



Health Policy Briefing

April 23, 2018

Trump Speech on Drug Prices Scheduled for ‘Near Future’

President Trump’s speech on prescription drug prices is set to take place in the near future, according to the latest reports. The speech was previously scheduled for April 26 but will now take place on a later date. The President is expected to speak about the proposals contained in his fiscal year 2019 budget to reduce the cost of prescription medication, such as capping Medicare out-of-pocket (OOP) drug costs and allowing several states to test Medicaid drug price negotiation. While no new policies are expected to be unveiled during the speech, his remarks will likely coincide with a request for information from the U.S. Department of Health and Human Services (HHS) on drug pricing policies. The Office of Management and Budget (OMB) began review of the HHS Strategy to Lower Drug Prices and Reduce Out-of-Pocket Costs on April 17. The notice, which is not proposed regulation, comes from the HHS Office of the Secretary, and is not ‘economically significant,’ meaning that the total cost to government or industry is less than \$100 million.

Latest News on the Opioid Crisis

Opioid Crisis Response Act Formally Introduced: Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) and Ranking Member Patty Murray (D-Wash.) have formally introduced the Opioid Crisis Response Act of 2018 (S. 2680). The bill contains 40 bipartisan proposals to address the epidemic of opioid abuse and misuse. A detailed summary of the legislation can be found [here](#). The HELP Committee is slated to markup the legislation on April 24. The bill will:

- Reauthorize and improve opioid prevention, response, and treatment grants to states and Indian Tribes for three more years;
- Spur development and research on non-addictive painkillers and other strategies to prevent, treat, and manage pain and substance use disorders through additional flexibility for the National Institutes of Health (NIH);
- Clarify the Food and Drug Administration’s (FDA) regulatory pathways for new non-addictive pain and addiction products through additional guidance;
- Clarify FDA authority to require packaging and disposal options for certain drugs for patients who may only need a three or seven-day supply of opioids;
- Strengthen FDA and

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- Customs and Border Protection coordination to improve detection and seizure of illegal drugs;
- Clarify FDA's post-market authorities for drugs that may have reduced efficacy over time by modifying the definition of an adverse drug experience;
- Improve state Prescription Drug Monitoring Programs (PDMPs) and encourage data sharing between states;
- Strengthen the health care workforce to increase access to mental health services in schools and community-based settings and to substance use disorder services in underserved areas;
- Authorize the Centers for Disease Control and Prevention's (CDC) work to combat the opioid crisis;
- Improve state plans of safe care for infants born with neonatal abstinence syndrome (NAS) and help address child and youth trauma;
- Authorize the Department of Labor to address the economic and workforce impacts for communities affected by the opioid crisis, through grants targeted at workforce shortages for the substance use and mental health treatment workforce, and to align job training and treatment services;
- Require the Drug Enforcement Administration (DEA) to issue regulations on how qualified providers can prescribe controlled substances in limited circumstances via telemedicine; and
- Allow hospice programs to safely and properly dispose of unneeded controlled substances.

House Energy and Commerce Committee to Consider Opioid Legislation: The House Energy and Commerce Health Subcommittee announced it will begin to markup legislation to combat the opioid crisis on Wednesday afternoon, April 25. Markup could spill over to more than one day since the subcommittee plans to consider a number of individual bills, as opposed to a larger package. The list of bills to be included in markup is expected to be released later today.

Finance Committee Plans Opioid Legislation: The Senate Finance Committee also plans to move legislation this spring related to the opioid crisis. Policy guidance for members **states** that that the Committee will focus on identifying changes in a number of different categories based on the stakeholder feedback received, including

- Improving efforts to prevent opioid misuse and abuse by evaluating and considering tools like prescriber and patient education, prescription drug management, and alternative pain treatments;
- Evaluating and improving access to and utilization of evidence-based care for patients to reduce and address the prevalence of substance use disorder (SUD);
- Improving services and systemic responses for families confronting SUD; and
- Enhancing data-sharing efforts such as strengthening the interaction between PDMPs and Medicare/Medicaid and increasing oversight of issues related to SUD.

The Committee only plans to consider policies that have bipartisan Finance member support and have little or no cost or have an identified bipartisan offset acceptable to Committee leadership.

House Ways and Means Trade Subcommittee Hearing: On Wednesday, the Trade Subcommittee will hold a hearing titled "The Opioid Crisis: Stopping the Flow of Synthetic Opioids in the International Mail System." The hearing will focus on efforts to improve the detection of synthetic opioids in the international mail system and prevent them from entering the United States. The hearing will also examine bipartisan legislative solutions to address vulnerabilities in the international mail system that have allowed synthetic opioids to go undetected.

