On September 28, the House passed a final bicameral agreement produced by the conference committee on H.R. 6 by a vote of 393 to 8. On October 3, the Senate voted on the final legislation, which has been sent to President Trump's desk for signature.

Senator Murkowski's following priorities were included in the final package:

- Title VII, Subtitle E, Sec. 7041: Cutting-Edge Research
- Title VII, Subtitle F: Jessie's Law
- Title VII, Subtitle H: NHSC Professionals in Schools
- **Title VII, Subtitle C, Section 7023:** National Milestones to Measure Progress in Ending the Opioid Epidemic Act
- Title VIII, Subtitle A: The STOP Act
- Title VII, Subtitle H: The Opioid Treatment Workface Shortage.-

Here is a section by section of the final legislation:

#### Bicameral Agreement to H.R. 6 breakdown:

# Title I – Medicaid Provisions to Address the Opioid Crisis

- Sec. 1001. At-risk youth Medicaid protection: Requires state Medicaid programs to suspend, as opposed to terminate a juvenile's medical assistance eligibility when a juvenile is incarcerated.
- Sect. 1002. Health Insurance for former Foster youth: Ensures former foster youth can keep their Medicaid coverage across state lines until 26; requires HHS to issue guidance within one year regarding best practices to enroll former foster youth in coverage.
- Sect. 1003. Demonstration project to increase substance use provider capacity under Medicaid: Requires CMS to carry out 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.
- Sect. 1004. Medicaid drug review utilization: Medicaid programs are required to have safety edits for opioid refills, monitor concurrent prescribing of opioids (and certain drugs) and monitor antipsychotic prescribing for children.
- Sect. 1005. Guidance and GAO report on infants with neonatal abstinence syndrome and their mothers: Requires HHS to issue best practices and recommendations, and guidance on improving care. Requires GAO to conduct a study on gaps in Medicaid coverage for pregnant and postpartum women with a substance use disorder.
- Sect. 1006. Medicaid health homes: 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.
- Sect. 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.
- Sect. 1008. Peer support enhancement and evaluation: This provision directs the GAO to study and submit a report on how Medicaid covers peer support services,
- Sect. 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.
- Sect. 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.
- Sect. 1011. Assessing barriers to opioid use disorder treatment: Requires GAO to analyze and issue a report on the barriers to access to substance use disorder treatment medications under various drug distribution models, as well as addressing options for state Medicaid programs to reduce or remove such barriers.
- Sect. 1012. Help for moms and babies: 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). 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.
- Sect. 1013. Securing flexibility to treat substance use disorders: 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.
- Sect. 1014. MACPAC study and report on MAT utilization controls under State Medicaid programs: Requires Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on utilization management controls applied to medication-assisted treatment options in both feed for-service and managed care Medicaid programs.
- Sect. 1015. Opioid addiction treatment programs enhancement: 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.
- Sect. 1016. Better data sharing to combat the opioid crisis: Clarifies states' ability to access and share data from prescription drug monitoring program databases.
- Sect. 1017. Report on innovative State initiatives and strategies to provide housing related services and supports to individuals struggling with substance use disorders under Medicaid: Directs HHS to issue a report on state initiatives and covered housing-related services that state Medicaid programs may use to provide supports to enrollees with substance use disorders who are experiencing homelessness or are at risk of homelessness.
- Sect. 1018. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid: Directs HHS to provide technical assistance to states to develop and coordinate housing services under Medicaid.

#### Title II – Medicaid Provisions to Address the Opioid Crisis

- Sect. 2001. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders: Expands the use of telehealth services furnished to Medicare beneficiaries for the treatment of substance use disorders and co-occurring mental health disorders, beginning July 1, 2019.
- Sect. 2002. Comprehensive screenings for seniors: 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 disorders, including a referral for treatment as appropriate.
- **Sect. 2003. Every prescription conveyed securely:** Deters prescription fraud and the diversion of opioids through the use of e-prescribing for opioids
- Sect. 2004. Requiring prescription drug plan sponsors under Medicare to establish
  drug management programs for at-risk beneficiaries: 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
- Sect. 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.
- Sect. 2006. Encouraging appropriate prescribing under Medicare for victims of opioid overdose: 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.
- Sect. 2007. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries: Requires that a beneficiary enrolled in Medicare Part D who is identified as potentially at-risk for prescription drug abuse
- Sect. 2008. Suspension of payments by Medicare prescription drug plans and MA-PD plans pending investigations of credible allegations of fraud by pharmacies: Permits 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**

- Sect. 3001. Clarifying FDA regulation of non-addictive pain products: Requires (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.
- Sect. 3002. Evidence-based opioid analgesic prescribing guidelines and report:
  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.

