Opioid Crisis Response Act of 2018

TITLE I: Reauthorization of Cures Funding	
Sec. 101. Cures Funding Extension.	• Reauthorizes and improves the state targeted response grants from the 21st Century Cures Act to provide funding to Tribes and to improve flexibility for states in using the grants.
TITLE II: Research and Innovation	
Sec. 201. Advancing Cutting-Edge Research.	• Allows NIH to use its "other transactions authority" for high impact cutting-edge research projects that respond to public health threats, including the opioid crisis and finding a new, non-addictive painkiller. NIH was given this authority for the Precision Medicine Initiative and fifty percent of the Common Fund in the 21st Century Cures Act.
Sec. 202. Pain Research	• Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the Food and Drug Administration.
TITLE III: Medical Products & Controlled Substances Safety	
Sec. 301. Clarifying FDA Regulations for Non-Addictive and Non-Opioids Products.	• Clarifies FDA's development and regulatory pathways for medical product manufacturers through guidance for new non-addictive medical products intended to treat pain or addiction. • Requires the FDA to hold one or more public meeting on the challenges and barriers to developing non-addictive medical products intended to treat pain, including how the risk of misuse and abuse may be incorporated into FDA's assessments, novel clinical trial designs, and evidentiary standards related to opioid sparing. • Requires the FDA to issue guidance to address: o *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. o *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. o *Opioid Sparing* – To help advance the development of products that can reduce, replace, or avoid patients' use of opioids to control pain, this would direct FDA to clarify requirements for opioid sparing data to be used in the label that a medicine is as effective at controlling pain and able to reduce, replace, or avoid the amount of opioids a patient needs to control pain. o *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.

Sec. 302. Clarifying FDA Packaging Authorities.	• Clarifies FDA's authority to require drug manufacturers to package certain opioids to allow for a set treatment duration – for example, a blister pack with a 3 or 7-day supply. • Clarifies FDA's authorities to require manufacturers to give patients simple and safe options to dispose of unused opioids, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable.
Sec. 303. Strengthening FDA & CBP Coordination & Capacity.	• Improves detection and seizure of illegal drugs, such as fentanyl, by strengthening coordination activities between FDA and the United States Customs and Border Protection, which may be carried out through a memorandum of understanding between such agencies. • Provides facility and physical infrastructure improvements, including renovations or upgrades, and laboratory capacity for purposes of detection and testing imports. • Provides that FDA has access to innovative detection technology and testing equipment to facilitate near-real-time information sharing. • Requires a report on implementation and summary of progress made towards near-real-time information sharing and the interoperability of such technologies.
Sec.304.Clarifying FDA post-market authorities.	• Clarifies FDA's post-market authorities for drugs, such as opioids, which may have reduced efficacy over time, by modifying the definition of an adverse drug experience to include such situations.
Sec. 306. First Responder Training.	• Expands a grant program authorized by the Comprehensive Addiction and Recovery Act, which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose, to include training on safety around fentanyl.
Sec. 307. Disposal of Controlled Substances by Hospice Programs.	• Provides certain health professionals in qualified hospice programs the legal authority to dispose of controlled substances after a hospice patient's death to help reduce the risk of diversion or misuse in the hospice setting.
Sec. 308. GAO Study and Report on Hospice Safe Disposal Management.	• Requires GAO to conduct a study and report on hospice programs' written policies and procedures on the management and disposal of controlled substances in the home of an individual.
Sec. 309. Delivery of a controlled substance by a pharmacy to be administered by injection, implantation, or intrathecal pump	• Permits implantable or injectable buprenorphine products, and intrathecal pumps, to be delivered by a pharmacy to an administering practitioner.
TITLE IV: Treatment & Recovery	
Sec. 401. Comprehensive Opioid Recovery Centers.	• Authorizes a grant program through the Substance Abuse and Mental Health Services Administration (SAMHSA) for entities to establish or operate comprehensive opioid recovery centers that serve as a resource for the community. These entities may utilize the ECHO model, which supports care coordination and services delivery through technology.

Sec. 402. Program to support coordination and continuation of care for drug overdose patients.	• Requires the Secretary of HHS to issue best practices for emergency treatment of a known or suspected drug overdose, coordination and continuation of care and treatment after an overdose, and provision of overdose reversal medication, as appropriate. • Authorizes a grant program for education on overdose prevention, the establishment or implementation of policies and procedures to treat and support recovery for individuals who have experienced a non-fatal overdose, and the use of recovery coaches to support recovery.
Sec.403.Alternatives to opioids.	• Requires HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management.
Sec.404.Peer support technical assistance.	• Requires HHS to provide technical assistance and support to organizations providing peer support services related to substance use disorder.
Sec. 405. Medication-Assisted Treatment for Recovery from Addiction.	• Codifies the ability of qualified physicians to prescribe medication assisted treatment (MAT) for up to 275 patients, to improve access to MAT.
Sec. 406. National Recovery Housing Best Practices.	• Requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid addiction with housing
Sec. 407. Addressing Economic & Workforce Impacts of the Opioid Crisis.	• Authorizes the Department of Labor to award dislocated worker grants to states through the Workforce Innovation and Opportunity Act to support local workforce boards and local partnerships in tackling shortages in substance use disorder and mental health treatment workforce and provide coordinated job training and treatment services to individuals in affected communities with opioid or substance use disorder.
Sec. 408. Youth Prevention and Recovery.	• Requires the Secretary of Health Human Services (HHS) in consultation with the Department of Education, to disseminate best practices and issue grants for prevention of and recovery from substance use disorder in children, adolescents and young adults.
Sec. 409. Plans of Safe Care.	• Provides support for states to collaborate and improve plans of safe care for substance-exposed infants. States may use funds to coordinate with various agencies responsible for child and family wellbeing, develop policies and procedures, train health care and child welfare professionals, establish partnerships, and develop and update technology and monitoring systems to more effectively implement plans of safe care. Requires the Secretary to extend technical assistance programs and issue guidance on plans of safe care.
Sec. 410. Regulations Relating to Special Registration for Telemedicine.	• Clarifies DEA's ability to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
Sec. 411. National Health Service Corps Behavioral and Mental Health Professionals Providing Obligated Services in Schools and other Community-Based Settings.	• Allows an entity to direct National Health Service Corps members to provide behavioral and mental health services at a school or other community-based setting located in a health professional shortage area, and for these services to be applied towards completion of their obligated service requirements.

