

# Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (H.R. 6): A Section-by-Section

#### Summary

House Sponsors: Reps. Greg Walden (R-OR), Frank Pallone (D-NJ), Kevin Brady (R-TX), Richard Neal (D-MA), David Roe (R-TN), Bill Shuster (R-PA), Virginia Foxx (R-NC), Bob Goodlatte (R-VA), Tim Walz (D-MN), Peter DeFazio (D-OR), and Michael Burgess (R-TX)

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#### TITLE I—MEDICAID PROVISIONS TO ADDRESS THE OPIOID CRISIS

#### Sec. 1001. At-risk youth Medicaid protection

This section specifies that a State Medicaid program may not terminate a juvenile's medical assistance eligibility because the 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.

A "juvenile" is defined as an individual who: (1) is under 21 years of age; or (2) has aged out of the State's foster care system, was enrolled in the State plan while in foster care, and is under 26 years of age.

#### Sec. 1002. Health Insurance for Former Foster Youth

Amends title XIX of the Social Security Act to ensure health insurance coverage continuity for former foster youth in any State they reside in until age 26.

This section requires the Sec. of HHS to issue guidance to State Medicaid programs on best practices for removing barriers and ensuring streamlined access to Medicaid coverage for former foster youth up to age 26, and conducting outreach and raising awareness among youth regarding Medicaid coverage options. The guidance shall include examples of States that have successfully extended Medicaid coverage to former foster youth up to age 26.

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

This section authorizes the Sec. of HHS, in consultation with AHRQ Director and Assistant Sec. for Mental Health and Substance Use to conduct a 54-month (18-month planning grants + 36 month demonstration) demonstration project for States to increase the treatment capacity of providers participating under the State plan (or a waiver) to provide SUD treatment or recovery services under the plan or waiver.

#### Sec. 1004. Drug management program for at-risk beneficiaries

This section requires Medicare prescription drug plan (PDP) sponsors, for plan years beginning on or after January 1, 2021, to establish drug management programs for at-risk beneficiaries. Current law authorizes, but does not require, PDP sponsors to establish such programs.

Calls for MACPAC report on best practices for operating PDPs. Also requires States operating qualified drug management programs to submit to CMS a report on how State plans provide coordinated care for individuals enrolled under the State plan (or waiver).

#### Sec. 1005. Medicaid drug review and utilization

Requires all State Medicaid programs to use drug utilization review activities to help combat the opioid crisis. States will be required to have State-determined limitations in place for opioid refills, monitor concurrent prescribing of opioids and other drugs (such as benzodiazepines and antipsychotics), monitor antipsychotic prescribing for children, and have at least one buprenorphine/naloxone combination drug on the Medicaid drug formulary.

# Sec. 1006. 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 section calls for Sec. of HHS to issue guidance to improve care for infants with neonatal abstinence syndrome and their families. Guidance shall include:

- (1) the types of services, including post-discharge services and parenting supports, for families of babies with neonatal abstinence syndrome that States may cover under the Medicaid program under title XIX of the Social Security Act;
- (2) best practices from States with respect to innovative or evidenced-based payment models that focus on prevention, screening, treatment, plans of safe care, and post-discharge services for mothers and fathers with substance use disorders and babies with neonatal abstinence syndrome that improve care and clinical outcomes;
- (3) recommendations for States on available financing options under the Medicaid program under title XIX of such Act and under the Children's Health Insurance Program under title XXI of such Act for Children's Health Insurance Program Health Services Initiative funds for parents with substance use disorders, infants with neonatal



abstinence syndrome, and home visiting services; and

(4) guidance and technical assistance to State Medicaid agencies regarding additional flexibilities and incentives related to screening, prevention, and post-discharge services, including parenting supports.

Also calls for GAO study on gaps in coverage for pregnant women with substance use disorder under the Medicaid program under title XIX of the Social Security Act, and gaps in coverage for postpartum women with substance use disorder who had coverage during their pregnancy under the Medicaid program under such title.

