



## Health Policy Briefing

June 18, 2018

### Opioid-Related News Update

The House of Representatives devoted last week to the passage of legislation to address the problem of opioid abuse and addiction. The chamber succeeded in passing nearly 40 bills. Most of the measures were approved with bipartisan support under suspension of the rules. The chamber is expected to consider over a dozen more opioid-related bills this week, including H.R. 6, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. The bill was introduced last week by bipartisan leadership of the House Energy and Commerce and Ways and Means committees. The bill includes reforms to the Medicare and Medicaid programs, and will serve as the underlying vehicle to move the majority of the House-passed opioid-related bills to the Senate.

The Senate Finance Committee unanimously advanced its Helping to End Addiction and Lessen (HEAL) Substance Use Disorders Act of 2018. The bill aims to prevent drug abuse and increase Medicare and Medicaid beneficiary access to education, prevention, and treatment of pain and addiction as well as non-opioid treatments for pain. It encourages states to expand access to residential treatment programs as well as telemedicine when treating substance use disorders. It would require doctors to screen Medicare patients for painkiller misuse and abuse during annual wellness visits. It would also expand and clarify how Medicaid can treat those suffering from addiction, removing lifetime limits for medication-assisted treatment (MAT). HEAL combines 22 individual bills introduced by committee members last month. The Senate Judiciary Committee and Health, Education, Labor, and Pensions (HELP) Committee have also approved opioid-related legislation. The full chamber is expected to vote on a broad package of bills to respond to the crisis over the summer.

Leadership of the House Energy and Commerce Committee sent a [letter](#) to the Food and Drug Administration (FDA) seeking information about efforts to stop the importation of illegal opioids and other potentially harmful products entering the country through international mail facilities (IMFs). The bipartisan group of lawmakers request

#### Inside

House Labor-HHS-Education Appropriations Bill Released.....	2
Senate Advances Medical Marijuana Protection.....	3
Judiciary Advances CREATES to Senate Floor.....	3
Ways and Means Holds Physician Red Tape Roundtable.....	3
Alexander Encourages Waiver Flexibility.....	4
Lawmakers Enter Debate on Protections for Preexisting Conditions.....	4
Court Finds Insurers Not Entitled to Risk Corridor Funds.....	4
Lawmakers Request Suicide Prevention Funding.....	4
Upcoming Congressional Meetings and Markups.....	5
Recently Introduced Health Legislation.....	6

details about the implementation of the Office of Criminal Investigations' (OCI) priorities and question whether OCI is effective at blocking illegal drugs at U.S. ports of entry. The committee asks the FDA to provide statistical data about the cases being generated through the port of entry initiative and its prosecution track record by Friday, June 22.

The National Institutes of Health (NIH) released its [research plan](#) for the Helping to End Addiction Long-term (HEAL) Initiative. HEAL is a trans-NIH effort launched in April of this year to advance national priorities to address the opioid crisis through science. The research plan outlines how the NIH will spend the \$500 million Congress has provided NIH to combat the opioid epidemic. The interdisciplinary research plan was written by NIH Director Francis Collins, Director of the National Institutes of Neurological Disorders and Stroke Walter Koroshetz, and Director of the National Institute on Drug Abuse Nora Volkow and focuses on two areas: improving treatments for opioid misuse and addiction, and enhancing strategies for pain management. The plan describes a multifaceted program that encompasses preclinical, clinical, drug repurposing, and community-based approaches.

The Health Resources and Services Administration (HRSA) released fiscal year (FY) 2018 Expanding Access to Quality Substance Use Disorder and Mental Health Services grants last week. These grants were appropriated in the March 2018 omnibus bill and help support local health centers in expanding substance use disorder (SUD) prevention efforts and medication-assisted treatment (MAT), and increasing access to quality integrated mental health services.

### ***House Labor-HHS-Education Appropriations Bill Released***

The House Appropriations Committee released the text of its fiscal year (FY) 2019 Labor, Health and Human Services, and Education funding bill last week. The bill contains \$177.1 billion in discretionary spending, in line with currently enacted levels. The U.S. Department of Health and Human Services (HHS) would receive \$89.2 billion, a \$1 billion increase over current funding levels and \$2.4 billion more than requested in the President's budget. It would prohibit any funds from going toward health care coverage that provides abortion, and prohibits the use of funds to implement the Affordable Care Act (ACA).

