



## Health Policy Briefing

April 9, 2018

### HELP Releases Bipartisan Draft Opioid Legislation

Leadership of the Senate Health, Education, Labor, and Pensions (HELP) Committee released a bipartisan discussion draft of legislation aimed at combating the opioid epidemic and improving data sharing between states. The proposal is the result of six hearings held by the Committee this Congress to examine how the federal government can better partner with states and communities dealing with the opioid crisis. A full summary of the Opioid Crisis Response Act can be found [here](#). Notably, the bill will

- Improve the regulatory pathway to develop non-addictive and non-opioid painkillers and other strategies to prevent and treat substance use disorders through additional flexibility for the National Institutes of Health (NIH) and guidance from the Food and Drug Administration (FDA);
- Clarify FDA authority to require manufacturers to package opioids in smaller quantities and to require manufacturers to give patients simple and safe options to dispose of unused opioids;
- Improve the detection and seizure of illegal drugs at the border through stronger FDA and Customs and Border Protection (CBP) coordination;
- Support improvement of state prescription drug monitoring programs (PDMPs) and encourage state data sharing on opioid prescribing and dispensing;
- Update how certain grants are administered so as to increase allotments for states hit hardest by the crisis and allow states to use funding until it runs out, instead of requiring it to be spent during a single year;
- Require the U.S. Department of Health and Human Services (HHS) to examine the impact of state laws that limit the length and dosage of opioid prescriptions; and
- Improve access to telemedicine and addiction treatment in rural and underserved areas.

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The Committee will hold a hearing on the draft

legislation on April 11, and requests comments on the bill from interested stakeholders be sent to [HelpFightsOpioids@help.senate.gov](mailto:HelpFightsOpioids@help.senate.gov) by the date of the hearing. Chairman Lamar Alexander (R-Tenn.) hopes to markup the legislation this spring.

### ***E&C to Consider Medicaid, Part B, Part D Bills in Final Opioid Hearing***

The House Energy and Commerce Health Subcommittee announced the bills to be considered during its third and final legislative hearing to examine the opioid crisis. The hearing is titled “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care For Patients.”

The Subcommittee will examine the following bills pertaining to the Medicaid program:

- H.R. \_\_, Provide IMD Services Up to 90 Days for Medicaid Beneficiaries with SUD
- H.R. \_\_, the Medicaid Pharmacy Home Act
- H.R. \_\_, the Medicaid Drug Review, Utilization, Good governance (DRUG) Improvement Act
- H.R. \_\_, the Medicaid Providers And pharmacists Required To Note Experiences in Record Systems to Help In-need Patients (PARTNERSHIP) Act
- H.R. \_\_, Medicaid Incentives for Health Homes to Treat Substance Use Disorder
- H.R. \_\_, the Medicaid Institutes for Mental Disease Are Decisive in Delivering Inpatient Treatment for Individuals but Opportunities for Needed Access are Limited without Information Needed about Facility Obligations Act (The Medicaid IMD ADDITIONAL INFO Act)
- H.R. \_\_, the Improving Medicaid Data Timeliness Act
- H.R. \_\_, the Improving the Transparency for Graduate Medical Education Funded by Medicaid Act
- H.R. \_\_, the Medicaid Helping Unite Managers who have Abilities with Novel Chances to Activate the Possibilities of Innovation, Transformation, And Leadership (HUMAN CAPITAL)
- H.R. \_\_, Require HHS to act within a certain timeframe in implementing GAO’s recommendation for HHS to execute a strategy related to infants with neonatal abstinence syndrome
- H.R. 3192, the CHIP Mental Health Parity Act
- H.R. 4998, the Health Insurance for Former Foster Youth Act,
- H.R. \_\_, Creation of a demonstration project for five years for up to 10 states that have committed to Medicaid delivery system advancements through substance use disorder demonstration waivers
- H.R. \_\_, Require state Medicaid programs to report on the 10 behavioral health measures that are included in CMS’ 2018 Core Set of Adult Health Care Quality Measures for Medicaid.
- H.R. 4005, the Medicaid Reentry Act,
- H.R. \_\_, Allow women who are pregnant and enrolled in Medicaid or who are and post-partum mothers of newborns and enrolled in Medicaid to continue to receive Medicaid benefits when in an IMD (up to first 12 months after delivery)
- H.R. 1925, the At-Risk Youth Medicaid Protection Act

