



## Health Policy Briefing

January 22, 2018

### Government Shutdown Begins Amidst Funding Lapse

Lawmakers have spent recent weeks debating a series of funding measures to avoid a government shutdown, but were unable to reach an agreement to keep the government open past January 19. In the absence of a spending plan, the federal government began to shut down non-essential operations at midnight on Friday.

Earlier in the week, House Republicans introduced a stopgap-spending bill (H.R. 195) that would fund the government through President's Day. The GOP's continuing resolution (CR) was intended to provide more time for Congress to agree upon a broader spending deal – a trillion-dollar omnibus bill that would fund the government through the end of the fiscal year (FY). H.R. 195 would have funded the Children's Health Insurance Program (CHIP) for six years. It also would have delayed several Obamacare taxes to gain the support of some Republicans hesitant to support a fourth CR in as many months. The plan would have delayed the medical device tax and the Cadillac tax for two-years as well as the health insurance tax for one year starting in 2019. The House successfully passed the CR by a vote of 230-197 on Thursday, with 11 Republicans in opposition and six Democrats crossing the aisle to support.

The government funding debate was complicated by disagreements among party leaders and President Trump over immigration reform. Senate Democrats demanded a permanent solution to maintain protections under the Deferred Action for Childhood Arrivals (DACA) program for the 700,000 young, undocumented immigrants known as Dreamers, which the White House previously rescinded with a delayed implementation until the end of March. Majority Leader Mitch McConnell (R-Ky.), however, has stated he will not schedule a vote on any immigration compromise that does not have the support of President Trump. Since the President reportedly rejected a bipartisan immigration deal last week, DACA negotiations have been at a standstill.

At least nine Senate Democrats were needed to advance the stopgap spending measure with the required 60 votes, but the Senate lacked the necessary support to stop government funding from formally lapsing. The procedural motion on the

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bill failed by a vote of 50-49. Five Democrats voted to advance the bill – Sens. Joe Manchin (W.Va.), Joe Donnelly (Ind.), Heidi Heitkamp (N.D.), Claire McCaskill (Mo.), and Doug Jones (Ala.). A number of Senate Republicans also withheld support for the House-passed bill, citing the negative impact temporary funding patches have on the military and defense. Republicans Rand Paul (Ky.), Lindsey Graham (S.C.), Mike Lee (Utah), and Jeff Flake (Ariz.) voted against the bill, while Sen. McCain (R-AZ) was unable to vote due to his ongoing cancer treatment.

Both the House and the Senate were in session over the weekend, but a vote has yet to be scheduled on reopening the federal government. Republicans appear to be insisting on reopening the government before resuming negotiations on immigration, while Democratic support continues to be attached to assurances of DACA protections.

A bipartisan group of 20 Senate centrists was working Sunday on a compromise plan to get the government funded for three more weeks while the immigration debate continues. But there was no assurance that party leaders -- or the House -- would go along. The group is pulling together a proposal to extend stopgap funding for the government through February 8. The deal also would guarantee of a separate vote on legislation to put into law a program that protects from deportation some of the undocumented immigrants brought to the U.S. as children, a central demand of Democrats. If the temporary funding plan gets the assent of McConnell and Schumer, there is a good chance an immigration bill could pass the Senate. Then it would be taken up in the House, where immigration hardliners show no signs of budging. President Donald Trump, who could give Republicans political cover to vote for immigration legislation, has been giving conflicting signals. Republican Senator **Lindsey Graham**, who's been one of the main negotiators on immigration, said White House staff are now demanding \$33 billion for border security when Trump said last week he could make a deal for less than \$18 billion.