Second Round of State Opioid Grants Released: HHS has released the second year of state opioid grants. A total of \$485 million was awarded to 50 states, four U.S. territories, Palau, and Micronesia last week. The money will support evidenced-based prevention, treatment, and recovery efforts. The grants will be administered by SAMHSA and were created as a part of the 21st Century Cures Act in 2016.

NIH Will Not Accept Private Funding in Opioid Partnership: Director of the NIH Francis Collins announced that the agency's opioid research partnership with the pharmaceutical industry will not access any funds from drug manufacturers and will instead rely exclusively on taxpayer money. The decision is in keeping with recommendations issued earlier this month by an NIH advisory panel. The experts were concerned about the perception of conflicts of interest and private sector influence over agency research. NIH will instead rely on industry to help establish a clinical trial network, determine biomarkers for drug development, and assist in data sharing.

DEA Issues Proposed Rule on Opioid Quotas: The DEA has released a proposed rule that would change the way the agency sets annual opioid production limits. If the DEA believes a company's opioids are being diverted for misuse, it can reduce the number of opioids the manufacturer can produce. The DEA would be able to use additional data from HHS, FDA, CDC, Medicare, and Medicaid to determine opioid quotas. States could also have input into production limits and could request a hearing if it believes a quota is too high. Attorney General Jeff Sessions also announced that the DEA and 48 state attorneys general have reached an agreement to increase prescription drug information sharing and reduce the diversion and trafficking of painkillers.

DOJ Takedown: The Department of Justice (DOJ) announced a takedown of a multi-state heroin and fentanyl distribution network known as the Peterson Drug Trafficking Organization. Approximately 100 defendants have been targeted for arrest, and at least 15 people have been charged in a federal indictment.

Lawmakers Request Update on Mental Health Parity

Leadership of the Senate HELP Committee have requested an update from the Administration on the implementation of mental health parity provisions included as a part of the 21st Century Cures Act (Cures). The lawmakers sent a letter to HHS Secretary Alex Azar, Labor Secretary Alexander Acosta, and Treasury Secretary Steve Mnuchin asking how they are enforcing mental health parity laws and question why the Administration has missed a number of deadlines set by Cures. Agencies were required to issue employer and insurer guidance to implement parity, set a plan of action to strengthen parity enforcement, and inform Congress of the number of federal parity investigations that have taken place by December 13, 2017. The senators ask to schedule a briefing with the secretaries and request a written response to their letter by May 1.

Grassley Inquires About Stem Cell Clinic

Sen. Chuck Grassley (R-Iowa) has **written** to the Food and Drug Administration (FDA) expressing concerns about the agency's oversight of stem cell clinics. Grassley cites a 2017 Washington Post article that exposed a Florida-based clinic, which performed unproven treatments that left several patients permanently blind. The clinic listed its study on ClinicalTrials.gov, leading at least one patient to believe she was participating in a government-sanctioned study. The FDA sent a warning letter to the clinic outlining its deviations from current good manufacturing practices and the clinic's efforts to impede the agency's investigation. "Despite the harm this clinic has already caused," Grassley writes, "this clinic is apparently only at risk of 'additional enforcement action' if it does not correct itself." He requests an update on the FDA's investigation into U.S. Stem Cell no later than April 27.

Energy and Commerce Posts RFI on Legacy Technologies

The House Energy and Commerce Committee has **posted** a request for information (RFI) about the use of legacy technologies in the health care sector. "Medical technologies face the same challenge that has vexed the information technology (IT) industry for decades; digital technologies age faster and less gracefully than their physical counterparts," the RFI states. The Committee cites the recent infection of hundreds of thousands of devices by WannaCry ransomware as reason to find and fix digital technology vulnerabilities. The Committee requests feedback be sent to supportedlifetimes@mail.house.gov by May 31, 2018.

Confirmation Hearing Scheduled for VA Secretary Nominee

Navy Rear Adm. Ronny Jackson, the President's nominee for VA Secretary, met with members of the Senate Committee on Veterans Affairs last week ahead of his confirmation hearing on Wednesday. According to Ranking Member Jon Tester (D-Mont.), Jackson pledged his opposition to efforts to privatize veterans' health care during their one-on-one meeting and expressed views that Tester interpreted as in line with those of former VA Secretary David Shulkin. Shulkin has blamed his firing on a push within the Administration to increase veteran access to private-sector health care providers. Conflicts surrounding privatization could complicate Jackson's confirmation. The nominee has also faced criticism for his lack of experience working with the VA and managing a large bureaucracy or health care organization.

