

Opioid Crisis Response Act of 2018

TITLE I: Opioid Crisis Response Act	
Sec. 1001. Definitions.	<ul style="list-style-type: none"> 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.
Subtitle A: Reauthorization of Cures Funding	
Sec. 1101. Cures Funding Extension.	<ul style="list-style-type: none"> 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.
Subtitle B: Research and Innovation	
Sec. 1201. Advancing Cutting-Edge Research.	<ul style="list-style-type: none"> Allows the National Institutes of Health (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. 1202. Pain Research	<ul style="list-style-type: none"> 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.
Subtitle C: Medical Products & Controlled Substances Safety	
Sec. 1301. Clarifying FDA Regulations for Non-Addictive and Non-Opioids Products.	<ul style="list-style-type: none"> Clarifies the development and regulatory pathways of the Food and Drug Administration (FDA) 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: <ul style="list-style-type: none"> <i>Expedited Pathways</i> – 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. <i>Pain Endpoints</i> – 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. <i>Opioid Sparing</i> – 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

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	<p>effective at controlling pain and able to reduce, replace, or avoid the amount of opioids a patient needs to control pain.</p> <ul style="list-style-type: none"> ○ <i>Risk Benefit related to Misuse and Abuse</i> – 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. 1302. Clarifying FDA Packaging Authorities.	<ul style="list-style-type: none"> ● 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. 1303. Strengthening FDA & CBP Coordination & Capacity.	<ul style="list-style-type: none"> ● Improves detection and seizure of illegal drugs, such as fentanyl, by strengthening coordination activities between FDA and the United States Customs and Border Protection (CBP), 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. 1304. Clarifying FDA post-market authorities.	<ul style="list-style-type: none"> ● 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. 1305. Restricting Entrance of Illicit Drugs	<ul style="list-style-type: none"> ● Codifies the current practice of FDA upon discovering or receiving a package containing an illegal opioid or controlled substance, FDA will transfer that package to CBP for destruction under CBP’s existing authorities. ● Debars a person from importing an FDA-regulated product into the US if they have been convicted of a felony related to importation of illegal drugs or controlled substances. ● Gives FDA greater ability to refuse the admission of counterfeit drugs.
Sec. 1306. First Responder Training.	<ul style="list-style-type: none"> ● 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, and to include training on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.
Sec. 1307. Disposal of Controlled Substances by Hospice Programs.	<ul style="list-style-type: none"> ● Provides certain health professionals in qualified hospice programs the legal authority to dispose of controlled substances in the hospice setting to help reduce the risk of diversion or misuse.

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<p>Sec. 1308. GAO Study and Report on Hospice Safe Disposal Management.</p>	<ul style="list-style-type: none"> Requires the Government Accountability Office (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.
<p>Sec. 1309. Delivery of a Controlled Substance by a Pharmacy to be Administered by Injection or Implantation.</p>	<ul style="list-style-type: none"> Permits implantable or injectable controlled substances for the purpose of maintenance or detoxification treatment to be delivered by a pharmacy to an administering practitioner, while maintaining proper controls, such as storage and record keeping.
<p>Subtitle D: Treatment & Recovery</p>	
<p>Sec. 1401. Comprehensive Opioid Recovery Centers.</p>	<ul style="list-style-type: none"> 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.
<p>Sec. 1402. Program to support coordination and continuation of care for drug overdose patients.</p>	<p>Requires the Secretary of the Department of Health and Human Services (HHS) to issue best practices for emergency treatment of a known or suspected drug overdose, use of recovery coaches after a non-fatal 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.</p>
<p>Sec. 1403. Alternatives to opioids.</p>	<ul style="list-style-type: none"> Requires HHS to provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. Authorizes a grant program to support hospitals and other acute care settings that manage pain with alternatives to opioids.
<p>Sec. 1404. Building communities of recovery.</p>	<ul style="list-style-type: none"> Reauthorizes and modifies the Building Communities of Recovery program to include peer support networks. This program provides funding for community organizations providing long-term recovery support services.
<p>Sec. 1405. Peer support technical assistance center.</p>	<ul style="list-style-type: none"> Requires HHS to establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support, to provide technical assistance and support to recovery community organizations and peer support networks providing peer support services related to substance use disorder.
<p>Sec. 1406. Medication-Assisted Treatment for Recovery from Addiction.</p>	<ul style="list-style-type: none"> Allows physicians who have recently graduated in good standing from an accredited school of allopathic or osteopathic medicine, and who meet the other training requirements to prescribe medication-assisted treatment (MAT), to obtain a waiver to prescribe MAT.
<p>Sec. 1407. Grant Program.</p>	<ul style="list-style-type: none"> Authorizes a grant program to support development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.
<p>Sec. 1408. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.</p>	<ul style="list-style-type: none"> Codifies the ability of qualified physicians to prescribe MAT for up to 275 patients, to improve access to MAT.