The measure includes \$38.3 billion for the National Institutes of Health (NIH), an increase of \$1.3 billion over FY 2018 and \$4.1 billion more than the White House's request. The bill would increase funding for several research initiatives, including:

- \$2.25 billion, a \$401 million increase, for Alzheimer's disease research,
- \$400 million, a \$100 million increase, for the Cancer Moonshot research initiative,
- \$429 million, a \$29 million increase, for the Brain Research through Application of Innovative Neurotechnologies (BRAIN) initiative,
- \$437 million, a \$147 million increase, for the All of Us research initiative,
- \$130 million, an increase of \$30 million, for research to develop a universal influenza vaccine,
- \$528 million, an increase of \$15 million, for research on Combating Antibiotic-Resistant Bacteria,
- \$366 million, an increase of \$15 million, for Institutional Development Awards, and
- \$12.6 million for the Gabriella Miller "Kids First" pediatric cancer research initiative.

The Centers for Disease Control and Prevention (CDC) would receive \$7.6 billion, a \$663 million cut, but \$2 billion more than the President's request. The bill would eliminate \$108 million for the CDC's teen pregnancy prevention grants. The bill would transfer the Strategic National Stockpile to the Assistant Secretary for Preparedness and Response (ASPR). It also includes \$300 million for the establishment of an Infectious Disease Rapid Response Reserve Fund to be used to quickly respond to a pandemic emergency.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is funded at \$5.6 billion, \$448 million above current levels and \$2.1 billion above the President's request. This includes funding for the Substance Abuse Block Grant, criminal justice activities, and efforts to address the opioid epidemic.

The Health Resources and Services Administration (HRSA) would receive \$6.5 billion, a \$196 million cut compared to FY 2018. It would increase funding for the Children's Hospital Graduate Medical Education and the Maternal and Child

Health Block Grant, but eliminate funding for Family Planning (Title X) Programs.

The Centers for Medicare and Medicaid Services (CMS) would receive \$3.5 billion, \$168 million below currently enacted levels and \$42 million below the President's request.

The Committee provides flat funding of \$334 million for the Agency for Healthcare Research and Quality (AHRQ). The President had proposed cuts to AHRQ while transferring the agency into the NIH.

The Public Health and Social Services Emergency Fund would receive \$2.8 billion, an increase of \$860 million and \$509 million above the White House budget request. This funding includes money for the Biomedical Advanced Research and Development Authority (BARDA), Project BioShield, the Strategic National Stockpile, Hospital Preparedness Program grants, and the National Disaster Medical System.

The bill was advanced by the House Appropriations subcommittee on Friday by voice vote. Panel members abstained from offering any contentious amendments, saving them for consideration by the full committee which will consider the bill this week.

In the Senate, Majority Leader Mitch McConnell (R-Ky.) filed cloture on a motion to proceed to a three-bill appropriations 'minibus,' which packages spending for Military Construction-VA, Energy and Water, and the Legislative Branch.

### ***Senate Advances Medical Marijuana Protection***

**T**he Senate Appropriations Committee approved language that will shield users or providers of medical cannabis operations from action by the Justice Department in states where its use is legal. The provision is a part of the Commerce-Justice-Science appropriations bill. The House version of the bill contains a similar measure. Attorney General Jeff Sessions is a strong critic of efforts to legalize marijuana, having previously changed an Obama Administration policy that provided states with flexibility around recreational marijuana use.

### ***Judiciary Advances CREATES to Senate Floor***

**T**he Senate Judiciary Committee advanced the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974) by a vote of 16-5. The legislation aims to lower drug prices by cracking down on the use of Risk Evaluation and Mitigation Strategies (REMS) by brand name drug companies to delay generic competition. It will allow generic manufacturers to sue to obtain samples used to develop generic drugs for approval by the Food and Drug Administration (FDA).

### ***Ways and Means Holds Physician Red Tape Roundtable***

**T**he House Ways and Means Committee held a roundtable last week to discuss how lawmakers can remove unnecessary regulatory burdens in the Medicare program. Panel members met with physician groups and medical advocacy associations to identify ways to improve quality of care through modernization of the Medicare program. Participants specifically critiqued the program's duplicative reporting requirements, federal standards and prior authorization guidelines, and the Stark Law and anti-kick back statutes. The committee has previously convened similar roundtables with post-acute care medical professionals as well as hospital representatives.

