

S. 2680, The Opioid Crisis Response Act of 2018

Legislation is the result of 7 bipartisan hearings on opioid crisis with FDA, NIH, CDC, SAMHSA, governors, experts, and families

To improve the ability of the Department of Health and Human Services, including the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Health Resources and Services Administration, as well as the Departments of Education and Labor, to address the crisis, including the ripple effects of the crisis on children, families, and communities, help states implement updates to their plans of safe care, and improve data sharing between states.

National Institutes of Health (NIH):

- **ACE Research Act** – To increase flexibility for NIH to approve high impact, cutting-edge projects that address the opioids crisis more quickly and efficiently, including finding a new, non-addictive painkiller, this would allow NIH to use “other transactional authority” for research to respond to public health threats.
- **Pain Research** – To improve scientific understanding of pain, including how to prevent, treat, and manage pain, and to advance scientific understanding of risk factors that could lead to substance use disorders, this would update the mission and reporting requirements for the Interagency Pain Research Coordinating Committee to better address issues related to the opioid crisis.

Food and Drug Administration (FDA):

- **Address the challenges in developing new non-addictive medical products intended to treat pain and addiction, and clarify regulatory pathways for these products, by holding public meetings and issuing guidance documents.**
 - **Expedited Pathways** – To help medical product manufacturers navigate FDA, this would clarify FDA’s interpretation of how the qualification parameters for expedited pathways like Breakthrough Designation and Accelerated Approval apply to novel non-addictive pain or addiction treatments.
 - **Pain Endpoints** – To help medical product manufacturers design clinical trials for innovative non-addictive pain treatments, this would require FDA to provide guidance on the appropriate use of pain endpoints across review divisions.
 - **Opioid Sparing** – To help advance the development of products that can reduce, replace, or prevent the use of opioids, this would direct FDA to clarify the requirements for opioid sparing data that can be included in medical product labeling.
 - **Risk-Benefit related to Misuse and Abuse** – To clarify FDA’s role in protecting public health, this would require FDA to provide clear guidance on how the agency would consider the risks and benefits of drugs that have a potential to be misused or abused.
- **Opioid Packaging** – To help encourage responsible prescribing behavior and limit overprescribing, this would clarify FDA’s authority to require drug manufacturers to package certain drugs, including opioids, for set treatment durations – for example, a blister pack with a 3 or 7-day supply.
- **Safe Disposal Systems** – To help prevent unneeded or unused opioids from falling into the wrong hands, this would clarify FDA’s authority to require manufacturers to provide a

simple and safe way to dispose of leftover drugs, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.

- **Improve FDA and Customs Border Protection (CBP) coordination at the border** – To help improve ability of FDA to find and seize illegal drugs, such as fentanyl, at the border, this strengthens coordination activities with CBP, which may be carried out through a memorandum of understanding. Provides that FDA has access to innovative detection technology and testing equipment to facilitate near-real-time information sharing, facility and physical infrastructure upgrades, and laboratory capacity.
- **Clarify FDA's post-market authorities** – Modifies the definition of an adverse drug experience to help FDA understand the long term effects of drugs, such as opioids, which may have reduced efficacy over time.

Substance Abuse and Mental Health Services Administration (SAMHSA):

- **Cures Grant Changes** – To focus federal funds on areas that have been hit hardest by the opioid crisis, this would allow HHS to provide additional funding to states with the highest age-adjusted mortality rate associated with opioid use disorders and would provide funding directly to Indian Tribes. This provision would also permit states and Tribes to direct funds to local needs related to substance use disorders, train health care practitioners to prevent diversion of controlled substances, and use the funds until they run out, rather than requiring states to spend them within the fiscal year.
- **Comprehensive Opioid Recovery Centers** – To provide the full continuum of treatment for patients in areas hit hardest by the opioid crisis, this would authorize a grant program for entities to establish or operate a comprehensive opioid recovery center and would require centers to serve as a resource for the community.
- **Recovery Housing Best Practices** – To assist those recovering from an opioid addiction with housing, this would require HHS to issue best practices for entities operating recovery housing facilities.
- **Opioid Prescription Limits** – To examine the impact of federal and state laws regulating the length, quantity, or dosage of opioid prescriptions, this would require the Secretary of HHS to issue a report on these laws, including the impact on overdose rates, diversion, and individuals for whom opioids are medically appropriate.
- **First Responder Training** – To support first responders so that they can safely respond to cases involving fentanyl, this would expand a grant program from the Comprehensive Addiction and Recovery Act (CARA) which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose.
- **Youth Prevention and Recovery Initiative** – To help prevent misuse of opioids, and to support recovery from opioid use disorder, in children, adolescents, and young adults, this program would require the Secretary of HHS in consultation with the Department of Education, to disseminate best practices and issue grants for prevention of and recovery from substance use disorder.
- **Coordination and Continuation of Care for Drug Overdose Patients** – To improve coordination and continuation of care and treatment, as appropriate, after an opioid overdose, and to reduce the likelihood of future relapse, recidivism, and overdose, this would require the Secretary to identify best practices and establish a grant program for the provision of care, overdose reversal medication, and follow up services to an individual after an overdose. Grantees would be required to offer recovery coaches, individuals with personal experience

with addiction and recovery, to persons who experience an overdose to help assist in their recovery.

- **Alternatives to Opioids** – To support hospitals and other acute care settings seeking to manage pain without using opioids, this would require the Secretary of HHS to provide technical assistance related to the use of alternatives to opioids, including for common painful conditions and certain patient populations, such as geriatric patients, pregnant women, and children.
- **Peer Support Technical Assistance** – To support long term recovery, requires HHS to provide technical assistance and support to organizations providing peer support services related to substance use disorder.

