H.R. 6

SUPPORT for Patients and Communities Act

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

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Section by Section

Title I—Medicaid Provisions to Address the Opioid Crisis

Section 1001. At-risk youth Medicaid protection.

This provision requires state Medicaid programs to suspend, as opposed to terminate, a juvenile's medical assistance eligibility when a juvenile is incarcerated. A state may suspend coverage while the juvenile is an inmate, but must restore coverage upon release without requiring a new application unless the individual no longer meets the eligibility requirements for medical assistance.

Section 1002. Health insurance for former foster youth.

This provision requires states to ensure that former foster youth are able to keep their Medicaid coverage across state lines until the age of 26. Requires states to adopt this policy in calendar year 2023 for individuals attaining the age of 18 that year, although a state may continue to adopt the policy sooner at state option. This section also requires HHS to issue guidance within one year of enactment regarding best practices to enroll former foster youth in coverage.

Section 1003. Demonstration project to increase substance use provider capacity under the Medicaid program.

This provision requires the Centers for Medicare & Medicaid Services (CMS) to carry out a demonstration project to provide an enhanced federal matching rate for state Medicaid expenditures related to the expansion of substance use disorder treatment and recovery services. The demonstration project would allow for at least ten states to receive planning grants while five states would be selected for the enhanced federal matching rate portion of the project.

Section 1004. Medicaid drug review and utilization.

This provision builds on current state Medicaid drug utilization review activities to help combat the opioid crisis. Under this section, state Medicaid programs are required to have safety edits in place for opioid refills, monitor concurrent prescribing of opioids and certain other drugs, and monitor antipsychotic prescribing for children.

Section 1005. Guidance to improve care for infants with neonatal abstinence syndrome and their mothers; GAO study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder.

This provision requires the Secretary of Health and Human Services to issue best practices, recommendations, and guidance to improve care for infants with neonatal abstinence syndrome and

their families. The section also requires the Comptroller General of the United States to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder.

Section 1006. Medicaid health homes for substance-use-disorder Medicaid enrollees.

This provision extends the enhanced matching rate for qualified activities for Medicaid health homes targeted towards Medicaid beneficiaries with substance use disorders from eight quarters to 10 quarters. This incentive is targeted at new SUD health home activities. It also includes a requirement for state Medicaid programs to provide coverage for medication-assisted treatment.

Section 1007. Caring recovery for infants and babies.

This provision 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.

Section 1008. Peer support enhancement and evaluation review.

This provision 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.

Section 1009. Medicaid substance use disorder treatment via telehealth.

This provision 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. This section also directs GAO to evaluate children's access to Medicaid services to treat substance use disorders, including options to improve access through telehealth. Additionally, it 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.

Section 1010. Enhancing patient access to non-opioid treatment options.

This provision directs CMS to issue guidance on states' options for treating and managing beneficiaries' pain through non-opioid pain treatment and management options under Medicaid.

Section 1011. Assessing barriers to opioid use disorder treatment.

This provision 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.

Section 1012. Help for moms and babies.

This provision 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.

Section 1013. Securing flexibility to treat substance use disorders.

This provision 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.

Section 1014. MACPAC study and report on MAT utilization controls under State Medicaid programs.

This provision 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 care Medicaid programs.

Section 1015. Opioid addiction treatment programs enhancement.

This provision 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.

Section 1016. Better data sharing to combat the opioid crisis.

This provision 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.

Section 1017. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.

This provision 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.

Section 1018. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.

This provision 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.

Title II—Medicare Provisions to Address the Opioid Crisis

Section 2001. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.

This provision expands the use of telehealth services by eliminating certain statutory originating site requirements for telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders and co-occurring mental health disorders, beginning July 1, 2019. It would allow payment for those services furnished via telehealth 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.

Section 2002. Comprehensive screenings for seniors.

This provision increases screening for opioid use disorder and other substance use disorders among Medicare beneficiaries, during Medicare wellness and preventive care visits, facilitating early detection and treatment. It would require 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.

Section 2003. Every prescription conveyed securely.

This provision deters prescription fraud and the diversion of opioids through the use of e-prescribing for opioids. Prescriptions for a Schedule II, III, IV, or V Controlled Substance covered under a Part D prescription drug plan or Medicare Advantage Prescription Drug Plan (MA-PD) are required to be transmitted in accordance with an electronic prescription drug program starting by January 1, 2021. The Secretary may waive this requirement in certain defined cases, such as reasonable technological limitations. It requires the Drug Enforcement Administration to update its regulations pertaining to how prescribers authenticate prescriptions using biometrics to keep up with changing technology.

Section 2004. Requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries.

This provision accelerates the development and use of drug management programs for at-risk beneficiaries within the Medicare program by mandating that all prescription drug plans use such a program by plan year 2022. Using a drug management programs for at-risk beneficiaries is currently voluntary.

Section 2005. Medicare coverage of certain services furnished by opioid treatment programs.

This provision expands Medicare coverage to include Opioid Treatment Programs (OTPs) for the purposes of delivering Medication-Assisted Treatment (MAT) to expand access to treatment options for Medicare beneficiaries. Currently, OTPs are not recognized as Medicare providers, meaning that beneficiaries receiving MAT at OTPs for their opioid use disorders must pay out-of-pocket. In 13 states, the highest rate of opioid-related inpatient stays is among the over 65 population. Under the provision Medicare will pay the outpatient OTPs through bundled payments made for wholistic services, including necessary medications, counseling, and testing.

Section 2006. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.

This provision requires that CMS identify beneficiaries enrolled in Medicare Part D with a history of opioid-related overdose and include them in the definition of beneficiaries potentially at-risk for prescription drug abuse under the Part D Drug Management Program.

Section 2007. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.

This provision requires that a beneficiary enrolled in Medicare Part D who is identified as potentially at-risk for prescription drug abuse (or who 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.

Section 2008. Suspension of payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies.

This provision applies provisions of Section 1862(o) of the Social Security Act to permit a Prescription Drug Plan sponsor to suspend payments if there is a credible allegation of fraud. A plan is required to report suspensions to the Secretary.

Title III—FDA and Controlled Substance Provisions

Subtitle A—FDA Provisions

Chapter 1—In General

Section 3001. Clarifying FDA regulation of non-addictive pain products.