### ***Alexander Encourages Waiver Flexibility***

Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) has **written** to the Trump Administration urging them to use Section 1332 State Innovation Waivers to lower health insurance costs. His letter to U.S. HHS Secretary Alex Azar and CMS Administrator Seema Verma recommends that the State Innovation Waiver guidance be rescinded to allow increased flexibility in health plan design. He also recommends that the waiver approval process be streamlined and that states be allowed to submit a State Innovation Waiver request together with a Medicaid 1115 Demonstration Waiver request. Chairman Alexander asks HHS to work with the National Association of Insurance Commissioners and the National Governors Association to educate and encourage states to apply for waivers.

### ***Lawmakers Enter Debate on Protections for Preexisting Conditions***

Lawmakers are once again debating the merits of Obamacare's consumer protections in light of the recent announcement by the Trump administration that the Department of Justice will argue that the community rating and guaranteed issue provisions of the law are unconstitutional. Senate Majority Leader Mitch McConnell (R-Ky.) stated that "everybody" in the Senate wants to preserve the Affordable Care Act's (ACA) consumer protections. Chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee Lamar Alexander (R-Tenn.) explicitly criticized the decision, characterizing the Administration's argument as "far-fetched" and stating that there is "no way Congress is going to repeal protections for people with pre-existing conditions who want to buy health insurance."

### ***Court Finds Insurers Not Entitled to Risk Corridor Funds***

A federal appeals court has ruled that insurers are not entitled to collect payments under the Affordable Care Act's (ACA) risk corridor program. The risk corridor program was established to encourage insurers to participate on the exchanges. It was meant to pay insurers who suffered heavy losses in the exchange, but too many insurers requested risk corridor money and too few paid into the fund. The court sided with the Trump administration: because Congress passed legislation that required the program to be budget neutral, the government could only pay out what it took in and cannot use other funds to compensate for insurer losses. The insurers are likely to appeal the decision.

### ***Lawmakers Request Suicide Prevention Funding***

The co-chairs of the bipartisan House Suicide Prevention Task Force have sent a letter to appropriators requesting more funding for suicide prevention efforts following a report showing rising rates of suicide across the nation. Funding for suicide prevention programs has remained flat or decreased in recent years. Reps. Don Beyer (D-Va.) and John Katko (R-N.Y.) ask the Appropriations Committee for \$150 million for suicide prevention research within the National Institutes of Mental Health. Data from the Centers for Disease Control and Prevention (CDC) indicates that suicide rates have increased in nearly every state since 1999, with some areas seeing an increase as much as 30 percent.

## Upcoming Congressional Meetings and Markups

*Senate Health, Education, Labor, and Pensions Committee hearing “Effective Administration of the 340B Drug Pricing Program;” 10:00 a.m., 430 Dirksen Bldg.; June 19*

*Senate Appropriations Subcommittee on State, Foreign Operations, and Related Programs markup of FY 19 appropriations; 3:00 p.m., 138 Dirksen Bldg.; June 19*

*House Homeland Security Subcommittee on Oversight and Management Efficiency hearing “Opioids in the Homeland: DHS Coordination with State and Local Partners to Fight the Epidemic;” 12:30 p.m., Room 205, Ryan Building, Pennsylvania Capitol Complex, N 3rd Street, Harrisburg, PA 17120; June 19*

*Senate Select Committee on Aging hearing to “examine changing the trajectory of Alzheimer’s, focusing on reducing risk, detecting early symptoms, and improving data;” 2:30 p.m., 106 Dirksen Bldg.; June 19*

*House Rules Committee hearing on H.R. 6, Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; H.R. 6082, Overdose Prevention and Patient Safety Act; and H.R. 5797, Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Delivery Act; 5:00 p.m., H-313 Capitol; June 19*

*House Appropriations Committee markup of FY 2019 Labor, Health and Human Services, and Education Appropriations Bill, and Foreign Operations Appropriations Bill; 10:00 a.m., 2154 Rayburn Bldg.; June 20*

