

MEMORANDUM

To: ACRM

From: Peter Thomas and Megan La Suer

Date: October 30, 2018

Re: Opioid Legislation Signed by President: Summary of Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (“SUPPORT”) for Patients and Communities Act

On Wednesday, October 24th, President Donald Trump signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (“SUPPORT”) for Patients and Communities Act, into law. This bill was widely supported by both parties, passing 393 to 8 in the House and 98 to 1 in the Senate.

H.R. 6 was originally introduced in the House by Energy and Commerce Committee Chairman Greg Walden (R-OR), Ways and Means Committee Chairman Kevin Brady (R-TX), Energy and Commerce Committee Ranking Member Frank Pallone, Jr. (D-NJ), and Ways and Means Committee Ranking Member Richard Neal (D-MA). Procedurally, the legislation retains the House bill number despite the fact that the Senate had a similar process, produced a different bill, and developed the final bill through a conference committee with the House. The conferenced bill is bipartisan and includes many of the House- and Senate-passed provisions aimed at combating the opioid crisis, reforming regulations to increase access to addiction treatments, encouraging research on non-opioid pain treatments, and increasing law enforcement activities to stop the importation of synthetic opioids into the U.S.

This memorandum provides a breakdown of key provisions and potential grant opportunities included in the 250-page legislation.

Prescriber Policy Changes

- **Prescribing Guidelines:** The Food and Drug Administration (“FDA”) is required to develop opioid analgesic prescribing guidelines for acute pain treatment. The FDA will consult stakeholders and gather public input when developing these guidelines. The guidelines will be intended to only inform clinical decision making, and are not meant to deny or restrict access to healthcare treatments (Section 3002).
- **Increase Access to Medication-Assisted Treatment:** Section 3201 increases the number of qualified healthcare providers that can prescribe or dispense buprenorphine, a well-known medication-assisted treatment (“MAT”). This provision authorizes clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe MAT.

Qualified physicians will now be able to prescribe MAT to as many as 100 patients upon becoming board-certified, and up to 275 one year after receiving an initial waiver.

Medicaid Specific Provisions

- Expanding Provider Capacity Project: Section 1003 establishes a demonstration project to help state Medicaid programs add new substance use disorder (“SUDs”) providers and expand the services they are qualified to provide. Grants will be used to help SUD providers acquire the technical assistance necessary for them to participate in the Medicaid program. The bill appropriates \$50 million to CMS for planning grants to at least ten states for the first 18-months of the project, and will select five of these states to receive 80 percent federal matching funds for the remaining 36 months of the demonstration. Preference for this demonstration project will be given to Medicaid programs in states that have a high prevalence of drug overdoses. CMS will also select states in a manner to ensure geographic diversity.
- Medicaid Program Integrity: Section 1004 expands current state Medicaid drug utilization review activities by requiring Medicaid programs to implement safety checks to monitor opioid refills, concurrent opioid prescriptions, and antipsychotic medications prescribed to children. Medicaid providers will also be required to check relevant prescription drug monitoring programs (“PDMPs”) before prescribing a Schedule II controlled substance and must also report all PDMP data and information to CMS (Section 5042).
- Institutions for Mental Diseases: Section 5052 expands Medicaid coverage to include services provided in Institutions for Mental Diseases (“IMDs”) for FY 2019 through FY 2023. This is a temporary suspension of the IMD exclusion, which did not allow for federal Medicaid funds to be used for services provided in IMDs with more than 16 beds. This provision allows for state Medicaid programs to receive federal reimbursement for up to 30 days of services provided in IMDs. Separate provisions allow for federal reimbursement for pregnant women in IMDs and also allow for Medicaid managed care plans to receive federal funding for up to 15 days of IMD services.

Medicare Specific Provisions

- Coverage Expansion: Medicare coverage will be expanded to include services provided in Opioid Treatment Programs (“OTPs”). This coverage expansion will increase access to MAT, counseling, and SUD testing services (Section 2005). The bill would also create a four-year demonstration program that will provide eligible doctors and health care entities with additional funding to provide MAT, care management and treatment planning, and counseling or social support services to Medicare beneficiaries. The bill appropriates out of the Federal Supplementary Medical Insurance Trust Fund up to \$10 million annually over a three-year period and would limit the number participating beneficiaries to 20,000 (Section 6042).
- Identifying At-Risk Beneficiaries: All prescription drug plans within the Medicare program will be required to develop and implement a drug management program for at-risk

beneficiaries. Other provisions require Medicare Part D plans to classify any beneficiary with a history of opioid-related overdose as “at-risk.” Part D beneficiaries will be able to appeal this designation to an external entity (Section 2007).

