

The Opioid Crisis Response Act of 2018

Proposals are the result of 6 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 Food and Drug Administration, the National Institutes of Health, 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.

Food and Drug Administration (FDA):

- **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, such as those that allow a set treatment duration – for example, a “blister pack,” for patients who may only need 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 patients a simple and safe way to dispose of leftover drugs as part of the packaging.
- **Improve FDA and Customs Border Protection (CBP) coordination at the border** – To help improve the ability to detect and seize illegal drugs, such as fentanyl, at the border, this would ensure FDA and CBP have the detection technology and testing equipment that allows near-real-time data sharing, facility and physical infrastructure upgrades, and laboratory capacity.
- **Clarify the development and regulatory pathways for new non-addictive and non-opioid pain products**
 - **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-opioid pain treatments.
 - **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 will consider the risks and benefits of drugs that have a potential to be misused or abused.
 - **Opioid Sparing** – To help advance the development of products that can reduce or eliminate patients’ use of opioids to control pain, this would direct FDA to clarify requirements for a labeling claim that a medicine is as effective at controlling pain and able to reduce the amount of opioids a patient needs to control pain.
 - **Pain Endpoints** – To help medical product manufacturers design clinical trials for innovative non-addictive and non-opioid pain treatments, this would require FDA to provide guidance on the appropriate use of pain endpoints across review divisions.

Substance Abuse and Mental Health Services Administration (SAMHSA):

- **Cures Grant Changes** – To focus federal funds on states and tribes that have been hit harder by the opioid crisis, update the funding formula authorized by the 21st Century Cures Act to

account for the number of overdose deaths in each state and allow the funds to be used 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 abuse and misuse and support treatment of, and recovery from, opioid use disorder, in children, adolescents, and young adults, this program would require the Secretary of HHS, in consultation with the Secretary of Education, to disseminate best practices and issue grants for prevention and treatment of and recovery from 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 will 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 will 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 will disseminate information to providers and the public, 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 will 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 will support state and federal efforts to collect data on such infections and identify and assist patients who may be at increased risk of infection.

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

- **Interagency Task Force** – 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.
- **Pilot Program on Delivery of Trauma-Informed Support Practices** – To better support children and families impacted by the opioids crisis, this will create a grant to increase student

support services and better integrate mental health care in schools, aimed at preventing and mitigating the effects of trauma in children and youth.

- **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 will 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 will target workforce shortages for the substance abuse and mental health treatment workforce, and facilitate the alignment of job training and treatment services.

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.
- **Improving Access to Telemedicine** – To allow community mental health and addiction treatment centers to register with DEA to treat patients through the use of telemedicine, this would allow qualified centers to register with DEA to treat more patients, particularly those living in rural areas that lack qualified providers.
- **Disposal of Controlled Substances by Hospice Care Providers** – To allow hospice care providers to safely and properly dispose of controlled substances for the deceased, this would require DEA to issue regulations to help hospice programs dispose unneeded substances to help reduce the risk of diversion or misuse in the hospice care setting.
- **Medication-Assisted Treatment** – To improve access to medication-assisted treatment (MAT), this would make permanent the ability of nurse practitioners and physician assistants to prescribe MAT and codifies the ability for physicians to prescribe MAT for up to 275 patients. In 2016, Congress allowed physician assistants and nurse practitioners to prescribe medication assisted therapy to combat opioid use disorder through 2021. CBO has preliminarily estimated that expanding this policy, including making it permanent, could increase federal spending by \$450 million over 10 years. If the Senate is able to develop bipartisan payfors to cover the cost of this policy, this policy will be included in the final legislation.

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:

- **Services in Areas with Health Providers Shortages** – To improve access to mental health, behavioral, substance use disorder services, this would allow health providers participating in the National Health Services Corps to provide services in schools located in areas with that have been hit hardest by the opioid crisis and with mental health professional shortages. This also

allows masters level, licensed substance use disorder treatment counselors to receive loan repayment for practicing in underserved areas.

- **Education and Training for Providers** – To improve tools for pain care providers, this updates and improves resources to assess, diagnose, prevent, treat, and manage acute or chronic pain, as well as to detect the early warning signs of opioid use disorders.