*Senate Homeland Security and Governmental Affairs hearing to examine Medicaid fraud and overpayments, focusing on problems and solutions; 10:00 a.m., 342 Dirksen Bldg.; June 20*

*Senate Foreign Relations Committee hearing to “examine United States Agency for International Development (USAID) resources and redesign;” 10:15 a.m., 419 Dirksen Bldg.; June 20*

*Senate Health, Education, Labor, and Pensions Committee executive session to consider S.3029, Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act (PREEMIE Act), S.1112, to support States in their work to save and sustain the health of mothers during pregnancy, childbirth, and in the postpartum period, to eliminate disparities in maternal health outcomes for pregnancy-related and pregnancy-associated deaths, to identify solutions to improve health care quality and health outcomes for mothers, S.808, to provide protections for certain sports medicine professionals who provide certain medical services in a secondary State, S.3039, to provide funding for the development of a predictive analytics pilot program to help children and families who come to the attention of the child welfare system, S. \_\_\_, a bill to reauthorize the Carl D. Perkins Career and Technical Education Act, and Nominations; 10:30 a.m., 430 Dirksen Bldg.; June 20*

*House Energy and Commerce Subcommittee on Oversight and Investigations hearing “Examination of the GAO Audit Series of HHS Cybersecurity;” 1:00 p.m., 2123 Rayburn Bldg.; June 20*

*House Armed Services Subcommittee on Military Personnel hearing “Military Health System Reform: Pain Management, Opioids Prescription Management and Reporting Transparency;” 3:30 p.m., 2212 Rayburn Bldg.; June 20*

*House Veterans’ Affairs Health Subcommittee hearing “More than Just Filing Vacancies: A Closer Look at VA Hiring Authorities, Recruiting, and Retention;” 10:30 a.m., 334 Cannon Bldg.; June 21*

*Senate Appropriations Committee markup of FY19 State, Foreign Operations, and Related Programs and the Department of Homeland Security; 10:30 a.m., 106 Dirksen Bldg.; June 21*

*House Committee on Veterans’ Affairs hearing “VA Electronic Health Record Modernization: The Beginning of the Beginning;” 10:00 a.m., 334 Cannon Bldg.; June 26*



Senate Health, Education, Labor, and Pensions Committee hearing “How to Reduce Health Care Costs: Understanding the Cost of Health Care in America;” 10:00 a.m., 430 Dirksen Bldg.; June 27

## Recently Introduced Health Legislation

H.R.6050 — To allow all individuals purchasing health insurance in the individual market the option to purchase a lower premium copper plan; Sponsor: Rep. Burgess, Michael C. [R-TX-26]; Committees: House - Energy and Commerce

H.R.6052 — To amend title XVIII of the Social Security Act to provide for coverage under the Medicare Program of hearing aids and related hearing services; Sponsor: Rep. Cartwright, Matt [D-PA-17]; Committees: House - Energy and Commerce, Ways and Means

H.R.6056 — To amend title XVIII of the Social Security Act to establish rules for payment for graduate medical education (GME) costs for hospitals that establish a new medical residency training program after hosting resident rotators for short durations; Sponsor: Rep. Gottheimer, Josh [D-NJ-5]; Committees: House - Ways and Means, Energy and Commerce

H.R.6057 — To amend the Controlled Substances Act to provide for enhanced penalties for trafficking in fentanyl, and for other purposes; Sponsor: Rep. Grothman, Glenn [R-WI-6]; Committees: House - Judiciary, Energy and Commerce

H.R.6062 — To amend title XVIII of the Social Security Act to provide coverage under the Medicare program for FDA-approved qualifying colorectal cancer screening blood-based tests, and for other purposes; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Energy and Commerce, Ways and Means

H.R.6066 — To amend title 38, United States Code, to improve the productivity of the management of Department of Veterans Affairs health care, and for other purposes; Sponsor: Rep. Wenstrup, Brad R. [R-OH-2]; Committees: House - Veterans' Affairs

S.3047 — A bill to establish a narcotic drug screening technology pilot program to combat illicit opioid importation, and for other purposes; Sponsor: Sen. McCaskill, Claire [D-MO]; Committees: Senate - Homeland Security and Governmental Affairs