According to the **plans** released by the U.S. Department of Health and Human Services (HHS), approximately half the staff at HHS will be furloughed. The Medicare and Medicaid programs will be largely unaffected by the shutdown, at least in the short term and payments will be made to eligible states from the remaining Children's Health Insurance Program (CHIP) carryover balances. The National Institutes of Health (NIH) will continue patient care for current NIH Clinical Center patients, but will not admit new patients (unless deemed medically necessary by the NIH Director), initiate new protocols, or take any actions on grant applications or awards. The Food and Drug Administration (FDA) will stop conducting routine inspections and cease some compliance and enforcement activities. FDA will maintain critical consumer protection to handle emergencies, high-risk recalls, civil and criminal investigations, import entry review, and other critical public health issues. The Centers for Disease Control and Prevention (CDC) will have a significantly reduced capacity to respond to outbreak investigations, processing of laboratory samples, and maintaining the agency's 24/7 emergency operations center. CDC staff will continue to support the ongoing hurricane response and World Trade Center Health Program. CDC activities that are supported by funding not impacted by the shutdown include: U.S. President's Emergency Plan for AIDS Relief (PEPFAR), CDC's Global AIDS program, the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), Vaccines for Children (VFC) program, certain asbestos exposure in Libby, Montana, Ebola response and preparedness, and Global Health Security Agenda implementation.

A new POLITICO/Morning Consult poll, conducted Thursday and Friday found more voters would blame Republicans in Congress for the government shutdown (41 percent) than would blame Democrats (36 percent). Democratic and Republican voters, by wide margins, held the other side responsible, but more independents said they would blame Republicans (34 percent) than Democrats (27 percent). Yet the shutdown is no clean political win for Democrats. Americans don't necessarily approve of the party's strategy to insist on a legislative solution for undocumented immigrants brought here as children before voting to reopen the government. In fact, both parties' immigration stances — Democrats' efforts to protect the so-called Dreamers and Trump's insistence on funding a border wall with Mexico — are viewed by voters as less important than keeping the government open.

## ***GAO Releases Report on Generic Complex Drugs***

The Government Accountability Office (GAO) recently released a **report** recommending that the Food and Drug Administration (FDA) update the public about the agency's plans to issue and revise guidance on non-biological complex drugs. The GAO recognized the steps taken by the FDA to address the unique challenges of generic non-biological complex drug approval, but encourages the agency to announce its plans to issue and revise product-specific guidance for drugs that are non-biological and complex. The U.S. Department of Health and Human Services (HHS) concurred with the recommendations contained within the report. The report was also praised by House Energy and Commerce Health Subcommittee Chairman Michael Burgess (R-Texas) and Ranking Member Gene Green (D-Texas).

## ***Senate Committees Advance HHS Nominees***

The Senate Finance Committee has advanced the nomination of Alex Azar to serve as Secretary of the U.S. Department of Health and Human Services (HHS). Republicans on the Committee were united in support of the nomination, with Sen. Tom Carper (D-Del.) being the only Democrat unopposed in the 15-12 roll call vote. Democratic opposition to the nomination largely stems from Azar's former ties to the pharmaceutical industry and doubts that he can lead the effort to lower the nation's rising drug prices. While a full Senate floor vote has not yet been scheduled, lawmakers hope to confirm Azar by the end of the month.

The Senate Health, Education, Labor, and Pensions (HELP) Committee advanced the nomination of Brett Giroir to be Assistant Secretary of Health. The nomination was approved by voice vote, despite objections by Democrats on the Committee. Ranking Member Patty Murray (D-Wash.) and her colleagues have expressed concerns about the nominee's ability to oversee the Department's programs on women's health in light of the current administration's ideological position on issues such as family planning and teen pregnancy. Giroir's nomination now awaits action by the full Senate.

## ***IRS to Provide Medical Device Tax Relief***

The Internal Revenue Service (IRS) announced that it would provide companies with nine months of relief from penalties resulting from a failure to pay the medical device tax. The 2.3 percent tax on medical devices created by the Affordable Care Act (ACA) was suspended in 2016 and 2017. The first installment of the tax is due on January 29, but the IRS announced that it won't apply penalties for failure to make the deposit during the first three quarters of 2018, due to the short time frame between the end of the moratorium period and the due date of the first deposit.