Centers for Disease Control and Prevention (CDC):

- **Prevention for States, Localities, and Tribes** – To establish or enhance evidence-based prevention activities, this program would award grants to carry out activities including PDMPs, innovative projects, and research.
- **Controlled Substance Data Collection** – To more rapidly assess and respond to the opioid crisis, this program would provide support to States, localities, and tribes to collect, analyze, and disseminate controlled substance overdose data.
- **Public and Provider Education** – To advance awareness regarding the risk of misuse and abuse of opioids, this program would disseminate information to providers and the public (including about prescribing and dispensing options related to partial fills of controlled substances), and support provider education, including through prescribing guidelines.
- **Neonatal Abstinence Syndrome Data Collection** – To collect and analyze data on the occurrence and prevention of neonatal abstinence syndrome, this program would support data collection and research on outcomes associated with prenatal opioid use.
- **Infections Associated with Injection Drug Use** – To prevent and respond to infections commonly associated with injection drug use, including viral hepatitis and HIV, this program would support state and federal efforts to collect data on such infections and identify and assist patients who may be at increased risk of infection.
- **Adverse Childhood Experiences Data Collection** – To help understand the causes and effects of adverse childhood experiences, this provision would authorize the CDC to support states in collecting and reporting data on adverse childhood experiences through public health surveys.

Supports for Children, Families, and Workers Impacted by the Crisis:

- **Interagency Task Force on Trauma-Informed Supports** – To help identify, prevent, and address the impact of trauma on children and youth, including trauma related to substance abuse, this creates a task force to recommend best practices for supporting children and families who have experienced or are at risk of experiencing trauma.
- **Demonstration Grants for Trauma-Informed Supports and Mental Health Care** – To better support children and families impacted by the opioid crisis, this would create a grant to increase student support services and better integrate mental health care in schools, aimed at preventing and mitigating the effects of negative childhood experiences.
- **Plans of Safe Care Implementation Grants** – To help states implement plans of safe care for substance-exposed infants included in the Comprehensive Addiction and Recovery Act

(CARA), these grants would facilitate collaboration and coordination between the agencies responsible for carrying out plans, and extend critical state technical assistance programs.

- **Grants Addressing Economic and Workforce Impacts of the Opioid Crisis** – To support state and local workforce boards and communities affected by the opioid crisis, these grants would target workforce shortages for the substance use disorder and mental health treatment workforce, and facilitate the alignment of job training and treatment services for individuals affected by opioid and substance use disorder.
- **Pregnant and Postpartum women and infants** – To better support the needs of pregnant and postpartum women and their infants, this would require the Secretary of HHS to submit a report on the implementation of the Final Strategy of the Protecting Our Infants Act. It also requires CDC to develop educational materials for pregnant women on pain management, and requires SAMHSA to disseminate the recommendations from the Final Strategy and information about substance use disorder for pregnant women.
- **Communication with Families During Emergencies** – To clarify that doctors are allowed to share certain health information with families and caregivers during an emergency such as an overdose, this requires the Secretary to notify providers annually of permitted disclosures during an emergency.

Drug Enforcement Administration (DEA):

- **Special Registration for Telemedicine** – To clarify DEA’s ability to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
- **Disposal of Controlled Substances by Hospice Care Providers** – To allow hospice care providers to safely and properly dispose of controlled substances and reduce the risk of drug diversion, this would give certain employees of qualified hospice programs the legal authority to dispose of controlled substances after a patient’s death.
- **Medication-Assisted Treatment** – To improve access to medication-assisted treatment (MAT), this codifies the ability for qualified physicians to prescribe MAT for up to 275 patients.
- **Delivery of Controlled Substances by a Pharmacy to an Administering Practitioner** - Permits implantable or injectable buprenorphine products, and intrathecal pumps, to be delivered by a pharmacy to an administering provider. This would help reduce diversion and ensure patients have adequate access to maintenance and detoxification treatments, while maintaining proper controls, such as storage and record keeping.

Data and Technology:

- **Supporting State Prescription Drug Monitoring Programs (PDMP)** – To encourage states to share PDMP data with one another, this would streamline federal requirements for PDMPs so doctors and pharmacies can know if patients have a history of substance use.
- **Jessie’s Law** – To make it easier for doctors to know if a patient has a history of opioid abuse, require HHS to develop best practices for prominently displaying this information in electronic health records, when requested by the patient.
- **Confidentiality of Substance Use Disorder Records** – To identify model training programs on how to protect and appropriately disclose confidential substance use disorder medical records for health care providers, patients, and their families.

Health Resources and Services Administration:

- **Access to Behavioral and Mental Health Services in Schools** – To improve access to mental health, behavioral, substance abuse disorder services, this provision would allow mental and behavioral health providers participating in the National Health Services Corps to provide services in schools and other community-based settings.
- **Substance Use Provider Workforce in Shortage Areas** – To strengthen the capacity of the behavioral health workforce, this provision would provide loan repayment to substance use disorder treatment providers, including masters level, licensed substance use disorder counselors, for practicing in substance use disorder treatment facilities and other health care settings in underserved areas through the National Health Service Corps.
- **Education and Training for Providers** – To improve tools for the health care workforce, this would update and improve resources for pain care providers to assess, diagnose, prevent, treat, and manage acute or chronic pain, as well as to detect the early warning signs of opioid use disorders. This provision also updates mental and behavioral health training programs to include trauma-informed care.