S.3048 — A bill to direct the Comptroller General of the United States to evaluate and report on the in-patient and outpatient treatment capacity, availability, and needs of the United States; Sponsor: Sen. Manchin, Joe, III [D-WV]; Committees: Senate - Health, Education, Labor, and Pensions

S.3053 — A bill to amend title XXI of the Social Security Act to ensure access to mental health and substance use disorder services for children and pregnant women under the Children's Health Insurance Program, and for other purposes; Sponsor: Sen. Stabenow, Debbie [D-MI]; Committees: Senate - Finance

S.3054 — A bill to amend title XVIII of the Social Security Act to create alternative sanctions for technical noncompliance with the Stark rule under Medicare, and for other purposes; Sponsor: Sen. Perdue, David [R-GA]; Committees: Senate - Finance

H.R.6071 — To amend the Public Health Service Act to clarify the intent of the 340B program and provide for enhanced 340B program integrity, and for other purposes; Sponsor: Rep. Matsui, Doris O. [D-CA-6]; Committees: House - Energy and Commerce, Ways and Means

H.R.6074 — To combat the heroin epidemic and drug sample backlogs; Sponsor: Rep. Esty, Elizabeth H. [D-CT-5]; Committees: House - Judiciary

S.3059 — A bill to require the Medicaid and CHIP Payment and Access Commission to publish an annual report on the estimated impact in each State of the Medicaid expansion added by the Patient Protection and Affordable Care

*Act, including the estimated impact that adopting such expansion would have in States that have not expanded their Medicaid coverage; Sponsor: Sen. Jones, Doug [D-AL]; Committees: Senate – Finance*

*S.3063 — A bill to delay the reimposition of the annual fee on health insurance providers until after 2020; Sponsor: Sen. Barrasso, John [R-WY]; Committees: Senate – Finance*

*H.Con.Res.123 — Supporting National Men’s Health Week; Sponsor: Rep. Payne, Donald M., Jr. [D-NJ-10]; Committees: House - Oversight and Government Reform*

*H.R.6 — To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes; Sponsor: Rep. Walden, Greg [R-OR-2]; Committees: House - Energy and Commerce, Ways and Means, Judiciary*

*H.R.6082 — To amend the Public Health Service Act to protect the confidentiality of substance use disorder patient records; Sponsor: Rep. Mullin, Markwayne [R-OK-2]; Committees: House - Energy and Commerce*

*H.R.6085 — To revise and extend the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act (PREEMIE Act); Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Committees: House - Energy and Commerce*

*H.R.6097 — To amend title I of the Patient Protection and Affordable Care Act to authorize the establishment of, and provide support for, State-based universal health care systems that provide comprehensive health benefits to State residents, and for other purposes; Sponsor: Rep. Jayapal, Pramila [D-WA-7]; Committees: House - Energy and Commerce, Ways and Means, Oversight and Government Reform, Armed Services, Education and the Workforce*

*S.Res.549 — A resolution designating June 15, 2018, as “World Elder Abuse Awareness Day”; Sponsor: Sen. Blumenthal, Richard [D-CT]; Committees: Senate – Judiciary*

*S.3067 — A bill to amend title XVIII of the Social Security Act to permit nurse practitioners and physician assistants to satisfy the documentation requirement under the Medicare program for coverage of certain shoes for individuals with diabetes; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate – Finance*

*H.R.6110 — To amend title XVIII of the Social Security Act to provide for the review and adjustment of payments under the Medicare outpatient prospective payment system to avoid financial incentives to use opioids instead of non-opioid alternative treatments, and for other purposes; Sponsor: Rep. Walorski, Jackie [R-IN-2]; Committees: House - Energy and Commerce, Ways and Means*

*H.R.6114 — To amend title II of the Social Security Act to eliminate the waiting periods for disability insurance benefits and Medicare coverage for individuals with metastatic breast cancer, and for other purposes; Sponsor: Rep. King, Peter T. [R-NY-2]; Committees: House - Ways and Means*

*H.R.6117 — To provide for the establishment of Medicare part E public health plans, and for other purposes; Sponsor: Rep. Richmond, Cedric L. [D-LA-2]; Committees: House - Energy and Commerce, Ways and Means, Education and the Workforce*