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<p>Sec. 1409. Recovery Housing Best Practices and Identification of Potentially Fraudulent Recovery Housing Operators.</p>	<ul style="list-style-type: none"> • Requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid addiction with housing. • Requires HHS to identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.
<p>Sec. 1410. Addressing Economic & Workforce Impacts of the Opioid Crisis.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1411. CAREER Act</p>	<ul style="list-style-type: none"> • Authorizes the Secretary of HHS to establish a grant program to support individuals in recovery from a substance use disorder transition to independent living and the workforce.
<p>Sec. 1412. Pilot Program to Help Individuals in Recovery from a Substance Use Disorder become Stably Housed</p>	<ul style="list-style-type: none"> • Authorizes a pilot program to provide individuals in recovery from a substance use disorder with stable, temporary housing.
<p>Sec. 1413. Youth Prevention and Recovery.</p>	<ul style="list-style-type: none"> • Requires 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 in children, adolescents and young adults.
<p>Sec. 1414. Plans of Safe Care.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1415. Regulations Relating to Special Registration for Telemedicine.</p>	<ul style="list-style-type: none"> • Clarifies the ability of the Drug Enforcement Administration (DEA) to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.
<p>Sec. 1416. National Health Service Corps Behavioral and Mental Health Professionals Providing Obligated Services in Schools and other Community-Based Settings.</p>	<ul style="list-style-type: none"> • Allows an entity to direct National Health Service Corps participants 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.
<p>Sec. 1417. Loan Repayment for Substance Abuse Treatment Providers.</p>	<ul style="list-style-type: none"> • 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.

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<p>Sec. 1418. Protecting moms and infants.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1419. Early interventions for pregnant women and infants.</p>	<ul style="list-style-type: none"> • Requires the Center for Substance Abuse Prevention to develop, in cooperation with the Centers for Disease Control and Prevention (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.
<p>Sec. 1420. Report on investigations regarding parity in mental health and substance use disorder benefits.</p>	<ul style="list-style-type: none"> • Requires the Assistant Secretary of Labor of the Employee Benefits Security Administration, in collaboration with the Administrator of the Centers for Medicare & Medicaid Services (CMS) and the Secretary of the Treasury, to provide additional information in annual reports to Congress on mental health parity compliance, including information on which agencies are conducting investigations and information about any coordination with State regulators.
<p>Subtitle E: Prevention</p>	
<p>Sec. 1501. Study on Prescribing Limits.</p>	<ul style="list-style-type: none"> • Requires HHS, in consultation with the Attorney General (AG), 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.
<p>Sec. 1502. Programs for health care workforce.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1503. Education and Awareness Campaigns.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1504. Enhanced Controlled Substance Overdoses Data Collection, Analysis, and Dissemination.</p>	<ul style="list-style-type: none"> • Authorizes the CDC’s work to combat the opioid crisis through the collection, analysis, and dissemination of data, including through grants for states, localities, and tribes.

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<p>Sec. 1505. Preventing Overdoses of Controlled Substances.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1506. CDC Surveillance and Data Collection for Child, Youth, and Adult Trauma</p>	<ul style="list-style-type: none"> • Authorizes CDC to support states' efforts to collect and report data on adverse childhood experiences through existing public health surveys.
<p>Sec. 1507. Reauthorization of NASPER.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1508. Jessie's Law.</p>	<ul style="list-style-type: none"> • Requires HHS to develop best practices for prominently displaying substance use treatment information in electronic health records, when requested by the patient.
<p>Sec. 1509. Development and Dissemination of Model Training Programs for Substance Use Disorder Patient Records.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1510. Communication with Families During Emergencies</p>	<ul style="list-style-type: none"> • Requires the Secretary to notify providers annually regarding sharing of certain health information with family and caregivers during an emergency such as an overdose.
<p>Sec. 1511. Prenatal and Postnatal Health.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1512. Surveillance and Education Regarding Infections Associated with Injection Drug Use and Other Risk Factors.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1513. Task Force To Develop Best Practices For Trauma-Informed Identification, Referral, and Support.</p>	<ul style="list-style-type: none"> • 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.
<p>Sec. 1514. Grants to Improve Trauma Support Services and Mental Health Care for Children and Youth in Educational Settings.</p>	<ul style="list-style-type: none"> • Authorizes the Secretary of Education, in coordination with the Assistant Secretary of Mental Health and Substance Use, 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.
<p>Sec. 1515. National Child Traumatic Stress Initiative.</p>	<ul style="list-style-type: none"> • Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to

