



Health Policy Briefing

March 26, 2018

Congress Passes FY 2018 Omnibus, Avoids Government Shutdown

Congress approved a \$1.3 trillion omnibus-spending bill last week before adjourning for a two-week recess. H.R. 1625, the Consolidated Appropriations Act (a.k.a., the “omnibus”) funds the government through the end of the current fiscal year (FY) -- September 30, 2018. It includes \$695 billion in defense funding and \$591 billion in nondefense funding. Lawmakers faced a March 23 deadline to pass a funding package to avoid a partial federal government shutdown. The omnibus passed the House of Representatives on Thursday by a vote of 256-167. The Senate passed the bill in the early hours of Friday morning by a vote of 65-32.

Conservatives threatened to delay proceedings due to concerns about the nation’s rising debt and deficit, criticizing the speed at which the 2,232-page bill was considered. Enough Republicans ultimately opposed the massive spending bill to require the support of Democrats in both chambers for passage. Because the omnibus is one of the final must-pass pieces of legislation before the November midterm elections, the release of the bill was delayed as members attempted to attach other issues to the bill.

Democratic leadership withdrew their previous demands that protections for Dreamers under the Deferred Action for Childhood Arrivals (DACA) program be included as a part of the FY 2018 omnibus. Instead, they called for both Republican and Democratic appropriators to drop all controversial poison-pill riders from the omnibus, like stricter immigration provisions, to avoid another government shutdown.

The **U.S. Department of Health and Human Services (HHS)** will receive \$88.1 billion in FY 2018, a \$10 billion increase compared to FY 2017 levels.

The omnibus will increase appropriations for the **National Institutes of Health (NIH)** to a total of \$37 billion in FY 2018. The additional \$3 billion is the largest funding increase for the agency in more than 15 years. The budget deal guaranteed at least a \$1 billion raise for NIH in FY 2018 and 2019, but lawmakers decided to increase investment in the agency even further. The omnibus includes an additional \$414 million for Alzheimer’s research, an

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additional \$40 million for research on a universal flu vaccine, and \$140 million more for brain research.

The **Centers for Disease Control and Prevention** (CDC) will receive \$8.3 billion, a \$1.1 billion increase over current spending.

The **Agency for Healthcare Research and Quality** (AHRQ) is provided with \$334 million, a \$10 million increase over FY 2017 levels. Rather than including the agency within the NIH, as the Trump budget proposed, the bill instead includes language requiring a study of how AHRQ can better coordinate with the federal health services research enterprise. The study will also identify research gaps and areas for consolidation at the agency and is required to be sent to Congress within one year.

The omnibus includes \$4 billion to fund prevention, treatment, and enforcement efforts for the **opioid epidemic** across HHS, Homeland Security, Justice, and Veterans Affairs. This includes \$1 billion in new grants for states and tribes, at least \$500 million for new opioid research at the NIH, an increase of \$350 million for related efforts at the CDC, \$130 million for the Rural Communities Opioid Response Program, and a nearly \$300 million increase for law enforcement grant funding to combat the epidemic. Congress rejected the White House's proposal to cut the Office of National Drug Control Policy (ONDCP) by 95 percent.

The omnibus includes more than \$2.3 billion in new spending for **mental health** programs, and will fund nearly 30 mental health provisions contained in the 21st Century Cures Act, including the Mental Health Block Grant, the National Traumatic Stress Network, the National Child Traumatic Stress Initiative, mental and behavioral health training grants, assisted outpatient treatment, and the National Suicide Prevention Lifeline.

The bill also includes funding for **gun-violence prevention measures** in schools. Seventy-five million dollars is allocated to train school employees to respond to an attack, purchase metal detectors, and create systems for reporting threats to schools. An additional \$100 million will be provided for such purposes between 2019 and 2028. Also included in the legislation was the stand-alone Fix NICS Act, which creates incentives and penalties to increase reporting to the Federal Bureau of Investigation's (FBI) National Instant Criminal Background Check System (NICS), which is already required under existing law and bars people with severe mental health conditions from purchasing a firearm. The omnibus report language also clarifies that the CDC is permitted to research the causes of gun violence as a public health issue. The agency had restricted research on gun violence as a result of its interpretation of the Dickey Amendment, which has been attached to government funding bills for more than two decades and states "none of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control."

The omnibus package includes \$249 million for the **Federal Emergency Management Agency's** pre-disaster mitigation program.