#### Sec. 1007. Medicaid health homes for opioid-use-disorder Medicaid enrollees

HHS Secretary may, at the request of the State with an SUD-focused State plan amendment, extend the application of the Federal medical assistance percentage (FMAP) to payments for the provision of health home services to SUD-eligible individuals under such State plan amendment, in addition to the first 8 fiscal year quarters the State plan amendment is in effect, for the subsequent 2 fiscal year quarters that the State plan amendment is in effect.

Calls for HHS Secretary to make publicly available on CMS website best practices for designing and implementing an SUD-focused State plan amendment, based on the experiences of States that have State plan amendments approved under this section that include SUD-eligible individuals.

#### TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 2001. Authority not to apply certain Medicare telehealth requirements in the case of certain treatment of a substance use disorder or co-occurring mental health disorder

Authorizes Sec. of HHS to waive certain Medicare telehealth requirements in the case of certain treatment of an opioid use disorder or co-occurring substance use and mental health disorder.

Calls for Sec. of HHS to submit to Congress a report on the impact of this waiver on the utilization of health care services related to substance use disorder, such as behavioral health services and emergency department visits, and health outcomes related to substance use disorder, such as substance use overdose deaths.

#### Sec. 2002. Encouraging the use of non-opioid analgesics for the management of post-surgical pain

Amends the Social Security Act to encourage the use of non-opioid analgesics for the management of post-surgical pain under the Medicare program.

# Sec. 2003. Requiring a review of current opioid prescriptions for chronic pain and screening for opioid use disorder to be included in the Welcome to Medicare initial preventive physical examination

Amends title XVIII of the Social Security Act to require a review of current opioid prescriptions for chronic pain and screening for opioid use disorder to be included in the "Welcome to Medicare" initial preventive physical examination.

#### Sec. 2004. Modification of payment for certain outpatient surgical services

Requires payment for for targeted procedures in ambulatory surgical centers from 2020-2025 to be equal to the payment amount for those procedures in 2016.

#### Sec. 2005. Requiring e-prescribing for coverage of covered part D controlled substances

Requires healthcare providers to use electronic prescribing for opioids and other controlled substances for Medicare Part D transactions beginning in 2021.

### Sec. 2006. Requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries

Requires Medicare prescription drug plan (PDP) sponsors, for plan years beginning on or after January 1, 2021, to establish drug management programs for at-risk beneficiaries. Current law authorizes, but does not require, PDP sponsors to establish these programs.

#### Sec. 2007. Medicare coverage of certain services furnished by opioid treatment programs

Expands Medicare coverage to include SAMHSA-certified OTPs. Medicare will pay OTPs through bundled payments made for services, including necessary medications, counseling, and testing. Treatment services are defined as:



- opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the FDA;
- dispensing and administration of such medications;
- substance use counseling by a professional;
- individual and group therapy with a physician or psychologist (or other mental health professional);
- toxicology testing, and
- other items and services that the HHS Secretary determines are appropriate (but in no event to include meals or transportation).

#### TITLE III—OTHER HEALTH PROVISIONS TO ADDRESS THE OPIOID CRISIS

#### Sec. 3001. Clarifying FDA regulation of non-addictive pain and addiction therapies

Requires HHS Sec. to hold a public meeting on the challenges of developing non-addictive medical products for pain and addiction treatment. Calls for Sec. to issue guidance with respect to the expedited approval of certain drugs.

#### Sec. 3002. Surveillance and Testing of Opioids to Prevent Fentanyl Deaths

Establishes a grant program to federal, State, and local agencies to establish/operate public health laboratories to detect fentanyl and other synthetic opioids. It also would direct the CDC to expand its drug surveillance program, with a particular focus on collecting data on fentanyl. Would also establish a pilot program for 5 State or local agencies in 5 States for point-of-use testing of illicit drugs, and to establish metrics to evaluate the pilot.

#### Sec. 3003. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders

Amends provision that passed in the Comprehensive Addiction and Recovery Act (CARA) of 2016 that allows nurse practitioners (NPs) and physician assistants (PAs) to prescribe buprenorphine by striking the sunset of 2021 for NPs/PAs to become "qualifying practitioners" and eliminating any time limitation.

Expands definition of "qualifying practitioner" to include "nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant." Sets time limit of Oct. 1, 2018-Oct. 1, 2023 for clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife to become a qualified practitioner.