This provision requires the Food and Drug Administration (FDA) to hold at least one public meeting to address the challenges and barriers of developing non-addictive medical products intended to treat pain or addiction, and issue new, or update existing, guidance documents. FDA guidance may include: clarifying how non-addictive medical products may qualify for expedited pathways, as well as how such products may appropriately use pain endpoints and how such endpoints will be evaluated across review divisions; describing how FDA will assess opioid sparing data for use in the labeling of non-addictive medical products that are as effective at controlling pain and able to reduce patient need of opioids to control pain; and addressing how FDA will consider misuse and abuse of a drug when weighing the risks and benefits of such product.

Section 3002. Evidence-based opioid analgesic prescribing guidelines and report.

This provision requires FDA to develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain where such guidelines do not exist. FDA will consult with public stakeholders, and other relevant federal agencies in developing such guidelines, and report on how the agency will use the guidelines to protect public health. Additionally, the FDA Commissioner is required to publish a clear statement of intent to accompany the guidelines stating that such guidelines are intended to inform clinical decisions by prescribers and patients and are not intended to restrict, limit, delay or deny coverage or access by individual health care professionals.

Chapter 2—Stop Counterfeit Drugs By Regulating and Enhancing Enforcement Now

Section 3012. Notification, non-distribution, and recall of controlled substances.

This provision gives the Secretary authority to issue an order requiring manufacturers, importers, distributors, or pharmacists to cease distribution of a controlled substance if the Secretary determines there is reasonable probability such controlled substance would cause serious adverse health consequences or death. The party subject to the order is entitled to an informal hearing after an order to cease distribution is issued to determine whether adequate evidence exists to require a recall, and if so, the actions required following an order to recall, including notification of appropriate persons affected. The Secretary is required to conduct a risk assessment to determine if recalling a controlled substance presents a greater health risk than not recalling the controlled substance. Additionally, this provision authorizes the Secretary to refuse admission into the US if a controlled substance is under a recall order.

Section 3013. Single source pattern of imported illegal drugs.

Under this provision, if the Secretary determines that a manufacturer, distributor, or importer who has been debarred as a result of a pattern of importing or offering to import illegal controlled substances,

then the Secretary may issue an order determining all drugs offered for import from such persons are adulterated or misbranded.

Section 3014. Strengthening FDA and CBP coordination and capacity.

This provision will help to improve detection and response to illegal controlled substances and drug imports by strengthening coordination between FDA and the U.S. Customs and Border Protection (CBP), including through a memorandum of understanding between such agencies. This section authorizes activities to improve facilities, technologies such as controlled substance detection and testing equipment, and inspection capacity, and improve coordination and response to illegal controlled substances and drug imports, including at sites of import. The Secretary of (HHS), in consultation with the Secretary of Homeland Security and the Post-Master General of the United States Postal Service, shall report to Congress within 6 months on the implementation of such actions.

Chapter 3 – Stop Illicit Drug Importation

Section 3022. Restricting entrance of illegal drugs.

This provision requires the FDA Commissioner to develop and periodically update a mutually-agreed upon list of controlled substances that the Secretary will refer to CBP when such substances are offered for import through international mail and appear to violate applicable laws. Not later than 9 months after the enactment of this bill, the FDA Commissioner and Secretary of Homeland Security shall report to Congress on the implementation of this agreement. Authorizes FDA to debar 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. Additionally, this provision clarifies when FDA will treat certain illicit articles that are being imported or offered for import as drugs.

Chapter 4 – Securing Opioids and Unused Narcotics With Deliberate Disposal and Packaging

Section 3032. Safety-enhancing packaging and disposal features.

This provision 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 and takes into consideration patients with functional limitations. This provision also clarifies FDA's authorities to require manufacturers to give patients safe options to dispose of unused opioids, such as safe disposal packaging or safe disposal systems for purposes of rendering unused drugs non-retrievable. Additionally, this provision requires a report by the Government Accountability Office (GAO) on the effectiveness of site-of-use, in-home controlled substance disposal products and packaging technologies, reference standards with respect to controlled substance disposal products and packaging technologies, and any recommendations for improvement including federal oversight and methods to ensure effectiveness of such products and technologies.

Chapter 5 – Post-Approval Study Requirements

Section 3041. Clarifying FDA postmarket authorities.

This provision 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. This provision also authorizes new information related to reduced effectiveness to be included in the requirements for additional studies of a drug that the Secretary determines should be included in the label. Requires FDA to issue guidance regarding postmarket studies or clinical trials with respect to the potential reduction in effectiveness, and how FDA may apply requirements related to new safety or effectiveness information related to the use of controlled substances for pain treatment.

Subtitle B – Controlled Substances Provisions

Chapter 1 – More Flexibility with Respect To Medication-Assisted Treatment for Opioid Use Disorders

Section 3201. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.

This provision will increase the number of waivered health care providers that can prescribe or dispense medication-assisted treatment (MAT)by authorizing clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists to prescribe MAT for five years. It also makes permanent the prescribing authority for physician assistants and nurse practitioners and allows waivered practitioners to immediately treat 100 patients at a time if the practitioner is board certified in addiction medicine or addiction psychiatry; or if the practitioner provides MAT in a qualified practice setting. This provision codifies the ability for qualified physicians to prescribe MAT for up to 275 patients. The Secretary of HHS, in consultation with the Drug Enforcement Administration, will be required to submit a report that assesses the care provided by physicians treating over 100 patients and non-physician practitioners treating over 30 patients.

Section 3202. Medication-assisted treatment for recovery from substance use disorder.

This provision ensures 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 MAT, to obtain a waiver to prescribe MAT.

Section 3203. Grants to enhance access to substance use disorder treatment.

This provision authorizes grants to support the development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.

Section 3204. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation.

This provision updates Federal law to allow for implantable or injectable controlled substances for the purposes 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.

Chapter 2 – Empowering Pharmacists In the Fight Against Opioid Abuse

Section 3212. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription.

This provision directs the Department of Health and Human Services (HHS) to help develop and disseminate materials, clarifying the circumstances of when pharmacists may decline to fill controlled substance prescriptions, such as when they suspect the prescriptions are fraudulent, forged, or of doubtful, questionable, or suspicious origin.

Chapter 3 – Safe Disposal of Unused Medication

Section 3222. Disposal of controlled substances of a hospice patient by employees of a qualified hospice program.

This provision will help reduce the number of unused controlled substances at risk of diversion or misuse by allowing qualified hospice employees to safely dispose of these medications on site after the death of a patient, or when the controlled substance is expired or no longer needed because the hospice patient's plan of care has been modified.

Section 3223. GAO study and report on hospice safe drug management.

This provision requires GAO to conduct a study and report within 18 months on hospice programs' written policies and procedures on the management and disposal of controlled substances in the home of an individual, as well as any challenges that hospice programs face regarding the disposal of controlled substances.