The omnibus also requires the Administration to publish information on the number of employees and contractors involved in the implementation and administration of the **Affordable Care Act** (ACA).

Despite assurances from White House budget director Mick Mulvaney that the measure had the support of the Administration, President Trump threatened to veto the omnibus funding package the morning after Senate passage of the bill, citing the absence of protections for DACA beneficiaries and inclusion of only a fraction of the money requested for border security and construction of a wall between the U.S. and Mexico. Despite the veto threat, President Trump signed the bill just hours later, while also calling on Congress to allow the President to make line-item vetoes on government spending bills and to end the Senate's filibuster rules.

The Senate is scheduled to reconvene on April 9, and the House of Representatives will return on April 10.

Lawmakers at Impasse on ACA Stabilization

One dispute during omnibus negotiations involved the possible inclusion of a measure to stabilize the Affordable Care Act's (ACA) individual health insurance market. Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.), House Energy and Commerce Committee Chairman Greg Walden (R-Ore.), Sen. Susan Collins (R-Maine) and Rep. Ryan Costello (R-Pa.) strongly pushed for the inclusion of their **proposal**, which would allocate \$30 billion over three years for the creation of high-risk pools. The plan would increase flexibility for states through reforms to the 1332 waiver process, pare back copper health plans, allow insurers to sell across state lines, expand access to some short-term insurance plans that don't meet ACA coverage requirements, and fund three-years of cost sharing payments for those earning less than 250 percent of the federal poverty limit (FPL). The plan also included language applying the Hyde Amendment, which restricts federal money from being spent on abortion, to any funds aimed at lowering Obamacare premiums. Democrats argued that this would prevent the government from spending money on any insurance plan that offered coverage for abortion. Democrats also opposed the Administration's short-term insurance expansion proposal, and sought to block it through the stabilization measure, not codify it. While President Trump reportedly expressed his support for funding health insurance subsidies within the omnibus, the House left the stabilization proposal out of their funding bill and HELP Committee Ranking Member Patty Murray (D-Wash.) blocked the amendment to the spending bill in the Senate. Although Murray said that she believes a compromise is still possible, Sens. Alexander and Collins expressed doubt that an agreement could be reached before insurers set their premium rates for 2019. Congressional action to stabilize the market is supported by a wide range of health care stakeholders, including America's Health Insurance Plans (AHIP), the American Hospital Association (AHA), and the American Medical Association (AMA), who wrote to House and Senate leadership last week urging passage of the fix.

White House Unveils Strategy to Combat Opioid Epidemic

The White House released the President's **Initiative to Stop Opioid Abuse and Reduce Drug Supply and Demand** last week. The Administration's three-pronged approach aims to slow overprescribing, reduce the supply of illicit drugs, and increase access to evidence-based treatment for those suffering from addiction. Many of the policies contained in the plan stem from the recommendations of the President's Opioid Commission released in November. The Administration's goal is to reduce the number of opioid prescriptions by one-third nationwide over the next three years.

The White House proposal would tighten the number of prescriptions that can be reimbursed in the Medicaid program. It would also create and incentivize states to move to a national prescription drug monitoring system. The plan calls for increasing first responders' supply of naloxone and expanding the use of medication assisted treatment (MAT). All federal inmates would be tested for opioid addiction and provided options for treatment upon completion of their sentences. The plan also includes new public outreach to deter drug use. The Administration expresses opposition to medically supervised drug consumption, noting the lack of evidence supporting the efficacy of such facilities.

The plan would also apply stiffer penalties for drug traffickers, including the death penalty, when appropriate under current law. The Administration calls on Congress to reduce the threshold for mandatory minimum sentencing on fentanyl dealers, and more aggressively police the Internet and mail for fentanyl purchases and shipments.

President Trump outlined the plan during a speech in New Hampshire last Monday. His remarks stressed the importance of tougher penalties for drug dealers and traffickers, eliminating sanctuary cities, and strengthening border protections to prevent drugs coming in from Mexico. During his remarks, the President called for increased funding for the development of non-addictive painkillers, and indicated that the Justice Department is considering federal litigation against opioid manufacturers. He also stated that drug companies would provide free naran to schools. The President's focus on punitive measures drew criticism from many public health stakeholders, who believe that underscoring a law enforcement approach overshadows the more important measures of the Administration's plan that are widely supported by addiction advocates.