Calls for Sec. of HHS to submit report to Congress that assesses the care provided by qualifying practitioners. The report will include recommendations on future applicable patient number levels and limits.

Allows qualifying practitioners to treat up to 100 patients (instead of 30) if:

- not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the HHS Secretary of the need and intent of the practitioner to treat up to 100 patients;
- the practitioner holds additional credentialing (board certification in addiction medicine or addiction psychiatry by
  the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American
  Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of
  Addiction Medicine); or
- the practitioner provides MAT in a qualified practice setting.

#### Sec. 3004. High-quality, evidence-based opioid analgesic prescribing guidelines and report

This section calls for the FDA Commissioner to develop (and periodically update) high-quality, evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain in the areas where such guidelines do not already exist. In developing the guidelines, the Commissioner of Food and Drugs shall conduct a public workshop, open to representatives of State medical societies and medical boards, various medical specialties including pain medicine specialty societies, patient groups, pharmacists, universities, and others; and provide a period for the submission of comments by the public.

Within 2 years of enactment of this Act, the Commissioner shall submit to the House Committee on Energy and Commerce Senate Committee on Health, Education, Labor, and Pensions, and post on the FDA website, a report on how the



guidelines will be utilized to protect the public health.

#### Sec. 3005. Report on opioids prescribing practices for pregnant women

This section calls for the Secretary of Health and Human Services, in coordination with the Centers for Disease Control and Prevention, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration, to develop and submit to the Congress a report—

- 1) on opioids prescribing practices for pregnant women and recommendations for such practices;
- 2) that provides recommendations for identifying and reducing opioids misuse during pregnancy;
- 3) on prescription opioid misuse during pregnancy in urban and rural areas;
- 4) on prescription opioid use during pregnancy for the purpose of medication-assisted treatment in urban and rural areas;
- 5) evaluating current utilization of non-opiate pain management practices in place of prescription opioids during pregnancy;
- 6) providing guidelines encouraging the use of non-opioid pain management practices during pregnancy when safe and effective; and
- 7) that provides recommendations for increasing public awareness and education of opioid use disorder in pregnancy, including available treatment resources in urban and rural areas.

#### Sec. 3006. Guidelines for prescribing naloxone

This section calls for the Secretary of Health and Human Services to issue guidelines for prescribing an opioid overdose reversal drug. The guidelines will cover:

- 1) Co-prescribing an opioid overdose reversal drug in conjunction with any prescribed opioid.
- 2) Dosage safety.
- 3) Prescribing an opioid overdose reversal drug to an individual other than a patient.
- 4) Standing orders.
- 5) Other distribution, education, and safety measures as determined necessary.

#### Sec. 3007. Requiring a survey of substance use disorder treatment providers receiving Federal funding

This section calls for the Secretary of Health and Human Services to conduct a survey of all entities that receive Federal funding for the purpose of providing substance use disorder treatment services. The survey shall direct such entities to provide the following information:

- 1) The length of time the entity has provided substance use disorder treatment services.
- 2) A detailed description of the patient population served by the entity, including but not limited to the number of patients, type of addictions, geographic area served, as well as gender, racial, ethnic and socioeconomic demographics of such patients.
- 3) A detailed description of the types of addiction for which the entity has the experience, capability, and capacity to provide such services.
- 4) An explanation of how the entity handles patients requiring treatment for a substance use disorder that the organization is not able to treat.
- 5) A description of what is needed, in the opinion of the entity, in order to improve the entity's ability to meet the addiction treatment needs of the communities served by that entity.
- 6) Based on the identified needs of the communities served, a description of unmet needs and inadequate services and how such needs and services could be better addressed through additional Federal, State, or local government resources or funding to treat addiction to methamphetamine, crack cocaine, other types of cocaine, heroin, opioids, and other commonly abused drugs.

Not later than 1 year after the date of the enactment of this Act, the Secretary shall develop and submit to Congress a plan to direct appropriate resources to entities that provide substance use disorder treatment services in order to address inadequacies in services or funding identified through the survey.