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**

- Sect. 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.
- Sect. 3013. Single source pattern of imported illegal drugs. 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
- Sect. 3014. Strengthening FDA and CBP coordination and capacity: 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.

# Chapter 3 – Stop Illicit Drug Importation

• Sect. 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.

# Chapter 4 – Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging

• Sect. 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.

# **Chapter 5 – Post-Approval Study Requirements**

• Sect. 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.

# **Subtitle B – Controlled Substances Provisions**

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

- Sect. 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.
- Sect. 3202. Medication-assisted treatment for recovery from substance use disorder: 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.
- Sect. 3203. Grants to enhance access to substance use disorder treatment: Authorizes grants to support the development of curriculum that will help health care practitioners obtain a waiver to prescribe MAT.
- Sect. 3204. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation: 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

• Sect. 3212. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription: Directs 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**

- Sect. 3222. Disposal of controlled substances of a hospice patient by employees of a qualified hospice program: 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.
- Sect. 3223. GAO study and report on hospice safe drug management: 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

• Sect. 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**

• Sect. 3241. Controlled substance analogues: Will set forth factors that may be considered as evidence to determine whether a controlled substance analogue is intended for human consumption.

#### Chapter 6 – Access to Increased Drug Disposal

 Sect. 3251 - 3260. Access to Increased Drug Disposal: Allows the Attorney General to award grants to five states to increase participation of eligible collectors as authorized collectors for drug-disposal programs

## Chapter 7 — Using Data to Prevent Opioid Diversion

• Sect. 3271 - 3274. Using Data to Prevent Opioid Diversion: 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.

#### Chapter 8 – Opioid Quota Reform

• **Sect. 3281 - 3282. Opioid Quota Reform:** Establish mandatory factors for DEA to consider when setting annual opioid quotas, including diversion, abuse, overdose deaths, and public health impacts.

#### **Chapter 9 – Preventing Drug Diversion**

• Sect. 3291 - 3292. Preventing Drug Diversion: Requires registrants to design systems to identify and report suspicious orders of opioids and requires 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

- Sect. 4001. Promoting value in Medicaid managed care: Provides an incentive for states voluntarily adopting a medical loss ratio (MLR) requirement for their Medicaid managed care organizations (MCOs) of 85 percent.
- Sect. 4002. Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program: Extends mandatory reporting requirements to include prescription drug coverage in order to better coordinate benefits related to Medicare Part D.
- Sec. 4003. Additional religious exemption from health coverage responsibility requirement: 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 product: 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). Expands current law requirement to cover patent settlements between biosimilar and biologic companies. This policy makes improvements to Sect. 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**

• Sect. 5001. Mandatory reporting with respect to adult behavioral health measures: Requires 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

 Sect. 5012. MACPAC exploratory study and report on institutions for mental diseases requirements and practices under Medicaid: Direct the Medicaid and CHIP Payment and Access Commission (MACPAC) to conduct a study on institutions for mental disease (IMD) that receive Medicaid reimbursement

# Subtitle C – CHIP Mental Health and Substance Use Disorder Parity

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

Require state CHIP to cover mental health benefits, including substance use disorder services for eligible pregnant women and children; 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**

• Sect. 5032. Promoting State innovations to ease transitions integration to the community for certain individuals: Require the Secretary of HHS to convene a stakeholder group to produce a report of best practices for states to consider in health care related transitions for inmates.

## **Subtitle E – Medicaid Partnership**

• Sect. 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

#### **Subtitle F – IMD CARE Act**

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

- Provides 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.
- Sec. 5061. Medicaid Improvement Fund: 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 CMS 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

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

• Sect. 6012. Study on abuse-deterrent opioid formulations access barriers under Medicare: 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**

- Sect. 6021. Medicare opioid safety education: 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.
- Sect. 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

• Sect. 6042. Opioid use disorder treatment demonstration program: Creates a demonstration project to increase access to comprehensive, evidence-based outpatient treatment for Medicare beneficiaries with opioid use disorders.

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

• Sect. 6052. Grants to provide technical assistance to outlier prescribers of opioids: Grants to eligible entities to provide outreach and education to outlier prescribers of opioids to reduce the amount of opioid prescriptions prescribed. Makes available \$75 million from the Supplementary Medical Insurance Trust Fund for the purpose of such education.

# Subtitle G – Preventing Addiction for Susceptible Seniors

- Sect. 6062. Electronic prior authorization for covered Part D drugs: 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.
- Sect. 6063. Program integrity transparency measures under Medicare parts C and D: 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.
- Sect. 6064. Expanding eligibility for medication therapy management programs under part D: Requires beneficiaries at risk for prescription drug abuse to be eligible for the Medication Therapy Management (MTM) Program beginning January 1, 2021.
- Sect. 6065. Commit to opioid medical prescriber accountability and safety for seniors: 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.