The Subcommittee will consider the following Part B bills:

- H.R. 3331, to amend title XI of the Social Security Act to promote testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology
- H.R. \_\_, Incentivizing Non-Opioid Drugs
- H.R. \_\_, CMS Action Plan
- H.R. \_\_, Use of Telehealth to Treat Opioid Use Disorder,
- H.R. \_\_, Alternative Payment Model for Treating Substance Use Disorder
- H.R. \_\_, Initial Pain Assessment
- H.R. \_\_, Adding Resources on Non-Opioid Alternatives to the Medicare Handbook
- H.R. \_\_, Post-Surgical Injections as an Opioid Alternative

Finally, the Subcommittee will consider the following Part D bills:

- H.R. 3528, the Every Prescription Conveyed Securely Act
- H.R. \_\_, Mandatory Lock-In

- H.R. 4841, the Standardizing Electronic Prior Authorization for Safe Prescribing Act
- H.R. \_\_, Beneficiary Education
- H.R. \_\_, Evaluating Abuse Deterrent Formulations
- H.R. \_\_, Prescriber Notification
- H.R. \_\_, Prescriber Education
- H.R. \_\_, Medication Therapy Management (MTM) Expansion
- H.R. \_\_, CMS/Plan Sharing

### ***Lawmakers Launch Cancer Drug Price Investigation***

A group of bipartisan senators is launching an investigation into why the price of lomustine has increased by 1,400 percent since 2013. Lomustine is used to treat brain tumors and Hodgkin lymphoma and was first introduced in 1976. It has no generic competition. Sens. Susan Collins (R-Maine), Claire McCaskill (D-Mo.), and Catherine Cortez Masto (D-Nev.) have **written** to the CEO of Tri-Source Pharma requesting more information about the price hike. The senators ask the company for details about expenses related to the sale of the drug, the drug's cost estimates and profit projections, and other drugs sold by the company that have increased in price by at least 200 percent in a single year. The cost of lomustine has been increased nine times since it was acquired by NextSource, a Tri-Source subsidiary, in 2013, when it cost \$50 per capsule. A capsule of the same dose now costs \$768.

### ***E&C Republicans Continue Nursing Home Investigation***

Republican leadership on the House Energy and Commerce Committee are continuing their probe into reports of abuse, neglect, and patient harm at skilled nursing facilities (SNFs) and nursing facilities (NFs) participating in the Medicare or Medicaid programs. The Committee's investigation into the issue began following the loss of 14 residents at a Florida nursing home in the wake of Hurricane Irma when the facility's air conditioning failed. The lawmakers **request** information from the Centers for Medicare and Medicaid Services (CMS) about the agency's role in overseeing SNFs and NFs and ensuring federal quality of care standards are being met. The letter was signed by Chairman Greg Walden (R-Ore.), Oversight and Investigations Subcommittee Chairman Gregg Harper (R-Miss.), Health Subcommittee Chairman Michael Burgess (R-Texas), and Committee member Rep. Gus Bilirakis (R-Fla.).

### ***Pallone Inquires on Drug Data Dashboards***

Ranking Member of the House Energy and Commerce Committee Frank Pallone (D-N.J.) has **written** to the Centers for Medicare and Medicaid Services (CMS) urging the agency to update its drug spending data dashboards. The dashboards provide information on how much the government spends on certain prescription drugs in the Medicare and Medicaid programs. They have not been updated since the Trump Administration began, which Pallone argues "raises questions about this Administration's supposed commitment to lowering the price of prescription drugs for the American people." Pallone requests that CMS provide the latest Medicare and Medicaid drug spending data from 2016. He also asks for an explanation for why the dashboards have not been updated and if and when the agency intends to do so.

### ***Proposed Tariffs May Impact Price of Drugs, Devices***

An increasing number of health care stakeholders are concerned that the President's proposed tariffs on products from China could result in significant increases in cost for dozens of drugs and medical devices. The Administration has proposed a 25 percent tariff on a list of Chinese-manufactured goods that includes supplies used to manufacture drugs and devices. Products like insulin, antidepressants, and epinephrine could be affected. Some of these drugs are already in short supply, and others have been criticized for recent increases in price. Additionally, one estimate indicates that 12 percent of medical devices imported into the U.S. come from China, and that the proposed tariffs could cost the medical device industry up to \$1.5 billion each year. It is still unclear whether the tariffs will be enacted or are a negotiating tactic.