Chapter 4 – Special Registration for Telemedicine Clarification

Section 3232. Regulations relating to special registration for telemedicine.

Federal law permits the Attorney General to issue a special registration to health care providers to prescribe controlled substances via telemedicine in legitimate emergency situations, such as a lack of access to an in-person specialist. Unfortunately, the waiver process has never been implemented through regulation, and some patients do not have the emergency access they need to treatment. This provision directs the Attorney General, with the Secretary of Health and Human Services, to issue final regulations within one year of enactment.

Chapter 5 – Synthetic Abuse and Labeling of Toxic Substances

Section 3241. Controlled substance analogues.

This provision will amend the Controlled Substances Act to set forth factors that may be considered as evidence to determine whether a controlled substance analogue is intended for human consumption. (Under current law, a controlled substance analogue that is intended for human consumption is treated as a schedule I controlled substance. A schedule I controlled substance is a drug, substance, or chemical that: has a high potential for abuse; has no currently accepted medical value; and is subject to regulatory controls and administrative, civil, and criminal penalties under the Controlled Substances Act.)
Chapter 6 – Access to Increased Drug Disposal

Section 3251 - 3260. Access to Increased Drug Disposal.

These provisions allow the Attorney General to award grants to five states to increase participation of eligible collectors as authorized collectors for drug-disposal programs. They also outline the requirements that a state must meet when submitting an application for a grant and limit the use of the grant that a state receives to the costs associated with drug disposal participation.

Chapter 7 — Using Data to Prevent Opioid Diversion

Section 3271 - 3274. Using Data to Prevent Opioid Diversion.

These provisions increase transparency in use of the Automated Reports and Consolidated Ordering System (ARCOS) by providing 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. The provisions further mandate that DEA share information with regulatory, licensing, attorneys general and law enforcement agencies of states on a semi-annual basis related to amounts, outliers, and trends of distributor and pharmacy registrants. The provisions also establish civil and criminal fines for drug manufacturers and distributors who fail to consider the ARCOS data when determining whether an order for opioids is suspicious and increases civil and criminal penalties for drug manufacturers and distributors who fail to report suspicious orders and keep accurate records.

Chapter 8 – Opioid Quota Reform

Section 3281 - 3282. Opioid Quota Reform.

These provisions establish mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts. It requires DEA to explain public health benefits if DEA approves any increase in annual opioid quota.

Chapter 9 – Preventing Drug Diversion

Section 3291 - 3292. Preventing Drug Diversion.

These provisions require registrants to design systems to identify and report suspicious orders of opioids. They also require DEA to establish a database for the collection of all suspicious orders reported by all registrants, and to share suspicious order information with the States.

Title IV—Offsets

Section 4001. Promoting value in Medicaid managed care.

This provision provides an incentive for states voluntarily adopting a medical loss ratio (MLR) requirement for their Medicaid managed care organizations (MCOs) of 85 percent. Under current CMS regulations, if a state chooses to require a MLR for Medicaid MCOs, the regulations state that it must be set at least at 85 percent. Because Medicaid is paid jointly by the state and federal government, the remittances are shared with the federal government at a state's applicable FMAP. This provision incentivizes states to adopt an MLR of 85 percent by allowing them, for a period of time, to keep a larger share of the remittances states collect from MCOs than under current law furthering program efficiencies.

Section 4002. Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program.

This provision extends mandatory reporting requirements to include prescription drug coverage in order to better coordinate benefits related to Medicare Part D. Although health plans offered by employers and unions are required by Medicare secondary payer-related law to report enrollment information on certain active employees, there is no requirement for other group health plans that offer a prescription drug benefit to report their plan enrollees with drug coverage to HHS or the Part D plan sponsors. Starting in 2020, this extension ensures that all prescription drug coverage provided by group health plans that is primary to Medicare coverage is communicated to HHS and to Part D sponsors, thereby permitting sponsors to comply with the statutory Medicare secondary payer requirements.

Sec. 4003. Additional religious exemption from health coverage responsibility requirement

This provision amends the Internal Revenue Code to expand the religious conscience exemption under the Affordable Care Act to exempt individuals who rely on a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs from the requirement to purchase and maintain minimum essential health care coverage, effective after December 31, 2018.

Sec. 4004. Modernizing the reporting of biological and biosimilar products

Current law requires that brand and generic drug companies file patent agreements that could lead to the delay of generic entry with Federal Trade Commission (FTC). A provision in S. 2554 (Section 3) that the

House passed by voice vote on suspension on September 25, 2018 expanded the current law requirement to cover patent settlements between biosimilar and biologic companies. This policy makes improvements to Section 3 of S.2554 to make sure all patent agreements regarding biosimilars are reported to FTC.

Title V—Other Medicaid Provisions

Subtitle A – Mandatory Reporting With Respect to Adult Behavioral Health Measures

Section 5001. Mandatory reporting with respect to adult behavioral health measures.

This provision would amend title XI of the Social Security Act to require state Medicaid programs to report on the behavioral health measures that are included in CMS' Core Set of Adult Health Care Quality Measures for Medicaid.

Subtitle B – Medicaid IMD Additional Info

Section 5012. MACPAC exploratory study and report on institutions for mental diseases requirements and practices under Medicaid.

These provisions direct the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on institutions for mental disease (IMD) that receive Medicaid reimbursement. The study is directed to report on the requirements and standards that state Medicaid programs have for IMDs. MACPAC, considering input from stakeholders, is instructed to summarize the findings and if appropriate, make recommendations on improvements and best practices and data collection. The report would be due no later than January 2020.

Subtitle C – CHIP Mental Health and Substance Use Disorder Parity

Section 5022. Ensuring access to mental health and substance use disorder services for children and pregnant women under the Children's Health Insurance Program.

These provisions require state Children's Health Insurance Programs (CHIP) to cover mental health benefits, including substance use disorder services for eligible pregnant women and children. In addition, states would not be allowed to impose financial or utilization limits on mental health treatment that are lower than limits placed on physical health treatment.

Subtitle D – Medicaid Reentry

Section 5032. Promoting State innovations to ease transitions integration to the community for certain individuals.

These provisions require the Secretary of the Department of Health and Human Services (HHS) to convene a stakeholder group to produce a report of best practices for states to consider in health care related transitions for inmates of public institutions.

Subtitle E – Medicaid Partnership

Section 5042. Medicaid providers are required to note experiences in record systems to help in-need patients.