#### TITLE IV—OFFSETS

#### Sec. 4001. Promoting value in Medicaid managed care

For Grants to States for Medical Assistance Programs for FY 2020-2025, the Secretary of HHS will substitute the Federal medical assistance percentage (FMAP) for the federal share percentage.

Sec. 4002. Extending period of application of Medicare secondary payer rules for individuals with end stage renal



#### disease

Extends the application period of Medicare secondary payer rules for individuals with end stage renal disease from 12 months to 33 months.

Sec. 4003. Requiring reporting by group health plans of prescription drug coverage information for purposes of identifying primary payer situations under the Medicare program

Requires group health plans to report on prescription drug coverage information in order to identify primary payers under the Medicare program.

#### TITLE V—OTHER MEDICAID PROVISIONS

Subtitle A-Mandatory Reporting with Respect To Adult Behavioral Health Measures

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

This section requires CMS to expand its core set of adult health quality measures for Medicaid-eligible adults to include measures specific to mental health and substance use. A State Medicaid program must report on these measures annually.

#### Subtitle B—Medicaid IMD Additional Info

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

This section directs 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 will report on the requirements and standards that some State Medicaid programs have for IMDs. MACPAC, considering input from stakeholders, will summarize the findings and 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 Parity

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

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

#### Subtitle D—Medicaid Reentry

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

Requires CMS to convene a stakeholder workgroup in order to develop best practices for States to: (1) ease the health care transition of inmates released from public institutions (such as by ensuring continuity of health insurance or Medicaid coverage), and (2) implement transitional measures within 30 days of an inmate's release. The CMS must also issue a letter to States outlining opportunities for Medicaid demonstration waivers based on identified best practices.

#### Subtitle E—Medicaid Partnership

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

This section requires Medicaid providers to check the prescription drug monitoring program (PDMP) before prescribing a Schedule II controlled substance. This provision encourages Medicaid providers to integrate PDMP usage into their clinical workflow. The provision also establishes standard criteria that a PDMP must meet to be counted as a qualified PDMP and requires state Medicaid programs to report to CMS on PDMP data and information.

#### 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

Sec. 6001. Testing of Incentive Payments for Behavioral Health Providers for Adoption and Use of Certified Electronic Health Record Technology

This section specifies that the Center for Medicare and Medicaid Innovation may test models to provide incentive payments to MH/SUD providers for: (1) adopting electronic health records technology, and (2) using that technology to improve the quality and coordination of care.



#### Subtitle B—Abuse-Deterrent Access

#### Sec. 6012. Study on Abuse-Deterrent Opioid Formulations Access Barriers under Medicare

This section requires CMS to report to Congress on the adequacy of access to abuse-deterrent opioid formulations for individuals with chronic pain enrolled in a prescription drug plan under Medicare or Medicare Advantage (MA). The report must account for any barriers preventing enrollees from accessing such formulations under Medicare or MA.

#### Subtitle C—Medicare Opioid Safety Education

Sec. 6022. Provision of Information Regarding Opioid Use and Pain Management as Part of Medicare & You Handbook

This section requires the "Medicare & You" handbook to include information about educational resources on opioid use and pain management, as well as a description of alternative, non-opioid pain management treatments covered by Medicare.

#### Subtitle D—Opioid Addiction Action Plan

Sec. 6032. Action Plan on Recommendations for Changes under Medicare and Medicaid to Prevent Opioid Addictions and Enhance Access to Medication-Assisted Treatment

This section calls for the Secretary of HHS, in collaboration with the Pain Management Best Practices Inter-Agency Task Force (established in CARA Sec. 101b), to establish an action plan, including studies, reports to Congress authored by HHS, as well as meetings with stakeholders, for the purpose of addressing the opioid crisis.

#### <u>Subtitle E—Advancing High Quality Treatment for Opioid Use Disorders in Medicare</u> Sec. 6042. Opioid Use Disorder Treatment Demonstration Program

This section calls for the Secretary of HHS to implement a 4-year demonstration program to increase access of Medicare beneficiaries to opioid use disorder treatment services. A maximum of 20,000 beneficiaries may participate in the program at any time. In order to participate in the program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participating provider. Participation under the program shall not affect coverage of or payment for any other item or service under this title for the applicable beneficiary.

