roadblocks

Following President Trump's endorsement of right-to-try legislation during his January 30th State of the Union Address, the bill (S. 204) has gained the attention of leadership from the House of Representatives. The bill's bicameral sponsors, Sen. Ron Johnson (R-Wis.), Rep. Andy Biggs (R-Ariz.), and Rep. Brian Fitzpatrick (R-Pa.) recently met with Speaker of the House Paul Ryan (R-Wis.), House Majority Leader Kevin McCarthy (R-Cal.), and House Energy and Commerce Committee Chairman Rep. Greg Walden (R-Ore.) to discuss the bill. The legislation would prevent the government from blocking access to drugs that have only undergone preliminary testing in humans.

While the House leadership has received a letter of support signed by more than 40 House Members, the proposal is facing pushback from several stakeholder groups. On Tuesday, a **letter** signed by 38 patient advocacy groups urged bipartisan House leaders to oppose the legislation if it is brought to the House floor. The groups argue that this approach is not likely to increase access to experimental therapies for patients in need, and would likely do more harm than good. They note that the bill would remove the Food and Drug Administration (FDA) from the process of facilitating increased access to unapproved medicines, which currently approves 99.7 percent of expanded access requests. They also argue that denials generally come from drug companies.

The bill was passed by unanimous consent in the Senate last year, and House leadership have reportedly expressed private support to the bill's sponsors, but the House Energy and Commerce Committee has continued to work on their own right-to-try proposal. While many in the House want the bill to receive an immediate floor vote, the sponsors have stated their commitment to moving the bill through the process of regular order. This would allow for committee hearings and amendments before the bill is voted on by the entire chamber. FDA Administrator Scott Gottlieb, MD, who has raised concerns on the bill regarding the scope of who would qualify for experimental drugs, said that the agency is committed to finding a solution that works on behalf of patients and has provided technical assistance to multiple proposals that are currently being considered on Capitol Hill.

Upcoming Congressional Hearings and Meetings

Senate HELP Committee hearing “Improving Animal Health: Reauthorization of FDA Animal Drug User Fees;” 10:00 a.m., 430 Dirksen Bldg.; February 13

House Ways and Means Committee hearing on President Trump’s fiscal year 2019 budget proposals for the Department of Health and Human Services; 10:00 a.m., 1100 Longworth Bldg.; February 14

House Energy and Commerce Oversight Subcommittee hearing “Examining the Impact of Health Care Consolidation;” 10:15 a.m., 2322 Rayburn Bldg.; February 14

Senate Finance Committee hearing “The President’s Fiscal Year 2019 Budget;” 9:00 a.m., 215 Dirksen Bldg.; February 15

House Judiciary Subcommittee on Immigration and Border Security hearing “The Effect of Sanctuary City Policies on the Ability to Combat the Opioid Epidemic;” 9:00 a.m., 2141 Rayburn Bldg.; February 15

House Committee on Education and the Workforce Subcommittee on Health, Employment, Labor, and Pensions hearing “The Opioids Epidemic: Implications for America’s Workplaces;” 10:00 a.m., 2175 Rayburn Bldg.; February 15

House Energy and Commerce Health Subcommittee hearing “Oversight of the Department of Health and Human Services;” 12:30 p.m., 2123 Rayburn Bldg.; February 15

Recently Introduced Health Legislation

H.Res.721 (introduced by Rep. Debbie Dingell): Expressing support for designation of February 4, 2018, as National Cancer Prevention Day; Energy and Commerce

H.Res.722 (introduced by Rep. Bobby Rush): Supporting the goals and ideals of “Black Women’s Heart Health Awareness Week;” Oversight and Government Reform

H.R.4922 (introduced by Rep. James F. Sensenbrenner): To amend the Controlled Substances Act to list fentanyl analogues as schedule I controlled substances; Energy and Commerce, Judiciary

H.R.4938 (introduced by Rep. Ann. M. Kuster): To address the opioid epidemic, and for other purposes; Energy and Commerce, Judiciary, Ways and Means, Education and the Workforce, Budget

H.R.4955 (introduced by Rep. Richard E. Neal): To provide certain protections from civil liability with respect to the emergency administration of opioid overdose drugs; Judiciary

H.Res.731 (introduced by Rep. Barbara Lee): Supporting the goals and ideals of National Black HIV/AIDS Awareness Day; Energy and Commerce

H.R.4957 (introduced by Rep. Linda T. Sanchez): To provide better care and outcomes for Americans living with Alzheimer’s disease and related dementias and their caregivers while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure; Energy and Commerce, Ways and Means

H.R.4964 (introduced by Rep. Debbie Dingell): To amend the Federal Food, Drug, and Cosmetic Act to require that children’s cosmetics containing talc include an appropriate warning unless the cosmetics are demonstrated to be asbestos-free, and for other purposes; Energy and Commerce

S.2387 (introduced by Sen. Shelley Moore Capito): A bill to provide better care and outcomes for Americans living with Alzheimer’s disease and related dementias and their caregivers while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure; Finance

S.2406 (introduced by Sen. Lamar Alexander): A bill to advance cutting-edge research initiatives of the National Institutes of Health; Health, Education, Labor, and Pensions

S.2410 (introduced by Sen. John Thune): A bill to amend the Internal Revenue Code of 1986 to permit high deductible health plans to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible; Finance

H.R. 4978 (introduced by Rep. Diane Black): A bill to amend the Internal Revenue Code of 1986 to permit high deductible health plans to provide chronic disease prevention services to plan enrollees prior to satisfying their plan deductible; Ways and Means

H.R. 4987 (introduced by Rep. Michael C. Burgess): A bill to amend title XVIII of the Social Security Act to provide for technical amendments to the Merit-based Incentive Payment System under Medicare; Energy and Commerce, Ways and Means

H.R. 4993 (introduced by Rep. Mike Kelly): A bill to amend the Internal Revenue Code of 1986 to authorize the designation of additional taxable vaccines; Ways and Means