- **Outlier Providers:** Under Section 6065, HHS will be required to notify and provide resources to providers who prescribe opioids above the threshold limit when compared to prescribers within the same specialty and geographic location. HHS is charged with establishing the threshold limits for outlier prescribers, however these thresholds will be determined based on informal consultation with stakeholders and could become a backdoor way for Medicare to implement prescribing guidelines.
- **Secured Transmission and Financial Incentives for Medicare Drugs:** Starting in year 2021, all prescriptions for a Schedule II, III, IV, or V Controlled Substance covered under a Part D prescription drug plan or MA prescription drug plan will be required to be transmitted in accordance with an electronic prescription drug program established under the Section 1860D of the Social Security Act.¹ Exceptions will be made for situations such as economic hardship or when the prescribing practitioner and dispensing pharmacy are the same entity (Section 2003). The Department of Health and Human Services (“HHS”) is also required to review payments made through the Outpatient Prospective Payment System and payments made to ambulatory surgery centers to ensure that providers are not receiving financial incentives to use opioids over non-opioid treatments (Section 6082).

Enforcement and Drug Rules

- **Packaging and Disposal of Opioids:** The section clarifies the FDA’s authority to require drug manufacturers to package opioids that pose a high risk of overdose in a way that would limit treatment duration and provide for a safe method of disposing any unused opioids. For example, the FDA may require a blister pack that holds a 3 or 7-day supply, as well as provide a disposal system that would render drugs non-retrievable (Section 3032).
- **Program Integrity:** HHS will develop and distribute educational materials to better help pharmacists identify fraudulent prescriptions and to help determine when it is appropriate to decline filling a prescription (Section 3212).
- **Opioid Quotas:** Various provisions require the Drug Enforcement Agency to establish mandatory factors that must be considered when setting annual opioid quotas, as well as implement safeguards to identify and stop opioid diversion (Sections 3271-3292).

Public Health and Other Grant Opportunities

¹ 42 U.S.C.A. § 1395w-104 (2018).

- CMS Guidance: Various provisions require CMS to issue guidance regarding federal reimbursement for using telehealth to provide SUD treatments, as well as guidance regarding options for treating and managing pain through non-opioid pain treatments.
- Expansion of Addiction Treatment in FQHCs and Rural Health Centers: Grants will be provided to FQHCs and Rural Health Clinics to help cover the costs associated with training providers on dispensing medications for treatment of SUDs. FQHCs and Rural Health Clinics must submit an application for funding for each physician that will be providing SUD treatment. The physician must be employed or working under a contract with the entity, and must first receive a waiver under section 303(g) of the Controlled Substances Act after January 1, 2019 (Section 6083).
- Pain Management Study: HHS is required to submit a report to Congress on how to improve reimbursement and coverage for multi-disciplinary, evidence-based, non-opioid chronic pain management. The report must include options for improving treatment and case management strategies for various high-risk patient populations (Section 6086).
- Hospital Care: HHS will provide resources to Medicare participating hospitals that detail best practices for reducing opioid use. A Technical Expert Panel (“TEP”) will also be established to review quality measures related to care, prevention, diagnosis, health outcomes, and treatments provided to individuals with opioid use disorder. A separate TEP consisting of medical and surgical specialty societies and various hospital organizations will be established to provide recommendations on best practices for pain management in surgical settings. The goal of the TEP is to provide recommendations for protocols that would limit the use of opioids in the perioperative setting (Sections 6092-6095).
- Research: Various provisions provide for increased funding and an expanded scope of opioid-related research. Section 7041 allows the National Institute of Health to use its “other transactions authority” to focus on the opioid crisis and on finding non-addictive alternatives for pain management. The bill also expands the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for SUDs and summarize advances in pain care research, including the use of non-pharmacologic treatments and non-addictive medical products (Section 7042).
- Patient Records: HHS is required to develop best practices for prominently displaying SUD treatment information on a patient’s electronic health record. This information will be included in the patient’s record only upon the patient’s request (Section 7051).
- Healthcare Workforce Education and Expansion: The bill aims at improving the SUD workforce by creating a six-year loan repayment program for SUD treatment professionals working in mental health professional shortage areas and counties that have been impacted the most by drug overdoses (Section 7071). This also bill includes improvements to grant programs established under Section 759 and Section 756 of the Public Health Service Act by requiring grantees to provide education and training to healthcare providers on the use of opioids and non-opioids for pain management. Section 7073 also revises the mental and