### ***GAO Releases Report on Medicare Data Security***

The Government Accountability Office (GAO) has released a new **report** calling for increased oversight by CMS over the data security of beneficiary information. The report was initially requested by the House Energy and Commerce Committee. Although CMS has an oversight program in place for Medicare Administrative Contractor (MAC) data, it does not have a similar program to monitor the security of Medicare beneficiary data used by researchers and qualified entities. The GAO recommends that the agency issue additional guidance on required security controls and more routinely track its oversight efforts.

### ***Azar Announces HHS Staff Reorganization***

Secretary of the U.S. Department of Health and Human Services (HHS) Alex Azar has issued a memo detailing the downsizing of the Immediate Office of the Secretary (IOS). According to the memo, the goal of the reorganization is to “establish an effective operating structure that reduces duplication and permits more efficient operating division/staff division reporting and regulation development and clearance.” The change is intended to unify the operations of the Secretary and Deputy Secretary, and eliminate up to 40 percent of core IOS policy staff. Single points of contact will be created within the IOS for all operating and staff divisions.

### ***Surgeon General Issues Public Health Advisory on Naloxone***

Surgeon General Jerome Adams has issued a public health advisory urging increased access to naloxone. The public health advisory reads as follows: “I, Surgeon General of the United States Public Health Service, VADM Jerome Adams, am emphasizing the importance of the overdose-reversing drug naloxone. For patients currently taking high doses of opioids as prescribed for pain, individuals misusing prescription opioids, individuals using illicit opioids such as heroin or fentanyl, health care practitioners, family and friends of people who have an opioid use disorder, and community members who come into contact with people at risk for opioid overdose, knowing how to use naloxone and keeping it within reach can save a life.”

### ***CDC Releases Latest Data on Overdose Deaths***

The Centers for Disease Control and Prevention (CDC) has released a new **report** examining 2016 data on drug overdose deaths. Their analysis indicates that deaths increased in all categories of drugs examined, for both men and women, all people over age 15, across all races and ethnicities, and across different levels of urbanization. The CDC notes that synthetic opioids continue to play a significant role in the overdose epidemic.

### ***DEA Sets National Prescription Drug Take Back Day Locations***

The Drug Enforcement Administration (DEA) has announced the locations for the National Prescription Drug Take Back Day, which will be held on Saturday, April 28. Last October, the DEA collected over 912,000 lbs. of pills across 5,321 collection sites in its 14th prescription drug take back day. A collection site locator for the upcoming April event can be found **[here](#)**.

### ***DOJ Looks to Join Opioid Settlement***

The U.S. Department of Justice (DOJ) is requesting permission to join settlement talks as a “friend of the court” in lawsuits filed against manufacturers and distributors of opioids by state and local governments seeking to recoup the costs stemming from the tide of opioid addiction and overdoses. This role would allow the DOJ to help determine non-monetary remedies for the opioid epidemic and indicates that the federal government does not have plans to join the more than 400 lawsuits consolidated against opioid makers. U.S. District Judge Dan Polster of Cleveland has expressed hope that both sides will negotiate a deal this year to address current pharmaceutical business practices and the roots of the opioid crisis.

### ***CMS Releases Final 2018 Exchange Enrollment Figures***

A final report from CMS shows that 11.8 million consumers enrolled for coverage in the 2018 health care insurance exchanges nationwide. This figure represents only a slight decrease from last year, despite deep cuts to advertising and outreach spending by the Trump Administration. The share of individuals 55 years of age and older enrolled in Healthcare.gov increased from 27 percent last year to 29 percent this year, whereas the share of young adults between the ages of 18 and 34 decreased slightly. CMS’ analysis also shows that average premiums have decreased from \$106 per month to \$89 when subsidies are taken into account; eight-three percent of customers qualified for premium subsidies, which is in line with last year. Unsubsidized monthly premiums rose from \$476 to \$621.

### ***Esty, Farenthold Announce Resignations***

Rep. Elizabeth Esty (D-Conn.) has announced that she will not run for reelection in the upcoming November midterms. Her decision follows allegations that she was slow to act after reports that her chief of staff assaulted and harassed another member of her office. Esty represents the most competitive congressional district in her state – Connecticut’s fifth district was lost by President Trump by only four points in the 2016 presidential election. Esty currently serves on the House Committee on Veterans’ Affairs.