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	communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.
Sec. 1516. National Milestones to Measure Success in Curtailing the Opioid Crisis	<ul style="list-style-type: none"> Requires the Secretary of HHS to develop or identify existing national indicators to measure success in curtailing the opioid crisis and significantly reversing the incidence and prevalence of opioid misuse and abuse and opioid-related morbidity and mortality in the United States within 5 years of enactment.
TITLE II: HEAL Act of 2018	
Sec. 2001. Short title.	<ul style="list-style-type: none"> “Helping to End Addiction and Lessen Substance Use Disorders Act of 2018” or the “HEAL Act of 2018”
Subtitle A: Medicare	
Sec. 2101. Medicare opioid safety education.	<ul style="list-style-type: none"> Requires that the annual <i>Medicare & You</i> handbook for Medicare beneficiaries include references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid Medicare-covered pain management treatments; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.
Sec. 2102. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.	<ul style="list-style-type: none"> Eliminates certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders, beginning January 1, 2019. Allows payment for substance use disorder treatment services furnished via telehealth to Medicare beneficiaries at originating sites, including a beneficiary’s home, regardless of geographic location. A separate facility fee would not be provided if the originating site is the beneficiary’s home.
Sec. 2103. Comprehensive screenings for seniors.	<ul style="list-style-type: none"> Requires that the Medicare Initial Preventive Physical Examination (also known as the “Welcome to Medicare” visit) and annual wellness visits include a review of the beneficiary’s current opioid prescriptions and screening for potential substance use disorders, including a referral for treatment as appropriate.
Sec. 2104. Every prescription conveyed securely.	<ul style="list-style-type: none"> Requires that physicians and other practitioners prescribe Part D-covered controlled substances electronically so as to improve tracking of opioid use and prevent diversion. Directs the Centers for Medicare and Medicaid Services (CMS) to establish a list of exceptions, as well as the penalty for failure to comply when the e-prescribing requirement applies, in consultation with stakeholders.

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<p>Sec. 2105. Standardizing electronic prior authorization for safe prescribing.</p>	<ul style="list-style-type: none">• Requires that prior authorizations related to Part D prescriptions that are processed electronically use a standard format, improving the efficiency with which prior authorizations are processed and enabling beneficiaries to more promptly receive needed drugs.
<p>Sec. 2106. Strengthening partnerships to prevent opioid abuse.</p>	<ul style="list-style-type: none">• Requires CMS to establish a web-based portal to enhance communication between the agency, Medicare Advantage plans with prescription drug plans (MA-PDs), standalone prescription drug plans, and Medicare Drug Integrity Contractors, enhancing the ability to address fraud, waste, and abuse.
<p>Sec. 2107. Commit to opioid medical prescriber accountability and safety for seniors.</p>	<ul style="list-style-type: none">• Requires CMS to notify Part D prescribers who are identified as a statistical outlier when it comes to prescribing opioids as compared to their peers, with the notification including the peer comparison details and information on evidence-based opioid prescribing guidelines.

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	<ul style="list-style-type: none"> • Directs CMS to connect the prescribers identified as a persistent statistical outlier with entities that provide educational assistance, and gives CMS authority to require those prescribers to enroll in Medicare.
<p>Sec. 2108. Fighting the opioid epidemic with sunshine.</p>	<ul style="list-style-type: none"> • Enhances the CMS-run Open Payments, or “sunshine”, program by expanding the types of professionals for whom a drug and device manufacturer is required to report when the manufacturer provides something of value to include: physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. • Sunsets the prohibition that prevents inclusion of the unique identification number, known as the National Provider Identifier, for all professionals and other entities displayed on the CMS Open Payments website.
<p>Sec. 2109. Demonstration testing coverage of certain services furnished by opioid treatment programs.</p>	<ul style="list-style-type: none"> • Requires that the HHS Secretary conduct a five-year demonstration project to test Medicare coverage and payment for opioid use disorder treatment services furnished by an eligible Opioid Treatment Program, to begin no later than January 1, 2021. • An eligible OTP selected to participate in the demonstration would receive a bundled payment made under Part B for opioid use disorder treatment services. Those treatment services would include dispensing and administering FDA-approved opioid agonist and antagonist treatment medications, substance use disorder counseling; individual and group therapy; toxicology testing; and other services determined appropriate by the HHS Secretary. • Directs the HHS Secretary to provide a report to Congress that includes an evaluation of the demonstration no later than two years after its completion.
<p>Sec. 2110. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.</p>	<ul style="list-style-type: none"> • Requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in its system for monitoring those potentially at-risk for prescription drug abuse, enabling prescription drug plans to take steps that inform prescribers and dispensing pharmacies and facilitate improved care.
<p>Sec. 2111. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.</p>	<ul style="list-style-type: none"> • Requires that a beneficiary enrolled in Medicare Part D who CMS identifies as potentially at-risk for prescription drug abuse (or is subsequently identified as at-risk) can automatically escalate an appeal of such designation to an entity external to the prescription drug plan if the plan affirms its own decision at the initial appeal level.
<p>Sec. 2112. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.</p>	<ul style="list-style-type: none"> • Clarifies that the CMS Center for Medicare and Medicaid Innovation may test payment and delivery models that provide incentive payments to behavioral health providers for the adoption and use of certified electronic health record technology to improve the quality and coordination of care through the electronic documentation and