behavioral health education and training grants to include trauma-informed care. Grants will be awarded to hospices, tribal health programs, and other public and nonprofit entities for FY 2019 through FY 2023.

- Coordination of Care: HHS will provide grants to assist hospitals and emergency rooms in developing a program to help physicians provide appropriate care to patients who present with a drug overdose. Grantees must develop protocols for discharging these patients, provide access to peer-recovery coaches, and provide coordination and continuation of care and treatment for patients after a drug overdose (Section 7081).
- Youth Prevention and Recovery: HHS, along with the Department of Education and the Department of Health Resources and Services Administration will provide grants to support programs that address SUDs among youth. Grants may be used to carry out prevention, recovery, and SUD treatment programs. Eligible grantees include local or state educational agencies, Indian tribes or Tribal organizations, or a nonprofit organization that is able to provide such services to children and young adults (Section 7102).
- Comprehensive Opioid Recovery Centers: The Substance Abuse and Mental Health Service Administration (SAMHSA) will provide \$10 million in appropriated funds over five years to eligible entities to establish comprehensive opioid recovery centers within their community. At least ten grants will be awarded to eligible entities that offer “treatment and other services for individuals with a substance use disorder.” Grant recipients may then carry out the required treatment and recovery services through referral, contractual arrangements, or through technology-based models (Section 7121).
- Infection Prevention: The bill authorizes \$40 million for FY 2019 through FY 2023 to expand the CDC’s program to prevent and respond to infections commonly associated with illicit drug use, such as hepatitis and HIV. Grants will be used to carry out the infection prevention program to support state and federal efforts in the collection of data, as well as assist individuals who are at a high risk of contracting these common infections (Section 7141).
- Peer Support Programs: HHS is required to establish a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, which will provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to SUDs. (Section 7152) The bill also appropriates \$5 million annually to independent non-profits in the Building Communities of Recovery program. Funds will be used to create peer support networks and enhance long-term recovery services (Section 7151).
- Prescription Drug Management Programs (PMDPs): The CDC is authorized to provide grants to states to help improve PDMPs, update PDMP program capabilities, promote community health interventions, and evaluate and develop interventions to prevent

controlled substance overdoses. This will help to improve information sharing between states and support research activities related to combating the opioid crisis (Section 7161 & 7162).

- Review of Providers: HHS is required to conduct a review of all entities that receive federal funding for providing SUD treatment services and report to Congress with a plan to address any inadequacies in services or funding (Section 7171). HHS must also work with the Pain Management Best Practices Interagency Task Force to develop an action plan for potential changes to the Medicare and Medicaid programs to better prevent opioid addictions and enhance access to MAT (Section 6032).
- Reauthorization of the 21st Century Cures Act: H.R. 6 authorizes \$500 million annually for FY 2019 through FY 2021 for the Opioid State Targeted Response grants created under the 21st Century Cures Act. Five percent of funds will be set aside for Indian Tribes and up to 15 percent will be set aside for States that have a high prevalence of drug overdoses (Section 7181).

This memorandum only provides an overview of select provisions. For a more detailed breakdown, please refer to the [full text](#) or a [section-by-section summary](#) of this legislation. Additional information and background can also be found on the Energy and Commerce Committee's [webpage](#).

There are numerous provisions in this newly-enacted legislation that will be regulated and implemented in the coming months and years. Opportunities for stakeholder input in various forms are noted throughout the legislation and we are ready to assist in monitoring these opportunities as they arise.