Dent to Resign in Coming Weeks

Rep. Charlie Dent (R-Pa.), a member of the House Appropriations Committee, announced plans to resign from Congress in the coming weeks, noting that his last day on the job would be sometime in May. Dent had already announced that he would not be running for reelection this year but has decided to leave the Hill early after discussions with his family. Dent currently serves as a co-chair of the moderate Tuesday Group. Pennsylvania Governor Tom Wolf (D) will have 10 days after Dent's seat becomes vacant to declare a special election, which must occur at least 60 days after the announcement. Nominees will be determined by party leaders rather than through a primary election.

HHS Staff Changes

HHS Secretary Alex Azar has named James Parker to serve as his senior adviser on health reform. Parker will also lead the Department's efforts to address the cost and availability of health insurance. Parker spent 20 years of his career with Anthem, Inc., and most recently worked as CEO for MDwise, an Indiana Medicaid managed care organization.

Upcoming Congressional Meetings and Markups

Senate Health, Education, Labor, and Pensions Committee executive session to consider S.2680, Opioid Crisis Response Act of 2018; S.2315, Over-the-Counter Drug Safety, Innovation, and Reform Act; S.2597, Children's Hospital GME Support Reauthorization Act of 2018; S.382, Firefighter Cancer Registry Act; and nominations; 10:00 a.m., 430 Dirksen Bldg.; April 24

Senate Appropriations Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee hearing to review the Fiscal Year 2019 funding request and budget justification for the Food and Drug Administration; 2:30 p.m., 124 Dirksen Bldg.; April 24

House Energy and Commerce Health Subcommittee markup on opioids legislation; time and place TBD; April 25

House Appropriations Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee FY 2019 Member Day; 1:30 p.m., 2362-A Rayburn Bldg.; April 25

House Ways and Means Trade Subcommittee hearing on the Opioid Crisis: Stopping the Flow of Synthetic Opioids in the International Mail System; 2:00 p.m., 1100 Longworth Bldg.; April 25

Senate Veterans' Affairs Committee hearing on the pending nomination of Ronny L. Jackson, MD; 2:30 p.m., G-50 Dirksen Bldg.; April 25

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

House Ways and Means Health Subcommittee hearing "Identifying Innovative Practices and Technologies in Health Care;" 10:00 a.m., 1100 Longworth Bldg.; April 26

House Energy and Commerce Oversight and Investigations Subcommittee hearing with the leadership of drug distributors in regards to alleged pill dumping in West Virginia; time and place TBD; May 8

Recently Introduced Health Legislation

H.R.5506 — To amend title XVIII of the Social Security Act to provide for direct payment to physician assistants under the Medicare program for certain services furnished by such physician assistants. Sponsor: Rep. Smith, Adrian [R-NE-3]; Committees: House - Energy and Commerce, Ways and Means

H.R.5507 — To amend title XVIII of the Social Security Act to remove the 96-hour physician certification requirement for inpatient critical access hospital services; Sponsor: Rep. Smith, Adrian [R-NE-3]; Committees: House - Ways and Means

H.R.5511 — To amend the Public Health Service Act to require that the recommendations of the United States Preventive Services Task Force on the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services be based on data for the respective populations, and for other purposes; Sponsor: Rep. Evans, Dwight [D-PA-2]; Committees: House - Energy and Commerce

H.R.5520 — To authorize the Secretary of Veterans Affairs to use the authority of the Secretary to conduct and support research on the efficacy and safety of medicinal cannabis, and for other purposes; Sponsor: Rep. Walz, Timothy J. [D-MN-1]; Committees: House - Veterans' Affairs

H.R.5521 — To amend title 38, United States Code, to provide for the non-applicability of non-Department of Veterans Affairs covenants not to compete to the appointment of certain Veterans Health Administration personnel, to permit the Veterans Health Administration to make contingent appointments, and to require certain Veterans Health Administration physicians to complete residency training; Sponsor: Rep. Hartzler, Vicky [R-MO-4]; Committees: House - Veterans' Affairs

S.2669 — A bill to provide for accelerated approval of pain and addiction therapies; Sponsor: Sen. Hatch, Orrin G. [R-UT]; Committees: Senate - Health, Education, Labor, and Pensions

S.2676 — A bill to permit certain disclosures of health information during emergencies, including overdoses; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2678 — A bill to direct the Secretary of Health and Human Services, acting through the Director of the Center for Substance Abuse Treatment of the Substance Abuse and Mental Health Services Administration, to publish and disseminate best practices for operating recovery housing, and for other purposes; Sponsor: Sen. Kaine, Tim [D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2680 — A bill to address the opioid crisis; Sponsor: Sen. Alexander, Lamar [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

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S.2680 — A bill to address the opioid crisis; Sponsor: Sen. Alexander, Lamar [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.5528 — To direct the Secretary of Defense to submit to Congress a plan for improvements to traumatic brain injury and post-traumatic stress research; Sponsor: Rep. Bacon, Don [R-NE-2]; Committees: House - Armed Services