# Subtitle H – Expanding Oversight of Opioid Prescribing and Payment

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

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

• Sect. 6082. Review and adjustment of payments under the Medicare outpatient prospective payment system to avoid financial incentives to use opioids instead of nonopioid 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.

- Sect. 6083. Expanding access under the Medicare program to addiction treatment in Federally qualified health centers and rural health clinics: 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.
- Sect. 6084. Studying the availability of supplemental benefits designed to treat or prevent substance use disorders under Medicare Advantage plans: 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.
- Sect. 6085. Clinical psychologist services models under the Center for Medicare and Medicaid Innovation; GAO study and report: 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.
- Sect. 6086. Dr. Todd Graham pain management study: 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, evidencebased non-opioid chronic pain management.

# Subtitle J – Combating Opioid Abuse for Care in Hospitals

- Sect. 6092. Developing guidance on pain management and opioid use disorder prevention for hospitals receiving payment under part A of the Medicare program: 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
- Sect. 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.
- Sect. 6094. Technical expert panel on reducing surgical setting opioid use; Data collection on perioperative opioid use: 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.
- Sect. 6095. Requiring the posting and periodic update of opioid prescribing guidance for Medicare beneficiaries: Within 180 days of enactment, requires the Secretary of HHS to publish on the CMS website all opioid prescribing guidance published after January 1, 2016, applicable to Medicare beneficiaries.

Subtitle K – Providing Reliable Options for Patients and Educational Resources

- Sect. 6102. Requiring Medicare Advantage plans and part D prescription drug
  plans to include information on risks associated with opioids and coverage of
  nonpharmacological 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
- Sect. 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.
- Sect. 6104. Revising measures used under the Hospital Consumer Assessment of Healthcare Providers and Systems survey relating to pain management: 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

• **Sect. 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.

#### Title VII - Public Health Provisions

#### **Subtitle A—Awareness and Training**

- Sect. 7001. Report on effects on public health of synthetic drug use: 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.
- Sect. 7002. First responder training: Expands a grant program authorized by the Comprehensive Addiction and Recovery Act, which was designed to allow first responders to administer a drug or device, like naloxone, to treat an opioid overdose, to include training on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.

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

• Sect. 7011. Pilot program for public health laboratories to detect fentanyl and other synthetic opioids: 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

- Sect. 7021. Establishment of substance use disorder information dashboard: 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.
- Sect. 7022. Interdepartmental Substance Use Disorder Coordinating Committee: 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.
- Sect. 7023. National milestones to measure success in curtailing the opioid crisis: 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.
- **Sect. 7024. Study on prescribing limits:** The HHS, in consultation with the Attorney General (AG), must 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

• Sect. 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.

# Subtitle E—Advancing Cutting Edge Research

- **Sect. 7041. Unique research initiatives:** 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
- Sect. 7042. Pain research: Updates the scope of the Interagency Pain Research Coordinating Committee to identify risk factors for, and early warning signs of, substance use disorders, and summarize advances in pain care research supported or conducted by the federal government, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs approved, or devices approved or cleared, by the FDA.

#### Subtitle F—Jessie's Law

• Sect. 7051. Inclusion of opioid addiction history in patient records. Requires the HHS to develop best practices for prominently displaying substance use disorder treatment information in electronic health records, when requested by the patient.

- Sect. 7052. Communication with families during emergencies. 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.
- Sect. 7053. Development and dissemination of model training programs for substance use disorder patient records: Requires HHS to identify model programs and materials to better train and educate providers, patients and families regarding the permitted uses and disclosures of patient records related to treatment for substance use disorders.

# **Subtitle G—Protecting Pregnant Women and Infants**

- Sect. 7061. Report on addressing maternal and infant health in the opioid crisis: 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.
- Sect. 7062. Protecting moms and infants. 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.
- Sect. 7063. Early interventions for pregnant women and infants: 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.
- **Sect. 7064. Prenatal and postnatal health:** 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.
- Sect. 7065. Plans of safe care: 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.

#### Subtitle H—Substance Use Disorder Treatment Workforce

- Sect. 7071. Loan repayment program for substance use disorder treatment workforce. 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.
- Sect. 7072. Clarification regarding service in schools and other community-based settings: 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.

Sect. 7073. Programs for health care workforce: 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.