Although the President stated his intent to spend "the most money ever on the opioid crisis," it remains unclear how the proposals contained in the White House's strategy will be paid for. The Administration has stated that negotiations

with Congress are underway on specific funding allocations.

There were a number of other opioid-related activities on Capitol Hill last week. The acting head of the Drug Enforcement Administration (DEA) testified about the agency's role in combating the opioid epidemic and alleged pill-dumping in West Virginia before the House Energy and Commerce Oversight and Investigations Subcommittee on Tuesday, and the House Energy and Commerce Committee considered 25 opioid-related bills over the course of a two-day hearing. The Committee aims to bring a bipartisan legislative package to the House floor by Memorial Day.

Administration Teases Drug Pricing Plan

During his speech to unveil the White House's strategy to combat the opioid crisis, President Trump also announced that he is planning a major news conference on the issue of prescription drug prices. The President blamed pharmaceutical companies and the drug distribution system for the rising cost of prescription medicines and criticized the high cost of treatments in the U.S. compared with prices for the same products in other countries. The Administration's plan, expected to be released in about a month, aims to decrease the cost of drugs and reform pharmacy benefit manager (PBM) discounts to the advantage of individual patients. Secretary of the U.S. Department of Health and Human Services (HHS) Alex Azar noted that the Administration's plan will also include a request for input from stakeholders, and stated that his goal is to bring down list prices and achieve the best net prices for government programs and private insurers.

In related news, Secretary Azar has reportedly hired Daniel Best, Vice President of CVS Caremark, to head the Department's effort to lower drug prices. While an official announcement has not been made, Best was added to the HHS staff directory as Senior Advisor to the Secretary for Drug Pricing Reform. Best headed CVS' Medicare Part D business, and previously worked as Director of Business Development for Pfizer.

Right-to-Try Bill Passes House

The House of Representatives passed H.R. 5247, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act, by a vote of 267-149 last week. Thirty-five Democrats voted for the bill, and two Republicans opposed it. The legislation would allow terminally ill patients who are ineligible for clinical trials and who have exhausted other available treatments to request access to experimental medicines that have not yet been approved by the Food and Drug Administration (FDA). Patients could request access to medicines without the permission of or oversight from the agency as long as the product has gone through a small-scale clinical trial and is currently under FDA consideration. The House attempted to pass the bill through expedited process last week but could not garner the two-thirds majority necessary for success.

Many Democrats oppose the bill because of concerns about patient safety. House Energy and Commerce Committee Ranking Member Frank Pallone (D-N.J.) pushed for adoption of an alternative proposal that would encourage pharmaceutical manufacturers to use the FDA's existing compassionate use program, but the plan did not gain any traction. Four former FDA commissioners also spoke out against right-to-try last week, arguing that the policy would erode protections for vulnerable patients. Commissioners Robert Califf and Margaret Hamburg, who served during the Obama Administration, and Mark McClellan and Andrew von Eschenbach, who served during the George W. Bush Administration, contend that there is no evidence that right-to-try would meaningfully improve access to treatments for patients.

Following Senate passage of the omnibus, Sen. Ron Johnson (R-Wis.) pushed for a vote on H.R. 5247, but Senate Minority Leader Chuck Schumer (D-N.Y.) objected. Johnson then called on the House to pass S. 204, his own version of the bill, which unanimously passed the Senate last year. Right-to-try is strongly supported by Vice President Pence and was cited as a priority for President Trump in his State of the Union address.

President Appoints New CDC Director

The White House announced the appointment of Robert Redfield, MD to be Director of the Centers for Disease Control and Prevention (CDC) and Administrator of the Agency for Toxic Substances and Disease Registry (ATSDR). Redfield worked as an HIV/AIDS researcher for two decades at Walter Reed Army Institute of Research and co-founded the Institute of Human Virology. He previously served on President George W. Bush's advisory council on HIV/AIDS and was also an advisor to the NIH during the Bush Administration. The White House touted Redfield's recent experience running a treatment network for HIV and Hepatitis C patients in Baltimore as good preparation for leading the CDC's efforts to combat the opioid crisis. Former CDC Director Brenda Fitzgerald resigned in January follow reports that she had traded tobacco, drug, and food stocks while heading the agency. The position does not require Senate confirmation.

Senate Health, Education, Labor, and Pensions (HELP) Committee Ranking Member Patty Murray (D-Wash.) has expressed concerns about Redfield's past support for a number of controversial policies, such as mandatory patient HIV testing in the 1980s, and **urged** the Administration to reconsider its choice of candidates.