H.R.5531 — To provide for a comprehensive, multifaceted approach to preventing and treating opioid addiction; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Energy and Commerce, Ways and Means, Budget, Veterans' Affairs, Oversight and Government Reform, Judiciary

H.R.5541 — To amend titles XVIII and XIX of the Social Security Act to provide equal coverage of in vitro specific IgE tests and percutaneous tests for allergies under the Medicare and Medicaid programs, and for other purposes; Sponsor: Rep. Upton, Fred [R-MI-6]; Committees: House - Energy and Commerce, Ways and Means

S.2690 — A bill to amend title XVIII of the Social Security Act to permit review of certain Medicare payment determinations for disproportionate share hospitals, and for other purposes; Sponsor: Sen. Rubio, Marco [R-FL]; Committees: Senate - Finance

S.2691 — A bill to hold pharmaceutical companies accountable for illegal marketing and distribution of opioid products and for their role in creating and exacerbating the opioid epidemic in the United States. Sponsor: Sen. Sanders, Bernard [I-VT]; Committees: Senate - Finance

H.R.5545 — To provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families; Sponsor: Rep. Cummings, Elijah E. [D-MD-7]; Committees: House - Energy and Commerce, Judiciary, Natural Resources

H.R.5546 — To authorize the use of certain Department of Defense funds for combating opioid trafficking and abuse in the United States; Sponsor: Rep. Knight, Stephen [R-CA-25]; Committees: House - Armed Services

H.R.5548 — To require the Administrator of the Environmental Protection Agency to conduct a study on the presence of pharmaceuticals and personal care products in sources of drinking water; Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Committees: House - Energy and Commerce

H.R.5557 — To amend the Comprehensive Addiction and Recovery Act of 2016 to authorize the Attorney General, in coordination with the Administrator of the Drug Enforcement Administration, the Secretary of Health and Human Services, and the Director of the Office of National Drug Control Policy, to award grants to covered entities to establish or maintain disposal sites for unwanted prescription medications, and for other purposes; Sponsor: Rep. Bonamici, Suzanne [D-OR-1]; Committees: House - Energy and Commerce

H.R.5558 — To require the Secretary of Health and Human Services to carry out under the Medicare program an alternatives to opioids in emergency departments demonstration project; Sponsor: Rep. Buchanan, Vern [R-FL-16]; Committees: House - Energy and Commerce, Ways and Means

H.R.5562 — To require the Secretary of Health and Human Services to develop a strategy implementing certain recommendations relating to the Protecting Our Infants Act of 2015, and for other purposes; Sponsor: Rep. Jenkins, Evan H. [R-WV-3]; Committees: House - Energy and Commerce

S.2697 — A bill to require the awareness campaign regarding the risk of abuse of prescription opioids if such drugs are not taken as prescribed to include information about dispensing options; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2700 — A bill to provide emergency assistance to States, territories, Tribal nations, and local areas affected by the opioid epidemic and to make financial assistance available to States, territories, Tribal nations, local areas, and public or private nonprofit entities to provide for the development, organization, coordination, and operation of more effective and cost efficient systems for the delivery of essential services to individuals with substance use disorder and their families; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate - Health, Education, Labor, and Pensions

S.2704 — A bill to amend title XVIII of the Social Security Act to provide for coverage of methadone under Medicare part B; Sponsor: Sen. Casey, Robert P., Jr. [D-PA]; Committees: Senate - Finance

S.2707 — A bill to amend title XVIII of the Social Security Act to provide educational resources regarding opioid use and pain management as part of the Medicare & You handbook; Sponsor: Sen. Nelson, Bill [D-FL]; Committees: Senate - Finance

S.2708 — A bill to provide for the establishment of Medicare part E public health plans, and for other purposes; Sponsor: Sen. Merkley, Jeff [D-OR]; Committees: Senate - Finance

S.2710 — A bill to improve treatment and early interventions for pregnant and postpartum women and infants affected by substance use disorder; Sponsor: Sen. McConnell, Mitch [R-KY]; Committees: Senate - Health, Education, Labor, and Pensions

S.2711 — A bill to amend section 303 of the Controlled Substances Act to facilitate waivers of the separate registration requirement for physicians dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment; Sponsor: Sen. Hassan, Margaret Wood [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.2719 — A bill to direct the Secretary of Veterans Affairs to establish a registry to ensure that members of the Armed Forces who may have been exposed to per- and polyfluoroalkyl substances on military installations receive information regarding such exposure, and for other purposes; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Committees: Senate - Veterans' Affairs