## ***E&C Subcommittee Advances Three Health Bills***

The House Energy and Commerce Health Subcommittee advanced three bills last week relating to public health and medical professionals. The Good Samaritan Health Professionals Act (H.R. 1876), which would shield health care professionals from liability when they volunteer during a federally declared disaster, was passed by voice vote and now awaits full Committee action.

The Pharmaceutical Information Exchange (PIE) Act (H.R. 2026) would clarify how drug and device companies can share information as it relates to an investigational use of a drug or device. The bill was reported to the full Committee by a vote of 18-14. Republican committee members argued that the bill would help ensure faster access to new treatments and cures, but many Democrats on the subcommittee expressed concerns about the legislation's potential to compromise patient safety.

The Subcommittee also considered a discussion draft of the Over-the-Counter (OTC) Monograph Safety, Innovation, and Reform Act. The bill would modernize the Food and Drug Administration's (FDA) OTC monograph framework and establish a user fee program for regulation of such OTC consumer health products. The Committee print was agreed to by voice vote and now awaits full Committee action.

## ***Opioid Emergency Declaration Extended***

**A**cting Secretary of the U.S. Department of Health and Human Services (HHS) Eric Hargan has signed a 90-day extension of the Administration's previous declaration of the opioid misuse and abuse crisis as a public health emergency. The renewal is effective January 24.

## **Upcoming Congressional Hearings and Meetings**

***Senate Health, Education, Labor, and Pensions (HELP) Committee hearing "Facing 21st Century Public Health Threats: Our Nation's Preparedness and Response Capabilities, Part II;" 10:00 a.m., 430 Dirksen Bldg.; January 23***

***Senate Homeland Security and Governmental Affairs Permanent Subcommittee on Investigations hearing to examine combatting the opioid crisis, focusing on exploiting vulnerabilities in international mail; 10:00 a.m., 342 Dirksen Bldg.; January 25***

## **Recently Introduced Health Legislation**

***H.J.Res.125 (introduced by Rep. Rodney P. Frelinghuysen): Making an extension of continuing appropriations for fiscal year 2018, and for other purposes; Appropriations, Ways and Means, Budget***

***H.R.4808 (introduced by Rep. Ed Perlmutter): To promote transparency in health care pricing; Energy and Commerce***

***S.2312 (introduced by Sen. Bill Cassidy): A bill to provide a moratorium on registration of new non-rural section 340B hospitals and associated sites, and for other purposes; Health, Education, Labor, and Pensions***

***S.2315 (introduced by Sen. Johnny Isakson): A bill 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; Health, Education, Labor, and Pensions***

***S.2317 (introduced by Sen. Edward J. Markey): A bill to amend the Controlled Substances Act to provide for additional flexibility with respect to medication-assisted treatment for opioid use disorders, and for other purposes; Health, Education, Labor, and Pensions***

***H.Res.702 (introduced by Rep. Janice D. Schakowsky): Recognizing the roles and the contributions of America's Certified Registered Nurse Anesthetists (CRNAs) and their role in providing quality healthcare for the public; Energy and Commerce***

***H.R.4820 (introduced by A. Donald McEachin): To extend funding for certain public health programs, and for other purposes; Energy and Commerce, Ways and Means***

***H.R.4825 (introduced by Rep. Rob Bishop): To improve medical research on marijuana; Energy and Commerce, Judiciary***

***H.R.4831 (introduced by Rep. Barbara Comstock): To extend the moratorium on the annual fee on health insurance providers; Ways and Means, Education and the Workforce***

***H.R.4841 (introduced by Rep. David Schweikert): To amend title XVIII of the Social Security Act to provide for electronic prior authorization under Medicare part D for covered part D drugs, and for other purposes; Energy and Commerce, Ways and Means***