These provisions require Medicaid providers to check relevant prescription drug monitoring programs (PDMPs) before prescribing a Schedule II controlled substance. The policy also encourages Medicaid providers to integrate PDMP usage into a Medicaid provider's clinical workflow and establishes standard

criteria that a PDMP must meet to be counted as a qualified PDMP. Finally, sections 5041 and 5042 require state Medicaid programs to report to CMS on PDMP data and information.

Subtitle F – IMD CARE Act

Section 5052. State option to provide Medicaid coverage for certain individuals with substance use disorders who are patients in certain institutions for mental diseases.

These provisions provide state Medicaid programs with the option to cover care in certain Institutions for Mental Diseases (IMD), which may be otherwise non-federally-reimbursable under the IMD exclusion, for Medicaid beneficiaries aged 21 to 64 with a substance use disorder for fiscal years 2019 to 2023. By allowing for payment in IMD's for eligible individuals, state Medicaid programs may receive federal reimbursement for up to 30 total days of care in an IMD during a 12-month period for eligible individuals. In order to qualify for the state option, state Medicaid programs must meet certain requirements including covering certain outpatient and inpatient levels of care, maintaining certain state spending requirements, and abiding by other reporting and notification rules. Nothing in the provision would otherwise prevent a state from conducting or pursuing an approved section 1115 demonstration project to improve access to and quality of substance use disorder treatment for eligible populations.

Sec. 5061. Medicaid Improvement Fund

This section makes available $31 million in the fund which is available to the Secretary of HHS to improve the management of the Medicaid program by the Centers for Medicare & Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects.

Title VI—Other Medicare Provisions

Subtitle A – Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology

Section 6001. Testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology.

This provision promotes the testing of incentive payments for behavioral health providers for adoption and use of certified electronic health record technology through the Center for Medicare and Medicaid Innovation (CMMI).

Subtitle B – Abuse Deterrent Access

Section 6012. Study on abuse-deterrent opioid formulations access barriers under Medicare.

This provision requires the Secretary of HHS to conduct a study and submit to Congress a report on: (1) the adequacy of access to abuse-deterrent opioid formulations and (2) the effectiveness of abuse deterrent opioid formulations in preventing opioid abuse or misuse.

Subtitle C – Medicare Opioid Safety Education

Section 6021. Medicare opioid safety education.

This provision requires that the annual Medicare & You handbook for Medicare beneficiaries include references to educational resources on opioid use and pain management; a description of categories of alternative, non-opioid pain management treatments covered by Medicare; and a suggestion that beneficiaries talk to their physicians about opioid use and pain management.

Section 6032. Action plan on recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to medication-assisted treatment.

This provision establishes an action plan, including studies, HHS-authored reports to Congress, and meetings with stakeholders, for the purpose of addressing the opioid crisis.

Subtitle E – Advancing High Quality Treatment for Opioid Use Disorders in Medicare

Section 6042. Opioid use disorder treatment demonstration program.

This provision creates a demonstration project to increase access to comprehensive, evidence-based outpatient treatment for Medicare beneficiaries with opioid use disorders. The provision would require demonstration participants to provide both medication as well as psychosocial supports, care management, and treatment planning for opioid use disorders for eligible beneficiaries. The model also includes the development of measures to evaluate the quality and outcomes of treatment, and rewards participants for performance on such quality measures.

Subtitle F – Responsible Education Achieves Care and Health Outcomes for User's Treatment

Section 6052. Grants to provide technical assistance to outlier prescribers of opioids.

This provision provides grants to eligible entities to provide outreach and education to outlier prescribers of opioids to reduce the amount of opioid prescriptions prescribed. This section makes available $75 million from the Supplementary Medical Insurance Trust Fund for the purpose of such education.

Subtitle G – Preventing Addiction for Susceptible Seniors

Section 6062. Electronic prior authorization for covered Part D drugs.

This provision requires the Secretary of HHS to establish a standard, secure electronic prior authorization system no later than January 1, 2021. Fax, proprietary payer portals that do not meet standards defined by the Secretary, and electronic forms will not be treated as an electronic submission for the purpose of electronic prior authorization.

Section 6063. Program integrity transparency measures under Medicare parts C and D.

This provision requires the Secretary of HHS, no later than two years after the date of enactment, to establish a secure web portal that allows for secure communication between the Secretary, Part D and MA plans, and the Medicare Drug Integrity Contractor (MEDIC) regarding certain program integrity activities. Beginning on or after January 1, 2021, plans are required to submit to the Secretary information on investigations or other actions taken by such plans related to providers who inappropriately prescribe opioids.

Section 6064. Expanding eligibility for medication therapy management programs under part D.

This provision requires beneficiaries at risk for prescription drug abuse to be eligible for the Medication Therapy Management (MTM) Program beginning January 1, 2021.

Section 6065. Commit to opioid medical prescriber accountability and safety for seniors.

This provision requires the Secretary of HHS, no later than two years after the date of enactment, to annually notify prescribers that they have been identified as an outlier prescriber of opioids compared to other prescribers in their specialty and geographic area. The Secretary may exclude the following individuals and prescribers from the analysis: (1) individuals receiving hospice services; (2) individuals with a cancer diagnosis; and (3) prescribers who are subjects of an investigation by the Inspector General. The Secretary may expand notifications to concurrent prescriptions used in combination with opioids that are considered to have adverse side effects when used in such combination.

Section 6066. No additional funds authorized.

No additional funds are authorized to be appropriated to carry out the sections in Subtitle G.

Subtitle H – Expanding Oversight of Opioid Prescribing and Payment

Section 6072. Medicare Payment Advisory Commission report on opioid payment, adverse incentives, and data under the Medicare program.

This provision requires the Medicare Payment Advisory Commission to submit a report to Congress on: (1) how Medicare pays for opioid and non-opioid pain management treatments in inpatient and outpatient hospital settings; (2) current incentives for prescribing opioid and non-opioid treatments under Medicare inpatient and outpatient prospective payment systems, along with recommendations to address any identified adverse incentives; and (3) how opioid use data is currently tracked and monitored through Medicare claims data, while identifying any areas in which further data and methods are needed for improving data and understanding of opioid use.

Section 6073. No additional funds authorized.

No additional funds are authorized to be appropriated to carry out the sections in Subtitle H.

Subtitle I – Dr. Todd Graham Pain Management, Treatment, and Recovery

Section 6082. Review and adjustment of payments under the Medicare outpatient prospective payment system to avoid financial incentives to use opioids instead of non-opioid alternative treatments.