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Sec. 2113. Medicare Improvement Fund.	<ul style="list-style-type: none">• Deposits \$65 million into the Medicare Improvement Fund that is available to CMS to make improvements under the original Medicare fee-for-service program.
Subtitle B: Medicaid	
Sec. 2201. Caring recovery for infants and babies.	<ul style="list-style-type: none">• Clarifies states' ability under Medicaid to provide care for infants with neonatal abstinence syndrome in residential pediatric recovery centers, as well as those centers' option to provide counseling or other services to mothers or caretakers provided those services are otherwise covered.

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<p>Sec. 2202. Peer support enhancement and evaluation review.</p>	<ul style="list-style-type: none"> • Directs the GAO to study and submit a report on how Medicaid covers peer support services, including: the types of services provided; payment models; states’ experiences providing peer support services; and how states measure the extent to which peer support services improve costs and outcomes for beneficiaries.
<p>Sec. 2203. Medicaid substance use disorder treatment via telehealth.</p>	<ul style="list-style-type: none"> • Directs CMS to issue guidance to states on options for providing services via telehealth that address substance use disorders under Medicaid. Requires guidance to cover state options for federal reimbursement for substance use disorder services and treatment using telehealth including, services addressing high-risk individuals, provider education through a hub-and-spoke model, and options for providing telehealth services to students in school-based health centers. • Directs GAO to evaluate children’s access to Medicaid services to treat substance use disorders, including options to improve access through telehealth. • Directs CMS to issue a report to Congress identifying best practices and potential solutions to barriers to furnishing services to children via telehealth to compare services delivered via telehealth to in-person.
<p>Sec. 2204. Enhancing patient access to non-opioid treatment options.</p>	<ul style="list-style-type: none"> • Directs CMS to issue guidance on states’ options for treating and managing beneficiaries’ pain through non-opioid pain treatment and management options under Medicaid.
<p>Sec. 2205. Assessing barriers to opioid use disorder treatment.</p>	<ul style="list-style-type: none"> • Directs GAO to analyze and issue a report to Congress on the barriers to access to substance use disorder treatment medications under various drug distribution models, such as buy-and-bill, as well as addressing options for state Medicaid programs to reduce or remove such barriers. GAO is directed to make recommendations, as appropriate.
<p>Sec. 2206. Help for moms and babies.</p>	<ul style="list-style-type: none"> • Modifies the “IMD exclusion” for pregnant and postpartum women to address a subset of the prohibition on Medicaid from paying for otherwise coverable Medicaid services for certain adults while in institutions for mental disease (IMD). Modifies Section 1905(a) of the Social security act to ensure that pregnant and postpartum women receiving care for substance use disorders in an IMD can continue to receive other Medicaid-covered care outside of the IMD, such as prenatal services.
<p>Sec. 2207. Securing flexibility to treat substance use disorders.</p>	<ul style="list-style-type: none"> • Clarifies flexibilities around Medicaid’s IMD exclusion where, in some cases, managed care plans may provide alternative services in lieu of other services that are not permitted under the state plan. Codifies regulations permitting managed care plans to cover treatment in an IMD for a certain number of days in a month in lieu of other types of services.
<p>Sec. 2208. MACPAC study and report on MAT utilization controls under State Medicaid programs.</p>	<ul style="list-style-type: none"> • Directs the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on utilization management controls applied to medication-assisted treatment options in both fee-for-service and managed Medicaid programs.