# **Subtitle I—Preventing Overdoses While in Emergency Rooms**

- Sect. 7081. Program to support coordination and continuation of care for drug overdose patients. Provides resources for hospitals and other entities to develop protocols on discharging patients who have presented with an opioid overdose.
- Sect. 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

- Sect. 7101. Establishment of regional centers of excellence in substance use disorder education: 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.
- Sect. 7102. Youth prevention and recovery. Requires 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

• Sect. 7111. Information from national mental health and substance use policy laboratory: 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**

• Sect. 7121. Comprehensive opioid recovery centers: Authorizes a SAMHSA grant program for entities to establish or operate comprehensive opioid recovery centers that serve as a resource for the community.

#### Subtitle N—Trauma-Informed Care

- Sect. 7131. CDC surveillance and data collection for child, youth, and adult trauma: Authorizes CDC to support state efforts to collect and report data on adverse childhood experiences through existing public health surveys.
- Sect. 7132. Task force to develop best practices for trauma-informed identification, referral, and support: Creates an interagency task force to make recommendations regarding best practices to identify, prevent, and mitigate the effects of trauma on infants,

- children, youth, and their families, and to better coordinate the Federal response to families impacted by substance use disorders and other formers of trauma.
- Sect. 7133. National Child Traumatic Stress Initiative: Increases the authorization level for the National Child Traumatic Stress Initiative. Funding will provide technical assistance, direct services to communities, and will support evaluations and dissemination of best practices in trauma-informed care for children and families.
- Sect. 7134. Grants to improve trauma support services and mental health care for children and youth in educational settings: Authorizes the Secretary of Education, in coordination with the 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.
- Sect. 7135. Recognizing early childhood trauma related to substance abuse: 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**

• Sect. 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**

- **Sect. 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.
- Sect. 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**

• Sect. 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.

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

• Sect. 7171. Review of substance use disorder treatment providers receiving Federal funding: Rquires 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

- Sect. 7181. State response to opioid abuse crisis: 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
- Sect. 7182. Report on investigations regarding parity in mental health and substance use disorder benefits: Rquires 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.
- **Sect. 7183.** Career Act: 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.

#### Title VIII - Miscellaneous

#### **Subtitle A—Synthetics Trafficking and Overdose Protection**

- Sect. 8003. Mandatory advance electronic information for postal shipments: Requires the 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
- Sect. 8004. International postal agreements: 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.
- **Sect. 8005. Cost recoupment:** 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.
- Sect. 8006. Development of technology to detect illicit narcotics: 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.
- **Sect. 8007. Civil Penalties for postal shipments**. Establishes civil penalties if USPS accepts international mail shipments without AED after December 31, 2020.

- Sect. 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 Sects 436 and 584 of the Tariff Act of 1930, as amended.
- **Sect. 8009. Effective date; regulations**: Provides that the changes made by this Act, other than amendments made by Sect. 8002, shall take effect on the date of the enactment of this Act.

# **Subtitle B—Opioid Addiction Recovery Fraud Prevention**

• Sect. 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.

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

• Sect. 8041. Addressing economic and workforce impacts of the opioid crisis. Authorizes the Department of Labor to award dislocated worker grants to states through the Workforce Innovation and Opportunity Act to support local workforce boards and local partnerships in tackling shortages in substance use disorder and mental health treatment workforce.

# **Subtitle D—Peer Support Counseling Program for Women Veterans**

• Sect. 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**

• Sect. 8062. Drug abuse mitigation initiative. 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

- Sect.. 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: 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.
- 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 atrisk 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

• Sect. 8092. Reauthorization of the comprehensive opioid abuse grant program: 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

- Sect. 8102. Alcohol and controlled substance testing of mechanical employees: 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.
- Sect. 8103. Department of Transportation public drug and alcohol testing database: 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.
- Sect. 8104. GAO report on Department of Transportation's collection and use of drug and alcohol testing data: 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.
- Sect. 8105. Transportation Workplace Drug and Alcohol Testing Program; addition of fentanyl and other substances: 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.
- Sect. 8106. Status reports on hair testing guidelines: 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.
- Sect. 8107. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid: Requires the Secretary of HHS to publish a final notice of mandatory guidelines for oral fluid testing not later than December 31, 2018,

- **Sect. 8108. Electronic recordkeeping:** Requires the HHS to ensure each certified laboratory that requests the use of paperless electronic chain of custody forms receives approval.
- Sect. 8109. Status reports on Commercial Driver's License Drug and Alcohol Clearinghouse: 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.

# Subtitle J—Eliminating Kickback in Recovery

- Sect. 8122. Criminal penalties: 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.
- **Sect. 8201 8222 Substance Abuse Prevention**: Reauthorizes the Office of National Drug Control Policy, the Drug Free Communities program, and the High Intensity Drug Trafficking Areas program.
- Subtitle L Budgetary Effects.