This provision requires the Secretary of HHS to review payments made through the Outpatient Prospective Payment System (OPPS) and payments to ambulatory surgery centers (ASCs) to ensure there are no financial incentives to use opioids instead of evidence-based non-opioid alternatives. If the Secretary identifies financial incentives to use opioids instead of evidence-based non-opioid alternatives, the Secretary will make revisions to OPPS and ASC payments through rulemaking. The Secretary may also review payments through a demonstration.

Section 6083. Expanding access under the Medicare program to addiction treatment in Federally qualified health centers and rural health clinics.

This provision provides grants to Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to help offset the cost of training providers to dispense medications for treatment of opioid use disorder.

Section 6084. Studying the availability of supplemental benefits designed to treat or prevent substance use disorders under Medicare Advantage plans.

This provision directs the Secretary of HHS to evaluate the extent to which MA plans offer MAT and cover non-opioid alternative treatments, not otherwise covered under traditional Medicare, as part of a

supplemental benefit. This section also directs the Secretary to evaluate potential barriers to these plans using their supplemental benefits to cover these types of services.

Section 6085. Clinical psychologist services models under the Center for Medicare and Medicaid Innovation; GAO study and report.

This provision directs the Secretary, under CMMI, to educate patients on the availability of psychologist services and explore the use of hotlines to reduce unnecessary hospitalizations in Medicare. It also mandates the Comptroller General of the United States to issue a report on mental and behavioral health under the Medicare program with information about services offered by psychiatrists, clinical psychologists, and other professionals.

Section 6086. Dr. Todd Graham pain management study.

This provision requires the Secretary of HHS, in consultation with relevant stakeholders, to submit a report to Congress on how to improve reimbursement and coverage for multi-disciplinary, evidence-based non-opioid chronic pain management. The report also includes options for improving treatment strategies and case management for various high-risk patient populations and options for improving and disseminating pain management education tools. This report is due no later than one year after the date of enactment of this Act.

Subtitle J – Combating Opioid Abuse for Care in Hospitals

Section 6092. Developing guidance on pain management and opioid use disorder prevention for hospitals receiving payment under part A of the Medicare program.

This provision requires the Secretary of HHS to develop a toolkit by July 1, 2019, that provides best practices to Medicare participating hospitals for reducing opioid use, and to post the toolkit including such guidance on the CMS website. The Secretary is required to develop this guidance in consultation with medical professional organizations, providers and suppliers of services, health care consumers, and other stakeholder organizations identified by the Secretary.

Section 6093. Requiring the review of quality measures relating to opioids and opioid use disorder treatments furnished under the Medicare program and other federal health care programs.

This provision requires the Secretary, within 180 days, to convene a Technical Expert Panel (TEP) to review quality measures related to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatments furnished to individuals with opioid use disorder. Within one year of the TEP's creation, the TEP will: (1) review existing measures related to opioids as well as those under development; (2) identify gaps in areas of quality measurement and establish priorities for development in gap areas; and (3) make recommendations to the Secretary regarding revisions of existing measures, development of new measures, and recommendations for inclusion of such measures in value-based payment programs. The Secretary is required to prioritize measures for development and endorsement for a period of at least 5 years.

Section 6094. Technical expert panel on reducing surgical setting opioid use; Data collection on perioperative opioid use.

This provision requires the Secretary, within six months, to convene a TEP consisting of medical and surgical specialty societies and hospital organizations to provide recommendations on best practices for pain management in surgical settings. Within one year of enactment, the Secretary is required to issue a public report on recommendations for broad implementation of pain management protocols that limit the use of opioids in the perioperative setting, while also analyzing perioperative opioid prescribing data for high-volume surgeries.

Section 6095. Requiring the posting and periodic update of opioid prescribing guidance for Medicare beneficiaries.

This provision requires, within 180 days of enactment, the Secretary of HHS to publish on the CMS website all opioid prescribing guidance published after January 1, 2016, applicable to Medicare beneficiaries. CMS is required to periodically update the posted guidance in consultation with medical professional organizations, providers and suppliers of services, healthcare consumers, and other stakeholder organizations the Secretary identifies.

Subtitle K – Providing Reliable Options for Patients and Educational Resources

Section 6102. Requiring Medicare Advantage plans and part D prescription drug plans to include information on risks associated with opioids and coverage of non-pharmacological therapies and nonopioid medications or devices used to treat pain.

This provision requires MA plans, for plan year 2021 and each subsequent plan year, to provide information to beneficiaries on the risks associated with prolonged opioid use and coverage of nonpharmacological therapies, devices, and non-opioid medications. It allows plans the flexibility to target this information to a specific subset of enrollees, such as those prescribed an opioid in the previous two years. It also allows for the information to be provided via either electronic or postal mail.

Section 6103. Requiring Medicare Advantage plans and prescription drug plans to provide information on the safe disposal of prescription drugs.

This provision requires plans, after January 1, 2021, that provide in-home risk assessments to ensure that during such assessment information is provided to Medicare beneficiaries on the safe disposal of prescription drugs that are controlled substances. After January 1, 2021, plans are also required through their MTM Programs to provide enrollees information on cost-effective means for safe disposal of controlled substances.

Section 6104. Revising measures used under the Hospital Consumer Assessment of Healthcare Providers and Systems survey relating to pain management.

This provision requires that starting in 2020, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey may not include questions about communication by hospital staff with an individual about pain unless such questions take into account whether a patient experiencing pain was informed about the risks of opioids and about non-opioid alternatives for pain management.

Subtitle L – Fighting the Opioid Epidemic With Sunshine

Section 6111. Fighting the opioid epidemic with sunshine.

This provision enhances the CMS-run Open Payments, or “sunshine”, program by expanding the types of professionals for whom a drug and device manufacturer are 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. The bill 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.

Title VII—Public Health Provisions

Subtitle A—Awareness and Training

Section 7001. Report on effects on public health of synthetic drug use.

This provision requires the Secretary, in coordination with the U.S. Surgeon General, to submit a report to Congress on the public health effects of the rise in synthetic drug use among adolescents and young adults in order to further educate parents and the medical community on the health effects of synthetics.

Section 7002. First responder training.

This provision 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, carfentanil, and other dangerous licit and illicit drugs.

Subtitle B—Pilot Program for Public Health Laboratories To Detect Fentanyl and Other Synthetic Opioids

Section 7011. Pilot program for public health laboratories to detect fentanyl and other synthetic opioids.

This provision authorizes grants to state and local agencies to improve coordination between public health laboratories and laboratories operated by law enforcement to improve detection of fentanyl, its analogues, and other synthetic opioids.

Subtitle C—Indexing Narcotics, Fentanyl, and Opioids

Section 7021. Establishment of substance use disorder information dashboard.