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<p>Sec. 2209. Opioid addiction treatment programs enhancement.</p>	<ul style="list-style-type: none"> Requires the Secretary to publish a data book detailing, for each state, statistics on the prevalence and treatment of substance abuse disorder among Medicaid beneficiaries, including beneficiaries receiving treatment under fee for service and managed care arrangements. Requires the data book to be issued within one year and use data from the Transformed Medicaid Statistical Information System (T-MSIS). Requires HHS to make T-MSIS data available to researchers in the same manner in which precursor data had been made available in the past, including relevant privacy and security protections.
<p>Sec. 2210. Better data sharing to combat the opioid crisis.</p>	<ul style="list-style-type: none"> Clarifies states' ability to access and share data from prescription drug monitoring program databases, consistent with the parameters established in state law, including with providers and managed care entities, and in adherence to applicable security and privacy protections and laws.
<p>Sec. 2211. Mandatory reporting with respect to adult behavioral health measures.</p>	<ul style="list-style-type: none"> Requires state Medicaid programs to report on all behavioral health quality measures included in the mandatory core set of adult health quality measures beginning 2024.
<p>Sec. 2212. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.</p>	<ul style="list-style-type: none"> Directs HHS to issue a report on innovative state initiatives and covered housing-related services that state Medicaid programs may use to provide supports to Medicaid enrollees with substance use disorders who are experiencing homelessness or are at risk of homelessness.
<p>Sec. 2213. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.</p>	<ul style="list-style-type: none"> Directs HHS to provide technical assistance to states to develop and coordinate housing-related supports and services under Medicaid, either through state plans or waivers, and care coordination services, for Medicaid enrollees with substance use disorders.
<p>Subtitle C: Human Services</p>	
<p>Sec. 2301. Supporting family-focused residential treatment.</p>	<ul style="list-style-type: none"> Requires HHS to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment programs by: <ul style="list-style-type: none"> Describing existing opportunities under Medicaid to support parents in family-focused residential treatment; Explaining how states can coordinate Medicaid, foster care, and other HHS funding to support substance abuse treatment and other services provided by treatment facilities; and Describing how states can coordinate Medicaid and foster care funding—specifically per the new authority granted in the <i>Family First Prevention Services Act</i>—to support children placed with their parents in family-based treatment facilities.
<p>Sec. 2302. Improving recovery and reunifying families.</p>	<ul style="list-style-type: none"> Provides \$15 million to HHS to replicate a “recovery coach” program for parents with children in foster care due to parental substance abuse, which has been shown to reduce the length of time children spend in foster care. This will allow HHS to determine whether the program can be replicated in another state and yield the same results.
<p>Sec. 2303. Building capacity for</p>	<ul style="list-style-type: none"> Beginning in FY 2020, states will be eligible to receive funding to provide evidence-based substance abuse prevention and treatment

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family-focused residential treatment.	services to families with children at risk of entering foster care (as a result of the <i>Family First Prevention Services Act</i>). This section authorizes \$20 million in funding for HHS to award to states to develop, enhance, or evaluate family-focused treatment programs to increase the number of evidence-based programs that will later qualify for funding under <i>Family First</i> .
Subtitle D: Synthetics Trafficking and Overdose Prevention	
See separate section by section of S.3057.	
TITLE III: JUDICIARY	
Subtitle A: Access to Increased Drug Disposal	
Sec. 3101. Short title.	<ul style="list-style-type: none"> • Access to Increased Drug Disposal Act of 2018
Sec. 3102. Definitions.	<ul style="list-style-type: none"> • Defines terms “Attorney General,” “authorized collector,” “covered grant,” and “eligible collector.”
Sec. 3103. Authority to make grants.	<ul style="list-style-type: none"> • Allows the AG to award grants to States to increase the participation of eligible collectors as authorized collectors for drug-disposal programs.
Sec. 3104. Application.	<ul style="list-style-type: none"> • Outlines the requirements that a state must meet if submitting an application for a grant, which includes: <ul style="list-style-type: none"> ○ Identifying a state agency that oversees pharmaceutical care; ○ Detailing a plan to increase participation rates of authorized collectors; and ○ Describing how the state will select eligible collectors to be served under the grant.
Sec. 3105. Use of grant funds.	<ul style="list-style-type: none"> • Limits the use of the grant that a state receives to the costs of installation, maintenance, training, purchasing, and disposal of controlled substance associated with the participation of collectors.
Sec. 3106. Eligibility for grant.	<ul style="list-style-type: none"> • Requires that the AG shall award a grant to five states, not less than three of which are in the lowest 25 percent of states in participation rates for drug take-back programs.
Sec. 3107. Duration of grants.	<ul style="list-style-type: none"> • Allows the AG to determine the period of years for which the grant is made to the state.
Sec. 3108. Accountability and oversight.	<ul style="list-style-type: none"> • Requires a state that receives a grant to provide a report to the AG that lists the recipients of grant amounts, describes the activities used by the grant amounts, and contains performance measures as to the effectiveness of the grant, including participation rates.
Sec. 3109. Duration of program.	<ul style="list-style-type: none"> • Limits the AG to award grants for each of the first 5 fiscal years after enactment.
Sec. 3110. Authorization of appropriations.	<ul style="list-style-type: none"> • Outlines that there are authorized to be appropriated to the AG such sums as may be necessary to carry out this Act.
Subtitle B: Using Data to Prevent Opioid Diversion	
Sec. 3201. Short title.	<ul style="list-style-type: none"> • Using Data to Prevent Opioid Diversion Act of 2018
Sec. 3202. Purpose.	<ul style="list-style-type: none"> • States the purpose of the bill, which is to provide drug manufacturers and distributors with access to anonymized information through ARCOS to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids which will in turn reduce diversion rates.
Sec. 3203. Amendments.	<ul style="list-style-type: none"> • Requires DEA to make anonymized information available to registrants with access to ARCOS, including the total number of distributors