Rep. Blake Farenthold (R-Texas) also announced his immediate resignation from Congress, in light of reports that he used taxpayer funds to settle a sexual harassment claim. Farenthold had initially planned to serve the remainder of his term. Farenthold was a member of the Oversight and Government Reform Committee and the Judiciary Committee.

### ***MS Officially Schedules Special Election***

Mississippi Governor Phil Bryant (R) has officially set a special Senate election for November 6 to fill the vacancy created by the resignation of Thad Cochran (R), which took effect April 1. Cochran’s term runs through January 2021. The election will include Republican candidates Cindy Hyde-Smith, who was appointed by the governor to fill Cochran’s seat in the interim period of time, and state senator Chris McDaniel. Former congressman and agriculture secretary Mike Espy (D) and Tupelo Mayor Jason Shelton (D) are also running for the seat. If a candidate does not receive a majority of the vote, a runoff election will be held on November 27.



## Upcoming Congressional Meetings and Markups

*House Oversight and Government Reform Subcommittee on Healthcare, Benefits, and Administrative Rules hearing “Local Responses and Resources to Curtail the Opioid Epidemic;” 10:00 a.m., 2154 Rayburn Bldg.; April 11*

*House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing “FY 2019 Budget Oversight Hearing;” 10:00 a.m., 2358-C Rayburn Bldg.; April 11*

*Senate Health, Education, Labor, and Pensions Committee hearing “The Opioid Crisis Response Act of 2018;” 10:00 a.m., 430 Dirksen Bldg.; April 11*

*House Energy and Commerce Oversight and Investigations Subcommittee hearing “Update on the Restoration of Puerto Rico’s Electric Infrastructure;” 2:00 p.m., 2123 Rayburn Bldg.; April 11*

*House Energy and Commerce Health Subcommittee hearing “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients;” 2:15 p.m., 2322 Rayburn Bldg.; April 11 (hearing will continue on April 12)*

*Senate Judiciary Crime and Terrorism Subcommittee hearing “Defeating Fentanyl: Addressing the Deadliest Drugs Fueling the Opioid Crisis;” 2:30 p.m., 226 Dirksen Bldg.; April 11*

*House Energy and Commerce Health Subcommittee continuation of hearing “Combating the Opioid Crisis: Improving the Ability of Medicare and Medicaid to Provide Care for Patients;” 10:00 a.m., 2322 Rayburn Bldg.; April 12*

*House Oversight and Government Reform Subcommittee on Government Operations hearing “Improper Payments in State-Administered Programs: Medicaid;” 10:00 a.m., 2154 Rayburn Bldg.; April 12*

*House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing “Investments in our Health Workforce and Rural Communities;” 10:00 a.m., 2358-C Rayburn Bldg.; April 12*

*House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations hearing “Global Health Supply Chain Management: Lessons Learned and Ways Forward;” 2:00 p.m., 2172 Rayburn Bldg.; April 12*

*House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies FY 2019 Members Day Hearing; 10:00 a.m., 2358-C Rayburn Bldg.; April 17*

*House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies FY 2019 Public Witnesses Hearing; 10:00 a.m., 2358-C Rayburn Bldg.; April 26*

## Recently Introduced Health Legislation

*H.R.5408 — To amend the Public Health Service Act to provide for prevention and treatment of substance abuse grants to recovery community organizations, and for other purposes; Sponsor: Rep. Brat, Dave [R-VA-7]; Committees: House - Energy and Commerce*

*H.R.5418 — Veterans Affairs Medical-Surgical Purchasing Stabilization Act; Sponsor: Rep. Bergman, Jack [R-MI-1]; Committees: House - Veterans’ Affairs*

*H.R.5423 — Gestational Diabetes ( GEDI) Act of 2018; Sponsor: Rep. Engel, Eliot L. [D-NY-16]; Committees: House - Energy and Commerce*

*H.R.5429 — To reauthorize the rural emergency medical services training and equipment assistance program under section 330J of the Public Health Service Act; Sponsor: Rep. Gianforte, Greg [R-MT-At Large]; Committees: House - Energy and Commerce*