This provision directs the Department of Health and Human Services (HHS) to establish a public information dashboard linking to HHS programs and publicly available data related to opioid and other substance use disorders.

Section 7022. Interdepartmental Substance Use Disorder Coordinating Committee.

This provision requires the Secretary of HHS, in coordination with the Director of National Drug Control Policy, to establish an interdepartmental committee to coordinate federal activities related to substance use disorders.

Section 7023. National milestones to measure success in curtailing the opioid crisis.

This provision 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.

Section 7024. Study on prescribing limits.

This provision 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.

Subtitle D—Ensuring Access to Quality Sober Living

Section 7031. National recovery housing best practices.

This provision requires HHS to issue best practices for entities operating recovery housing facilities, to assist those recovering from an opioid use disorder with housing. This provision also requires HHS to identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.

Subtitle E—Advancing Cutting Edge Research

Section 7041. Unique research initiatives.

This provision 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 new, non-addictive drugs for pain management. NIH was given this authority for the Precision Medicine Initiative and fifty percent of the Common Fund in the 21st Century Cures Act.

Section 7042. Pain research.

This provision 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 F—Jessie's Law

Section 7051. Inclusion of opioid addiction history in patient records.

This provision requires HHS to develop best practices for prominently displaying substance use disorder treatment information in electronic health records, when requested by the patient.

Section 7052. Communication with families during emergencies.

This provision requires the Secretary to notify providers annually regarding sharing of certain health information with family members, caregivers, and health care providers during an emergency such as an overdose.

Section 7053. Development and dissemination of model training programs for substance use disorder patient records.

This provision 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.

Subtitle G—Protecting Pregnant Women and Infants

Section 7061. Report on addressing maternal and infant health in the opioid crisis.

This provision requires the Secretary to issue a report to Congress offering recommendations for pain management practices during pregnancy and for prevention, identification, and reduction of opioid and other substance use disorders during pregnancy.

Section 7062. Protecting moms and infants.

This provision requires the Secretary 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. This provision reauthorizes the Residential Treatment for Pregnant and Postpartum Women grant program.

Section 7063. Early interventions for pregnant women and infants.

This provision requires the Center for Substance Abuse Prevention at SAMHSA 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. This provision requires implementation and dissemination, as appropriate, of the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy," issued by HHS in 2017.

Section 7064. Prenatal and postnatal health.

This provision authorizes data collection and analysis of neonatal abstinence syndrome and other outcomes related to prenatal substance abuse and misuse, including prenatal opioid abuse and misuse.

Section 7065. Plans of safe care.

This provision authorizes the Secretary to provide 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. This provision requires the Secretary to provide states with technical assistance and guidance to support their implementation of the plans of safe care assurance, including by enhancing their understanding of the law, addressing state-identified challenges, sharing best practices, and supporting collaboration.

Subtitle H—Substance Use Disorder Treatment Workforce

Section 7071. Loan repayment program for substance use disorder treatment workforce.

This provision requires the Secretary to enter into 6-year loan repayment agreements with substance use disorder treatment professionals in mental health professional shortage areas or counties that have been hardest hit by drug overdoses.

Section 7072. Clarification regarding service in schools and other community-based settings.

This provision allows mental and behavioral health providers participating in the National Health Service Corps to provide care at a school or other community-based setting located in a health professional shortage area as part of their obligated service requirements.

Section 7073. Programs for health care workforce.

This provision improves programs that support education and training in pain care by requiring grant recipients to develop comprehensive education and training plans that include information on the dangers of opioid abuse, early warning signs of opioid use disorders, safe disposal options, and other innovative deactivation mechanisms. This section also requires pain care education and training grantees to include alternatives to opioid pain treatment, such as non-addictive and non-opioid pain treatments, and non-pharmacologic medical products. In addition, this provision updates mental and behavioral health education and training grants to support trauma-informed care.

Subtitle I—Preventing Overdoses While in Emergency Rooms

Section 7081. Program to support coordination and continuation of care for drug overdose patients.

This provision provides resources for hospitals and other entities to develop protocols on discharging patients who have presented with an opioid overdose. These protocols would address the provision of an overdose reversal medication, such as naloxone, upon discharge, connection with peer-support specialists, and the referral to treatment and other services that best fit the patient's needs.

Subtitle J—Alternatives to Opioids in the Emergency Department

Section 7091. Emergency department alternatives to opioids demonstration program.

This provision establishes a demonstration program to test alternative pain management protocols to limit the use of opioids in hospital emergency departments, and provides technical assistance to acute care settings, including hospital emergency departments on best practices on alternatives to opioids for pain management.

Subtitle K—Treatment, Education, and Community Help To Combat Addiction

Section 7101. Establishment of regional centers of excellence in substance use disorder education.

This provision requires the Secretary to establish Centers of Excellence to support the improvement of health professional training resources related to substance use disorder prevention, treatment, and recovery.

Section 7102. Youth prevention and recovery.

This provision requires the Secretary, in consultation with the Secretary of Education, to disseminate best practices and issue grants for prevention of and recovery from substance use disorders in children, adolescents, and young adults.

Subtitle L—Information From National Mental Health and Substance Use Policy Laboratory

Section 7111. Information from national mental health and substance use policy laboratory.

This provision directs SAMHSA to provide information for entities applying for grants or cooperative agreements from SAMHSA, including to encourage the implementation and replication of evidence-based practices.

Subtitle M—Comprehensive Opioid Recovery Centers

Section 7121. Comprehensive opioid recovery centers.

This provision authorizes a SAMHSA grant program 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.

Subtitle N—Trauma-Informed Care

Section 7131. CDC surveillance and data collection for child, youth, and adult trauma.

This provision authorizes CDC to support state efforts to collect and report data on adverse childhood experiences through existing public health surveys.

Section 7132. Task force to develop best practices for trauma-informed identification, referral, and support.

This provision 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, and to better coordinate the Federal response to families impacted by substance use disorders and other formers of trauma. It requires the task force to develop a set of best practices regarding prevention strategies, identification of trauma, community-based practices, and state- and local-level partnerships to support children and their families. This provision calls for a national strategy on how federal agencies can implement a coordinated response, including by coordinating existing federal authorities and grant programs where trauma-informed practices are allowable. The task force is required to submit a final report of findings and recommendations to Congress, relevant cabinet Secretaries, Governors, and the general public not less than three years after its first meeting

Section 7133. National Child Traumatic Stress Initiative.

This provision 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.

Section 7134. Grants to improve trauma support services and mental health care for children and youth in educational settings.