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	<p>serving a single pharmacy or practitioner, and the total number of opioid pills distributed to a single pharmacy or practitioner.</p> <ul style="list-style-type: none"> • Mandates that DEA share information on amounts, outliers, and trends of distributor and pharmacy registrants. • Increases civil and criminal penalties for drug manufacturers and distributors.
Sec. 3204. Report.	<ul style="list-style-type: none"> • Requires DEA to report to Congress on how it is using ARCOS data to identify and stop suspicious orders of opioids.
Subtitle C: Substance Abuse Prevention	
Sec. 3301. Short title.	<ul style="list-style-type: none"> • Substance Abuse Prevention Act of 2018
Sec. 3302. Reauthorization of the Office of National Drug Control Policy.	<ul style="list-style-type: none"> • Reauthorizes the Office of National Drug Control Policy (ONDCP) at the White House, which oversees all Executive Branch efforts on narcotics control, including the development of a national drug control strategy.
Sec. 3303. Reauthorization of the Drug-Free Communities Program.	<ul style="list-style-type: none"> • Reauthorizes the Drug-Free Communities (DFC) Program through 2022. DFC is a grant program administered by ONDCP that works to prevent youth substance abuse and reduce the demand for illicit narcotics at a community level.
Sec. 3304. Reauthorization of the National Community Anti-Drug Coalition Institute.	<ul style="list-style-type: none"> • Reauthorizes the National Community Anti-Drug Coalition Institute through 2022.
Sec. 3305. Reauthorization of the High-Intensity Drug Trafficking Area Program.	<ul style="list-style-type: none"> • Reauthorizes the ONDCP High-Intensity Drug Trafficking Area (HIDTA) Program. HIDTA provides funding for federal, state, and local law enforcement task forces operating in our nation’s most critical drug trafficking regions.
Sec. 3306. Reauthorization of drug court program.	<ul style="list-style-type: none"> • Reauthorizes Department of Justice funding for drug courts through 2022.
Sec. 3307. Drug court training and technical assistance.	<ul style="list-style-type: none"> • Allows non-profit organizations to provide important training and technical assistance to drug courts.
Sec. 3308. Drug overdose response strategy.	<ul style="list-style-type: none"> • Improves upon the HIDTA by targeting funds for implementing a coordinated drug overdose response strategy, which includes: <ul style="list-style-type: none"> ○ Coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdose; ○ Increasing data sharing among public safety and public health officials on drug-related abuse trends; and ○ Enabling collaborative resources on substance use addiction and narcotics trafficking.
Sec. 3309. Protecting law enforcement officers from accidental exposure.	<ul style="list-style-type: none"> • Provides supplemental grants to law enforcement agencies to protect law enforcement from accidental exposure to dangerous narcotics. • Grants may be used for purchasing portable equipment to test for fentanyl and other substances, training law enforcement officers and first responders on best practices, and purchasing protective equipment.
Sec. 3310. COPS Anti-Meth Program.	<ul style="list-style-type: none"> • Authorizes the AG to make competitive grants available to state law enforcement agencies with high seizures of precursor chemicals, methamphetamine, and laboratories for the purpose of investigating