Latest Staff Changes at HHS

John Bardis, Assistant Secretary of Administration at the U.S. Department of Health and Human Services (HHS), has announced plans to resign effective April 6. Bardis' office has been the subject of an internal probe by the Office of the Inspector General (OIG) for signing off on the use of charter-jet flights for routine domestic travel, leading to the resignation of former HHS Secretary Tom Price. Bardis indicated that he plans to return to the private sector. It remains unclear who will be responsible for Bardis' portfolio at HHS following his departure.

It was also announced that John Brooks, counselor to the Secretary, is moving to a position on the White House Domestic Policy Council. At HHS, Brooks was responsible for advising the Secretary on drug pricing, the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the Agency for Healthcare Research and Quality (AHRQ), and the Office of the Assistant Secretary for Planning and Evaluation (ASPE). John O'Brien, Deputy Assistant Secretary at ASPE, will assume Brooks' former position.

MS Governor Announces Cochran's Replacement

Mississippi Commissioner of Agriculture and Commerce Cindy Hyde-Smith has been picked by Governor Phil Bryant (R) to fill the seat vacated by Sen. Thad Cochran (R-Miss.), who announced his resignation from the Senate last week amid health challenges. Hyde-Smith will serve in his place until a replacement is picked in the November 6 election. The winner of the special election will serve the remainder of Cochran's term, which ends in January 2021.

Lawmakers Request Info on Medicaid Rebate Program

A group of bipartisan members of the House Energy and Commerce Committee and Senate Finance Committee have **written** to the Centers for Medicare and Medicaid Services (CMS) regarding agency oversight of the Medicaid drug rebate program. The lawmakers express concerns about the misclassifications of certain prescription drugs that have resulted in inappropriately high Medicaid expenditures. The Office of the Inspector General (OIG) found that misclassifications of 10 drugs cost the Medicaid program \$1.3 billion in improper rebates. The lawmakers request more information on what steps CMS has taken to address these errors, and whether the agency needs broader authority to ensure better compliance with current law.

Recently Introduced Health Legislation

S.Res.437 — A resolution supporting the goals of World Tuberculosis Day to raise awareness about tuberculosis. Sponsor: Sen. Brown, Sherrod [D-OH]. Committees: Senate - Foreign Relations

S.Res.439 — A resolution supporting the goals and ideals of Multiple Sclerosis Awareness Week. Sponsor: Sen. Casey, Robert P., Jr. [D-PA]. Committees: Senate - Health, Education, Labor, and Pensions

S.2567 — A bill to amend the Public Health Service Act to enhance the national strategy for combating and eliminating tuberculosis, and for other purposes. Sponsor: Sen. Brown, Sherrod [D-OH]. Committees: Senate - Health, Education, Labor, and Pensions

S.2568 — A bill to amend section 5000A of the Internal Revenue Code of 1986 to provide an additional religious exemption from the individual health coverage mandate, and for other purposes. Sponsor: Sen. Brown, Sherrod [D-OH]. Committees: Senate - Finance

H.R.5324 — To improve school safety and mental health services, and for other purposes. Sponsor: Rep. Ferguson, A. Drew, IV [R-GA-3]. Committees: House - Education and the Workforce

H.R.5327 — To amend title V of the Public Health Service Act to establish a grant program to create comprehensive opioid recovery centers, and for other purposes. Sponsor: Rep. Guthrie, Brett [R-KY-2]. Committees: House - Energy and Commerce

H.R.5329 — To amend the Public Health Service Act to reauthorize and enhance the poison center national toll-free number, national media campaign, and grant program, and for other purposes. Sponsor: Rep. Brooks, Susan W. [R-IN-5]. Committees: House - Energy and Commerce

H.R.5333 — To amend the Federal Food, Drug, and Cosmetic Act to clarify the regulatory framework with respect to certain nonprescription drugs that are marketed without an approved new drug application, and for other purposes. Sponsor: Rep. Latta, Robert E. [R-OH-5]. Committees: House - Energy and Commerce

S.2575 — A bill to amend title XVIII of the Social Security Act to provide for treatment of audiologists as physicians for purposes of furnishing audiology services under the Medicare program, to improve access to the audiology services available for coverage under the Medicare program and to enable beneficiaries to have their choice of a qualified audiologist to provide such services, and for other purposes. Sponsor: Sen. Warren, Elizabeth [D-MA]. Committees: Senate - Finance