This provision authorizes the Secretary of Education, in coordination with the Assistant Secretary for Mental Health and Substance Use, to make grants to 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. It requires the Secretary of Education to conduct a rigorous, independent analysis and disseminate findings from the grants.

Section 7135. Recognizing early childhood trauma related to substance abuse.

This provision requires the Secretary of Health and Human Services to disseminate information, resources, and if requested, technical assistance to early childhood care and education providers and professionals working with young children on ways to recognize and respond appropriately to early childhood trauma, including trauma related to substance use.

Subtitle O—Eliminating Opioid Related Infectious Diseases

Section 7141. Reauthorization and expansion of program of surveillance and education regarding infections associated with illicit drug use and other risk factors.

This provision reauthorizes and builds upon CDC's program to prevent and respond to infections commonly associated with illicit drug use, including viral hepatitis, HIV, and infective endocarditis, by supporting state and federal efforts to collect data on such infections and identify and assist individuals who may be at risk.

Subtitle P—Peer Support Communities of Recovery

Section 7151. Building communities of recovery.

This provision 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.

Section 7152. Peer support technical assistance center.

This provision 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.

Subtitle Q—Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies

Section 7161, 7162. Preventing overdoses of controlled substances; Prescription drug monitoring program.

This provision authorizes CDC's support for states and localities to improve their Prescription Drug Monitoring Programs (PDMPs), collect public health data, and implement other evidence-based prevention strategies. It also encourages data sharing between states and supports other prevention and research activities related to controlled substances, including education and awareness efforts.

Subtitle R—Review of Substance Use Disorder Treatment Providers Receiving Federal Funding

Section 7171. Review of substance use disorder treatment providers receiving Federal funding.

This provision requires the Secretary of HHS to conduct a review of entities that receive Federal funding for the provision of substance use disorder treatment services and submit a report to Congress regarding a plan to address inadequacies in services or funding identified as a result of the review.

Subtitle S—Other Health Provisions

Section 7181. State response to the opioid abuse crisis.

This provision 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.

Section 7182. Report on investigations regarding parity in mental health and substance use disorder benefits.

This provision 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.

Section 7183. Career Act.

This provision requires the Secretary of HHS to continue or establish a program to support individuals in recovery from a substance use disorder transition to independent living and the workforce. This provision requires a report to Congress on the effectiveness of these grants and recommendations regarding best practices for health care professionals to support individuals in recovery so that they can participate in the workforce.

Title VIII—Miscellaneous

Subtitle A—Synthetics Trafficking and Overdose Protection

Section 8002. Customs fees.

This provision amends section 13031(b)(9) of the Consolidated Omnibus Reconciliation Act of 1985 (19 U.S.C. 58c(b)(9)) to establish a new $1 fee on Inbound Express Mail Service items, to be split between U.S. Customs and Border Protection (CBP) and the U.S. Postal Service (USPS), for customs processing associated with the new requirements.

Section 8003. Mandatory advance electronic information for postal shipments.

This provision amends section 343(a)(3)(K) of the Trade Act of 2002 to require USPS to transmit advance electronic data (AED) to CBP on merchandise arriving to the United States through the international mail and mandates that the agencies meet specific and detailed requirements regarding the transmission of AED – including that USPS transmit AED on at least 70 percent of international mail shipments by December 31, 2018 (including 100 percent of shipments from China), and 100 percent by December 31, 2020. This provision provides limited authority to exclude a country from the AED requirement if the CBP Commissioner determines that a country: (1) lacks the capacity to collect and transmit AED; (2) is a low risk for shipments that violate relevant U.S. laws; and (3) has low volumes of mail shipments that can be effectively screened for compliance with U.S. laws through an alternate means.

This provision requires USPS to refuse shipments for which AED is not furnished after December 31, 2020, unless the agencies determine that remedial action, including other law enforcement initiatives or the failure to provide the AED, is warranted. This provision also authorizes the agencies, with the concurrence of the Secretary of State and in coordination with other Federal agencies, as appropriate, to undertake capacity building to enhance the capacity of foreign postal operators to gather and provide AED to the United States.

This provision also establishes rigorous oversight mechanisms to ensure that the agencies are accountable to Congress. These accountability measures include: (1) a joint strategic plan detailing specific performance measures for achieving transmission of AED and for the percentage of targeted mail presented by USPS to CBP for inspection; (2) biannual requirements to report to Congress on the progress made in achieving the transmission of AED; and (3) annual reporting requirements on mandates established by Congress. This provision also requires the Government Accountability Office to: (1) report on the agencies' progress in achieving the legislative mandates, including an assessment of the

quality of AED transmitted to CBP and the ability of USPS to present targeted shipments to CBP for inspection; and (2) make recommendations to improve USPS's compliance with the new requirements.

Section 8004. International postal agreements.

This provision directs the State Department to secure any needed changes to international postal agreements to ensure that the United States is not in violation of those agreements. The provision further directs the State Department to consult with Congress before entering into any international postal agreement related to the ability of the United States to secure AED from foreign postal operators and to expeditiously conclude any new international postal agreement that would improve the ability of the United States to secure AED from foreign postal operators.

Section 8005. Cost recoupment.

This provision requires USPS, to the extent practicable and permitted by law, to ensure that all costs associated with complying with this Act are charged directly to foreign shippers or foreign postal operators and clarifies that any recovery of costs under this section shall not be considered revenue for purposes of subchapter I and II of chapter 36 of title 39, United States Code.

Section 8006. Development of technology to detect illicit narcotics.

This provision directs the Commissioner of CBP and the Postmaster General, in coordination with the heads of other Federal agencies as appropriate, to collaborate to identify and develop technology that will improve the detection of synthetic opioids, as well as other narcotics and psychoactive substances, entering the United States by mail.

Section 8007. Civil Penalties for postal shipments.

This provision establishes civil penalties if USPS accepts international mail shipments without AED after December 31, 2020 and provides the CBP Commissioner with discretion to modify the penalties upon making certain findings, including if USPS has a low error rate in compliance with this Act; is cooperating with CBP; or has taken remedial action to prevent future violations. If CBP determines that there is an ongoing lack of compliance by USPS, it may impose civil penalties until corrective action is taken.

Section 8008. Report on violations of arrival, reporting, entry, and clearance requirements and falsity or lack of manifest.

This provision requires the Commissioner of CBP to submit to the appropriate congressional committees an annual report providing information related to the effectiveness of the issuance of penalties for violations of sections 436 and 584 of the Tariff Act of 1930, as amended.

Section 8009. Effective date; regulations.