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	illicit activities, such as diversion, laboratories, or methamphetamine trafficking.
Sec. 3311. COPS anti-heroin task force program.	<ul style="list-style-type: none"> • Authorizes the AG to make competitive grants available to state law enforcement agencies in states with high rates of treatment admissions, for the purpose of investigating illicit activities. • This task force will function through statewide collaboration with the greater effort to dismantle the distribution of heroin, fentanyl, Carfentanil, or the unlawful distribution of prescription opioids.
Sec. 3312. Comprehensive Addiction and Recovery Act education and awareness.	<ul style="list-style-type: none"> • Allows the AG to may grants to entities that focus on addiction and substance use disorders and specialize in family and patient services.
Sec. 3313. Protecting children with addicted parents.	<ul style="list-style-type: none"> • Requires HHS to disseminate best practices for states on interventions and strategies to keep families affected by substances use disorder together. • Allows the Secretary of HHS to award grants to states, units of local government, and tribal governments to: <ul style="list-style-type: none"> ○ Develop programs designed to keep pregnant women who have substance use disorder together with their newborns; and ○ Support the attendance of children who have a family member with substance use disorder at therapeutic camps or programs aimed at addiction prevention education, coping strategies, and family support initiatives aimed at keeping families together.
Sec. 3314. Reimbursement of substance use disorder treatment professionals.	<ul style="list-style-type: none"> • Mandates the Comptroller General to submit to Congress a report examining how substance use disorder services are reimbursed. • This is required no later than January 1, 2020.
Sec. 3315. Sobriety Treatment and Recovery Teams (START).	<ul style="list-style-type: none"> • Authorizes SAMHSA to provide grants to establish Sobriety Treatment and Recovery Teams (START) to determine the effectiveness of pairing social workers and mentors with families that are struggling with substance use disorder and child abuse or neglect.
Sec. 3316. Provider education.	<ul style="list-style-type: none"> • Requires the AG and Secretary of HHS to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances.
Subtitle D: Synthetic Abuse and Labeling of Toxic Substances	
Sec. 3401. Short title.	<ul style="list-style-type: none"> • Synthetic Abuse and Labeling of Toxic Substances Act of 2017
Sec. 3402. Controlled substance analogues.	<ul style="list-style-type: none"> • Addresses gap in identifying synthetic analogs to controlled substances that are “not intended for human consumption,” which allows bad actors to get around prosecution. • Provides factors to consider when determining whether a controlled substances is intended for human consumption, including marketing and labeling of the substance, difference between advertised vs. sale price, diversion from legitimate channels, and whether the defendant knew the substance intended to be consumed by injection, inhalation, or ingestion.
Subtitle E: Opioid Quota Reform	
Sec. 3501. Short title.	<ul style="list-style-type: none"> • Opioid Quota Reform Act

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<p>Sec. 3502. Strengthening considerations for DEA opioid quotas.</p>	<ul style="list-style-type: none"> • Sets mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts. • Requires DEA to explain health benefits if DEA approves any increase in annual opioid quota.
<p>Subtitle F: Preventing Drug Diversion</p>	
<p>Sec. 3601. Short title.</p>	<ul style="list-style-type: none"> • Preventing Drug Diversion Act of 2018
<p>Sec. 3602. Improvements to prevent drug diversion.</p>	<ul style="list-style-type: none"> • Requires registrants to design systems to identify and report suspicious orders; also requires DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with States.
<p>TITLE IV: COMMERCE</p>	
<p>Subtitle A: Fighting Opioid Abuse in Transportation</p>	
<p>Sec.4101.Short title.</p>	<ul style="list-style-type: none"> • Provides that the bill may be cited as the “Fighting Opioid Abuse in Transportation Act.”
<p>Sec. 4102. Rail mechanical employee controlled substances and alcohol testing.</p>	<ul style="list-style-type: none"> • Requires the Secretary of Transportation to publish a final rule to designate rail mechanical employees as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
<p>Sec. 4103. Rail yardmaster controlled substances and alcohol testing.</p>	<ul style="list-style-type: none"> • Requires the Secretary of Transportation to publish a final rule to designate yardmasters as employees responsible for safety-sensitive functions for the purposes of railroad drug and alcohol testing requirements.
<p>Sec. 4104. Department of Transportation public drug and alcohol testing database.</p>	<ul style="list-style-type: none"> • Requires the Secretary of Transportation to establish and make publicly available on its website a database of drug and alcohol testing data reported by employers for each mode of transportation and to update the database annually, while protecting commercially sensitive data and ensuring individual employers and employees are not identified.
<p>Sec. 4105. GAO report on Department of Transportation’s collection and use of drug and alcohol testing data.</p>	<ul style="list-style-type: none"> • Requires the GAO to review Department of Transportation’s Drug and Alcohol Testing Information Management System and to submit a report on the review, including potential recommendations for improvement, to relevant congressional committees.
<p>Sec. 4106. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl.</p>	<ul style="list-style-type: none"> • Requires the Secretary of HHS to determine, within 6 months, whether the inclusion of fentanyl on the panel of drugs authorized for testing is justified and—if justified— requires the Secretary to issue a revision to HHS mandatory guidelines to include fentanyl on the testing panel. • Requires, if the Secretary of HHS justifies the inclusion of fentanyl and revises the guidelines, the Secretary of Transportation to publish a final rule adding fentanyl to Department of Transportation’s testing panel.
<p>Sec. 4107. Status reports on hair testing guidelines.</p>	<ul style="list-style-type: none"> • Requires the Secretary of HHS to report to Congress on the status of the final notice for the statutorily-required scientific and technical guidelines for hair testing, within 30 days of enactment of this bill and every 6 months thereafter, until the agency publishes a final notice of guidelines for hair testing. • Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.