# Subtitle F—Responsible Education Achieves Care and Health Outcomes for Users' Treatment Sec. 6052. Grants to Provide Technical Assistance to Outlier Prescribers of Opioids

Requires CMS to award grants, contracts, or cooperative agreements to qualifying organizations (an organization that has demonstrated experience providing technical assistance to health care professionals on a State or regional basis, or a quality improvement entity) in order to support efforts to curb outlier prescribers of opioids under the Medicare prescription drug benefit and Medicare Advantage prescription drug plans.

#### Subtitle G—Preventing Addiction for Susceptible Seniors

Sec. 6062. Electronic Prior Authorization for Covered Part D Drugs

This section requires electronic prescription programs to enable the secure transmittal of prior authorization requests for covered drugs.

#### Sec. 6063. Program Integrity Transparency Measures Under Medicare Parts C and D

This section requires CMS to establish a secure online portal to allow: (1) data sharing among the CMS, Medicare prescription drug benefit plans, and Medicare Advantage (MA) plans; and (2) referrals by such plans of substantiated fraud, waste, or abuse in order to initiate or assist investigations by contracted entities under the Medicare Integrity Program.

#### Sec. 6064. Expanding Eligibility for Medication Therapy Management Programs Under Part D

Establishes individuals who are identified as at-risk beneficiaries for prescription drug abuse as qualifying participants in medication therapy management programs.

#### Sec. 6065. Medicare Notifications to Outlier Prescribers of Opioids

This section requires CMS to (1) identify outlier prescribers of opioids under Medicare prescription drug benefit plans and Medicare Advantage plans, based on specialty and geographic area; and (2) annually notify such prescribers of their status



and provide them with resources on proper prescribing methods.

#### Sec. 6066. No Additional Funds Authorized

This section notes that no funds are authorized to be appropriated for carrying out subtitle G of this Act.

#### Subtitle H—Expanding Oversight of Opioid Prescribing and Payment

Sec. 6072. Medicare Payment Advisory Commission Report on Opioid Payment, Adverse Incentives, and Data under the Medicare Program

This section calls for the Medicare Payment Advisory Commission to submit to Congress a report on: 1) how Medicare pays for opioid and non-opioid pain management treatments; 2) incentives under the hospital inpatient prospective payment system for prescribing opioids and non-opioids; and 3) how opioid use is tracked and monitored through Medicare claims data and other mechanisms.

#### Sec. 6073. No Additional Funds Authorized

This section notes that no funds are authorized to be appropriated for carrying out subtitle H of this Act.

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

Sec. 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 section calls for the Secretary of HHS to review payments under the Medicare prospective payment system for opioids and non-opioid alternatives for pain management in order to ensure that there aren't financial incentives to use opioids instead of non-opioid alternatives.

# Sec. 6083. Expanding Access under the Medicare Program to Addiction Treatment in Federally Qualified Health Centers (FQHC) and Rural Health Clinics

This section authorizes additional Medicare payments to be made to federal qualified health centers (FQHCs) and rural health clinics that have a DATA-waivered physician or practitioner to treat substance use disorders. This section authorizes \$6 million for FQHCs, to remain available until expended, and \$2 million for rural health clinics, to remain available until expended.

# Sec. 6084. Studying the Availability of Supplemental Benefits Designed to Treat or Prevent Substance Use Disorders under Medicare Advantage Plans

This section requires the Secretary of HHS to submit to Congress a report on the availability of supplemental health care benefits to treat or prevent substance use disorders under Medicare Advantage plans. The report will review Medicare Advantage coverage of MAT, counseling, peer supports, or other treatments; non-opioid alternatives to treat pain; challenges of offering supplemental benefits related to SUD treatment; and the impact of increasing the applicable rebate percentage for plans offering SUD treatment; and ways to improve coverage for SUD treatment.

# Sec. 6085. Clinical Psychologist Services Models under the Center for Medicare and Medicaid Innovation; GAO Study and Report

The Center for Medicare and Medicaid Innovation tests innovative payment and service delivery models to reduce program expenditures. This section expands the criteria of CMI testing models to include: supporting ways to familiarize individuals with their coverage for qualified psychologist services; and exploring ways to avoid unnecessary hospitalization or emergency department visits for mental health and behavioral health services through a 24/7 help line that may held inform individuals about the availability of treatment options, including psychologist services.