This provision provides that the changes made by this Act, other than amendments made by Section 8002, shall take effect on the date of the enactment of this Act and that regulations necessary to carry out this Act shall be prescribed not later than one year after the date of enactment of this Act.

Subtitle B—Opioid Addiction Recovery Fraud Prevention

Section 8021 – 8023. Opioid Addiction Recovery Fraud Prevention.

Unfair or deceptive acts with respect to substance use disorder treatment services or substance use disorder treatment products are subject to civil penalties for first time violations by the FTC. The provisions include a savings clause for existing FTC and FDA authorities.

Subtitle C—Addressing Economic and Workforce Impact of the Opioid Crisis

Section 8041. Addressing economic and workforce impacts of the opioid crisis.

This provision 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. Grants are targeted to provide coordinated job training and treatment services to individuals in affected communities with opioid or substance use disorder, and to support the treatment workforce in significantly impacted areas.

Subtitle D—Peer Support Counseling Program for Women Veterans

Section 8051. Peer support counseling program for women veterans.

This provision will direct the Department of Veterans Affairs (VA) to increase the number of female peer counselors so that female veterans who are separating or newly separated from military service can receive support from other female veterans.

Subtitle E—Treating Barriers to Prosperity

Section 8062. Drug abuse mitigation initiative.

These provisions will clarify that the Appalachian Regional Commission (ARC) may enter into contracts with and provide grants to people and organizations in Appalachia for projects and other activities aimed at reducing drug abuse and the negative effects of drug abuse, including opioid abuse, in the region.

Subtitle F—Pilot Program to Help Individuals in Recovery From a Substance Use Disorder Become Stably Housed

Section. 8071. Pilot program to help individuals in recovery from a substance use disorder become stably housed.

Authorizes a pilot program to provide individuals in recovery from a substance use disorder with stable, temporary housing

Subtitle G—Human Services

Sec. 8081. Supporting family-focused residential treatment.

This provision would require HHS to develop and issue guidance to states identifying opportunities to support family-focused residential substance abuse treatment programs.

Sec. 8082. Improving recovery and reunifying families.

This provision 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. This provision also contains language clarifying that the provision of new prevention services paid for through the *Family First Prevention Services Act* will not supplant services funded by other programs.

Sec. 8083. Building capacity for family-focused residential treatment.

Beginning in FY 2019, states are eligible for federal matching funds for maintenance costs when an at-risk child is placed in family-focused residential treatment, as well when the child is placed in foster care. In FY 2020, states will also be eligible to receive funding to provide evidence-based substance abuse prevention and treatment services to families with children at risk of entering foster care, even if the child is not placed in, or eligible for, federally-funded foster care. This provision 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 *Family First Prevention Services Act.*

Subtitle H—Reauthorizing and Extending Grants for Recovery From Opioid Use Programs

Section 8092. Reauthorization of the comprehensive opioid abuse grant program.

This provision will amend the Omnibus Crime Control and Safe Streets Act of 1968 to reauthorize the DOJ comprehensive opioid abuse grant program through 2023, and to raise the amount authorized for the program, consistent with appropriated funding levels.

Subtitle I—Fighting Opioid Abuse in Transportation

Section 8102. Alcohol and controlled substance testing of mechanical employees.

This provision requires the Secretary of Transportation to publish a rule to apply drug and controlled substance testing requirements to all employees of railroad carriers who perform mechanical activities.

Section 8103. Department of Transportation public drug and alcohol testing database.

This provision 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.

Section 8104. GAO report on Department of Transportation's collection and use of drug and alcohol testing data.

This provision requires the GAO to review Department of Transportation's Drug and Alcohol Testing Information Management System and to submit a report to Congress on the review, including potential recommendations for improvement.

Section 8105. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl and other substances.

This provision 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. This provision requires the Secretary of HHS to consider whether to include any other drugs or other substances in its determination on the expansion of the drug testing panel. It requires, if the Secretary of HHS justifies the inclusion of fentanyl, or any other drug or substance, and revises the guidelines, the Secretary of Transportation to publish a final rule adding fentanyl or such other drug or substance to Department of Transportation's testing panel.

Section 8106. Status reports on hair testing guidelines.

This provision 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 60 days of enactment of this bill and every year thereafter, until the agency publishes a final notice of guidelines for hair testing. It also 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.

Section 8107. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid.

This provision 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. It also 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.

Section 8108. Electronic recordkeeping.

This provision 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. It also 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.

Section 8109. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse.

This provision requires the Federal Motor Carrier Safety Administration to submit a report to Congress on the implementation of the final rule for the Commercial Driver's Drug and Alcohol Clearinghouse, within 60 days of enactment of this bill and every year thereafter, until January 6, 2020 or such rule is fully implemented.

Subtitle J—Eliminating Kickback in Recovery

Section 8122. Criminal penalties.

This provision makes it illegal to knowingly and willfully pay or receive kickbacks in return for referring a patient to a recovery home or clinical treatment facilities. Those found guilty shall be fined up to $200,000 or 10 years in prison, or both. Provides common sense exceptions for legitimate referrals, including ensuring legitimate entities can continue to refer patients to reputable treatment providers, similar to those that are applicable in Medicare and Medicaid.

Subtitle K—Substance Abuse Prevention

Section 8201 - 8222. Substance Abuse Prevention

These provisions will reauthorize the Office of National Drug Control Policy, the Drug Free Communities program, and the High Intensity Drug Trafficking Areas program. They will also improve upon the HIDTA program by targeting funds for implementing a coordinated drug overdose response strategy and prioritize protecting law enforcement officers from accidental exposure to dangerous narcotics. The National Drug Control Strategy is updated to focus on roles of partner agencies; report every two years to improve strategic focus, reduce administrative burden, and improve continuation of strategic mission during transition years; and include annual performance assessment reporting to Congress and the President on progress toward goals in the National Drug Control Strategy. These provisions also improve

oversight and transparency of the National Drug Control Program budget by ensuring both certifications and decertifications are reported to Congress. In addition, these provisions focus on overcoming current and future substance use issues, by requiring federal agency partners to complete a plan for educating and training medical practitioners in best practices for prescribing controlled substances and focusing on upcoming threats through the establishment of an Emerging Threats Coordinator and Committee to monitor emerging drug threats in coordination with state, local, and tribal governments.

Subtitle L – Budgetary Effects

Section 8231. Budgetary Effect

The budgetary effects of this Act shall not be entered on either statutory PAYGO scorecard required by the Statutory Pay-As-You-Go Act of 2010, nor on the Senate PAYGO scorecard required by H. Con. Res. 71 (115th Congress).