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<p>Sec. 4108. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid.</p>	<ul style="list-style-type: none">• Requires the Secretary of HHS to publish a final notice of mandatory guidelines for oral fluid testing not later than December 31, 2018, based on the notice of proposed mandatory guidelines published in 2015.
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	<ul style="list-style-type: none"> Includes a provision to address positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.
Sec. 4109. Electronic recordkeeping.	<ul style="list-style-type: none"> Requires the HHS, not later than 1 year from the date of enactment of this bill, to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval. Requires the Secretary of Transportation, not later than 30 months from the date of enactment of this bill, to issue a final rule authorizing the use of electronic signatures for all paperless chain of custody forms under part 40 of title 49, Code of Federal Regulations.
Sec. 4110. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.	<ul style="list-style-type: none"> Requires the Federal Motor Carrier Safety Administration to submit a report to Congress biannually on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse, until such rule is fully implemented.
Subtitle B: Opioid Addiction Recovery Fraud Prevention	
Sec. 4201. Short title.	<ul style="list-style-type: none"> This section would title the subtitle as the "Opioid addiction Recovery Fraud Prevention Act of 2018."
Sec. 4202. Definitions.	<ul style="list-style-type: none"> This section would define the term "Opioid Treatment Product" to mean a product, including any supplement or medication, for use or marketed for the use in the treatment, cure, or prevention of an opioid use disorder. It would define the term "Opioid Treatment Program" to mean a program that provides treatment for people diagnosed with, having, or purporting to have an opioid use disorder. It would define the term "Opioid Use Disorder" to mean a cluster of cognitive, behavioral, or physiological symptoms in which the individual continues the use of opioids despite significant opioid-induced problems, such as adverse health effects.
Sec. 4203. False or misleading representations with respect to opioid treatment programs and products.	<ul style="list-style-type: none"> Section 4203(a) would affirmatively establish that it is unlawful to make any deceptive representation with respect to the cost, price, efficacy, performance, benefit, risk, or safety of any opioid treatment program or opioid treatment product. Section 4203(b) provides that any such violation would be considered a violation of a Federal Trade Commission (FTC) trade regulation rule (TRR), allowing the FTC to seek civil penalties under Section 5 and the remedies set forth in Section 19 of the FTC Act, in addition to injunctive relief and other equitable remedies that it can already obtain under the FTC Act. The maximum civil penalty amount the FTC may seek for violations of TRRs is \$41,484 per violation, as currently adjusted for inflation. <i>See</i> 15 U.S.C. § 45(m)(1)(A) and 16 C.F.R. § 1.98. The Section 19 remedies for TRR violations include "rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation . . . except that nothing in this subsection is intended to authorize the imposition of any exemplary or punitive damages." <i>See</i> 15 U.S.C. § 57b(b). Section 4203(c) would empower states to bring actions in federal court against entities for violations of this section and to obtain appropriate relief. It would also require states to notify the FTC in writing before

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	<p>filing a case if possible, or if not feasible immediately upon filing the action. The FTC would have the authority to intervene in the state action. Once the FTC or the AG on the FTC's behalf files an action, states may not file during the pendency of the FTC action their own actions against a party named in the FTC action alleging the same violation. This section also addresses venue and service of process issues.</p> <ul style="list-style-type: none">• Section 4203(d) would preserve the authority of the FTC and the FDA such that nothing in this title shall be construed to limit the authority of the FTC or the FDA.
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