This section also requires the Comptroller General to conduct and submit to Congress a study on mental and behavioral health services under the Medicare program. The report will include information about services furnished by psychiatrists, clinical psychologists, and other professionals, and ways that Medicare beneficiaries familiarize themselves about the availability of Medicare payment for qualified psychologist services.



#### Sec. 6086. Pain Management Study

This section authorizes the Secretary of HHS to conduct a study and submit to Congress a report analyzing best practices and payment/coverage for pain management services under Medicare.

#### Subtitle J—Combating Opioid Abuse for Care in Hospitals

Sec. 6092. Developing Guidance on Pain Management and Opioid Use Disorder Prevention for Hospitals Receiving Payment under Part A of the Medicare Program

This section calls for the Secretary of HHS to develop and publish on the CMS website guidance for hospitals receiving payment under Part A of the Medicare program.

# Sec. 6093. Requiring the Review of Quality Measures Relating to Opioids and Opioid Use Disorder Treatments Furnished under the Medicare Program and Other Federal Programs

This section establishes a technical expert panel for the purposes of reviewing quality measures related to opioids and opioid use disorders under the Medicare program.

# Sec. 6094. Technical Expert Panel on Reducing Surgical Setting Opioid Use; Data Collection on Perioperative Opioid Use

This section establishes a technical expert panel to provide recommendations on reducing opioid use in inpatient and outpatient surgical settings and on best practices for pain management.

#### Sec. 6095. Requiring the Posting and Periodic Update of Opioid Prescribing Guidance for Medicare Beneficiaries

This section requires the Secretary of HHS to post on the CMS website all guidance published by HHS on/after January 1, 2016 on prescribing of opioids for individuals covered under Medicare Part A or Part B. The guidance shall be updated periodically.

# <u>Subtitle K—Stop Excessive Narcotics in Our Retirement (SENIOR) Communities Protection</u> Sec. 6102. Suspension of Payments by Medicare Prescription Drug Plans and MA-PD Plans Mending Investigations of Credible Allegations of Fraud by Pharmacies

This section authorizes the suspension of payments to a pharmacy under the Medicare prescription drug benefit and Medicare Advantage prescription drug plans pending the investigation of a credible allegation of fraud by the pharmacy. A fraud hotline tip, without other evidence, may not be considered a credible allegation of fraud.

#### Subtitle L—Providing Reliable Options for Patients and Educational Resources (PROPER)

Sec. 6112. Requiring Medicare Advantage Plans and Part D Prescription Drug Plans to Include Information on Risks Associated with Opioids and Coverage of Nonpharmacological Therapies and Non-Opioid Medications or Devices Used to Treat Pain

This section requires Medicare Advantage plans and part D prescription drug plans (PDP) to inform beneficiaries at the time of enrollment, and at least annually thereafter, about the risks associated with opioid use, as well as a description of the beneficiaries' coverage for non-opioid and nonpharmacological alternatives.

# Sec. 6113. Requiring Medicare Advantage Plans and Prescription Drug Plans to Provide Information on the Safe Disposal of Prescription Drugs

Requires Medicare Advantage plans and part D prescription drug plans to include information on the safe disposal of prescription drugs.

# Sec. 6114. Revising Measures Used Under the Hospital Consumer Assessment of Healthcare Providers and Systems Survey Relating to Pain Management

This section revises the Hospital Consumer Assessment of Healthcare Providers and Systems survey by stating that the survey may not include questions about communication by hospital staff with an individual about the individual's pain



unless questions take into account, as applicable, whether an individual experiencing pain was informed about risks associated with the use of opioids and about non-opioid alternatives for the treatment of pain.

#### TITLE VII—OTHER HEALTH PROVISIONS

Subtitle A—Synthetic Drug Awareness

Sec. 7002. Report on Effects on Public Health of Synthetic Drug Use

Requires the Surgeon General to submit a report to Congress on the effects of increased synthetic drug use among 12-18 year old youth on public health in order to educate parents and the medical community on the health effects of synthetics.