S.2579 — A bill to amend the Public Health Service Act to reauthorize and expand a program of surveillance and education, carried out by the Centers of Disease Control and Prevention, regarding infections associated with injection drug use. Sponsor: Sen. Young, Todd C. [R-IN]. Committees: Senate - Health, Education, Labor, and Pensions

H.R.5343 — To amend the Public Health Service Act to nullify certain contractual provisions prohibiting or penalizing a pharmacist's disclosure of the availability of therapeutically equivalent alternative drugs, or alternative methods of purchasing the prescription drug, that are less expensive, and for other purposes. Sponsor: Rep. Carter, Earl L. "Buddy" [R-GA-1]. Committees: House - Energy and Commerce

H.R.5353 — To amend the Public Health Service Act to reauthorize and expand a program of surveillance and education, carried out by the Centers for Disease Control and Prevention, regarding infections associated with injection drug use. Sponsor: Rep. Lance, Leonard [R-NJ-7]. Committees: House - Energy and Commerce

S.2582 — A bill to provide health insurance reform, and for other purposes. Sponsor: Sen. Warren, Elizabeth [D-MA]. Committees: Senate - Finance

S.Res.451 — *A resolution recognizing the significance of endometriosis as an unmet chronic disease for women and designating March 2018 as “Endometriosis Awareness Month”. Sponsor: Sen. Duckworth, Tammy [D-IL]. Committees: Senate – Judiciary*

S.2589 — *A bill to amend title V of the Public Health Service Act to establish a grant program to create comprehensive opioid recovery centers, and for other purposes. Sponsor: Sen. Hassan, Margaret Wood [D-NH]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2597 — *A bill to amend the Public Health Service Act to reauthorize the program of payments to children’s hospitals that operate graduate medical education programs, and for other purposes. Sponsor: Sen. Casey, Robert P., Jr. [D-PA]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2606 — *A bill to require the Secretary of Health and Human Services to award grants for training health professionals to treat opioid addiction and other substance use disorders through using technology-enabled models, and for other purposes. Sponsor: Sen. Schatz, Brian. Committees: Senate - Health, Education, Labor, and Pensions*

S.2608 — *A bill to provide that a risk evaluation and mitigation strategy communication plan may include information about Federal and State prescribing requirements for controlled substances. Sponsor: Sen. Warren, Elizabeth [D-MA]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2609 — *A bill to amend the Public Health Service Act to provide grants for State alcohol and drug agencies to use recovery coaches in hospital emergency departments, and for other purposes. Sponsor: Sen. Murphy, Christopher [D-CT]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2610 — *A bill to require the Secretary of Health and Human Services to provide coordinated care to patients who have experienced a non-fatal overdose after emergency department discharge, and for other purposes. Sponsor: Sen. Capito, Shelley Moore [R-WV]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2613 — *A bill to amend title XVIII of the Social Security Act to improve access to mental health services under the Medicare program. Sponsor: Sen. Stabenow, Debbie [D-MI]. Committees: Senate – Finance*

S.2615 — *A bill to establish an interagency One Health Program, and for other purposes. Sponsor: Sen. Smith, Tina [D-MN]. Committees: Senate - Health, Education, Labor, and Pensions*

S.2622 — *A bill to require directors of medical facilities of the Department of Veterans Affairs to submit plans to the Secretary of Veterans Affairs on how to improve such facilities, and for other purposes. Sponsor: Sen. Inhofe, James M. [R-OK]. Committees: Senate - Veterans’ Affairs*

S.2626 — *A bill to clarify the requirements for receiving certain grants through the National Mental Health and Substance Use Policy Laboratory. Sponsor: Sen. Young, Todd C. [R-IN]. Committees: Senate - Health, Education, Labor, and Pensions*

H.Res.805 — *Supporting the goals and ideals of National Public Health Week. Sponsor: Rep. Roybal-Allard, Lucille [D-CA-40]. Committees: House - Energy and Commerce*

H.R.5385 — *To amend the Public Health Service Act to reauthorize the program of payments to children’s hospitals that operate graduate medical education programs, and for other purposes. Sponsor: Rep. Green, Gene [D-TX-29]. Committees: House - Energy and Commerce*

H.R.5397 — *To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to furnish, at the request of an eligible veteran, nursing home care and hospital care at State licensed or certified residential care facilities. Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]. Committees: House - Veterans’ Affairs*