Sec. 412. Loan Repayment for Substance Abuse Treatment Providers.	• Requires the Secretary of HHS to enter into contracts to provide loan repayment to behavioral health providers practicing in substance use disorder treatment facilities in mental health professional shortage areas through National Health Service Corps authorities.
Sec. 413. Improving treatment for pregnant and postpartum women.	• Requires the Secretary of HHS to issue and periodically update a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to the Protecting Our Infants Act of 2015. • Reauthorizes the Residential Treatment for Pregnant and Postpartum Women grant program.
Sec.414. Early intervention.	• Requires the Center for Substance Abuse Prevention to develop, in cooperation with the CDC, educational materials for clinicians to use with pregnant women for shared decision-making regarding pain management during pregnancy. • Requires implementation and dissemination, as appropriate, of the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy," issued by HHS in 2017.
TITLE V: Prevention	
Sec. 501. Study on Prescribing Limits.	• Requires HHS, in consultation with the Attorney General, to submit to Congress a report on the impact of federal and state laws and regulations that limit the length, quantity, or dosage of opioid prescriptions.
Sec. 502. Programs for health care workforce.	• Increases education and training in pain care by requiring grant recipients to develop a comprehensive education and training plan. Such plan would include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. • Updates pain care programs to include alternatives to opioid pain treatment and by promoting non-addictive and non-opioid pain treatments, and non-pharmacologic treatment. • Updates mental and behavioral health education and training grant program to include trauma-informed care.
Sec. 503. Education and Awareness Campaigns.	• Advances education and awareness among the public and providers. With regards to providers, advances continuing education to promote improved prescribing practices and improved education on and use of evidence-based prescribing guidelines across health care settings. • Provides education and awareness for providers, patients, and consumers about the prescribing and dispensing options related to partial fills of controlled substances in the Controlled Substances Act.
Sec. 504. Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.	• Authorizes the Centers for Disease Control and Prevention (CDC)'s work to combat the opioid crisis through the collection, analysis, and dissemination of data, including through grants for states, localities, and tribes.
Sec. 505. Preventing Overdoses of Controlled Substances.	• Provides support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs) and implement other evidence-based prevention strategies, encourages data sharing between states, and supports other prevention and research activities related to controlled substances.

Sec. 506. CDC Surveillance and Data Collection for Child, Youth, and Adult Trauma	• Authorizes CDC to support states' efforts to collect and report data on adverse childhood experiences through existing public health surveys.
Sec. 507. Reauthorization of NASPER.	• Reauthorizes this HHS grant program to allow states to develop, maintain, or improve PDMPs and improve the interoperability of PDMPs with other states and with other health information technology.
Sec. 508. Jessie's Law.	• Requires HHS to develop best practices for prominently displaying substance use treatment information in electronic health records, when requested by the patient.
Sec. 509. Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records.	• Requires HHS to identify Model Programs and Materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.
Sec. 510. Communication with Families During Emergencies	• Requires the Secretary to notify providers annually regarding sharing of certain health information with family and caregivers during an emergency such as an overdose.
Sec. 511. Prenatal and Postnatal Health.	• Authorizes data collection and analysis on neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.
Sec. 512. Surveillance and Education Regarding Infections Associated with Injection Drug Use and Other Risk Factors.	• Reauthorizes and builds upon CDC's program to prevent and respond to infections commonly associated with injection drug use, including viral hepatitis and HIV, by supporting state and federal efforts to collect data on such infections and identify and assist patients who may be at risk of infection.
Sec. 513. Task Force To Develop Best Practices For Trauma-Informed Identification, Referral, and Support.	• Creates an interagency task force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants, children, youth, and their families. • Requires the task force to develop a set of best practices and national strategy, and to identify existing federal authorities and grant programs where trauma-informed practices are allowable. • Requires the task force to submit a final report of findings and recommendations to Congress, relevant cabinet Secretaries, and the general public not less than three years after its first meeting.
Sec. 514. Grants to Improve Trauma Support Services and Mental Health Care for Children and Youth in Educational Settings.	• Authorizes the Secretary of Education, in coordination with the Director of SAMHSA, to make grants that link educational agencies with mental health systems in order to increase student access to evidence-based trauma support services to help prevent and mitigate trauma that children and youth experience. • Requires the Secretary to conduct a rigorous, independent analysis and disseminate findings from the demonstration grants.
Sec. 515. National Child Traumatic Stress Initiative.	• Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.