#### Subtitle B—Empowering Pharmacists in the Fight Against Opioid Abuse

Sec. 7012. Programs and Materials for Training on Certain Circumstances under which a Pharmacist may Decline to Fill a Prescription

Requires HHS Secretary, in consultation with the DEA Administrator, CDC Director, and Assistant Secretary for Mental Health and Substance Use, to develop and disseminate training programs and materials on: (1) the circumstances under which a pharmacist may refuse to fill a controlled substance prescription suspected to be fraudulent, forged, or indicative of abuse or diversion; and (2) federal requirements related to such refusal.

#### Subtitle C—Indexing Narcotics, Fentanyl, and Opioids

Sec. 7022. Establishment of Substance Use Disorder Information Dashboard

This section calls for the Secretary of HHS, in consultation with the Director of the Office of National Drug Control Policy (ONDCP), to establish and periodically update a public information dashboard that coordinates information on programs within HHS related to the reduction of substance use disorders, including opioid use disorders; provide publicly available data on SUDs; provide regional and population-specific SUD prevention and treatment strategy data; provide recommendations for health care providers on alternatives to controlled substance for pain management; provide guidelines and best practices for health care providers regarding SUD treatment.

#### Sec. 7023. Interagency Substance Use Disorder Coordinating Committee

This bill requires the Secretary of HHS, in coordination with the ONDCP Director, to establish an Interagency Substance Use Disorder Coordinating Committee to coordinate all HHS efforts concerning SUDs (at least 2 members will be SSAs). The Committee would:

- (1) monitor opioid use disorder and other substance use disorder research, services, and support and prevention activities across all relevant Federal agencies, including coordination of Federal activities with respect to opioid use disorder and other substance use disorders;
- (2) identify and provide to the Secretary recommendations for improving Federal grants and programs for the prevention and treatment of, and recovery from, opioid use disorder and other substance use disorders;
- (3) review substance use disorder prevention and treatment strategies in different regions and populations in the United States and evaluate the extent to which Federal substance use disorder prevention and treatment strategies are aligned with State and local substance use disorder prevention and treatment strategies;
- (4) make recommendations to the Secretary regarding any appropriate changes with respect to the activities and strategies described in paragraphs (1) through (3);
- (5) make recommendations to the Secretary regarding public participation in decisions relating to opioid use disorder and other substance use disorders and the process by which public feedback can be better integrated into such decisions; and
- (6) make recommendations to ensure that opioid use disorder and other substance use disorder research, services, and support and prevention activities of the Department of Health and Human Services and other Federal agencies are not unnecessarily duplicative.

The Committee shall terminate after 6 years of establishment.

# Subtitle D—Ensuring Access to Quality Sober Living Sec. 7032. National Recovery Housing Best Practices

Authorizes the Secretary of HHS, in consultation with the Secretary for HUD and other stakeholders, such as the National Alliance for Recovery Residences (NARR), to identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.



The Sec. of HHS will disseminate the best practices to State agencies, recovery housing entities, and the public.

The term "recovery housing" means a shared living environment free from alcohol and illicit drug use and centered on peer support and connection to services, including medication-assisted treatment services, that promote sustained recovery from substance use disorders.

This section authorizes \$3 million for FY 2019-2021.

#### Subtitle E—Advancing Cutting Edge Research

#### Sec. 7042. Unique Research Initiatives

This section authorizes the Director of the National Institutes of Health (NIH) to approve requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out high-impact cutting-edge research that fosters scientific creativity and increases understanding of the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat.

#### Subtitle F—Jessie's Law

#### Sec. 7052. Inclusion of Opioid Addiction History in Patient Records

Calls for HHS to develop best practices on the circumstances under which OUD information, at a patient's request, be prominently displayed on medical records (including EHR). Best practices will be disseminated to health care providers and State agencies.

#### Sec. 7053. Communication with Families During Emergencies

This section authorizes the Sec. of HHS, acting through the CMS Administrator and AHRQ Administrator, to annually develop and disseminate written materials to health care providers regarding permitted disclosures during health emergencies, including overdoses, of certain health information to families, caregivers, and health care providers.

#### Subtitle G—Safe Disposal of Unused Medication

# Sec. 7062. Disposal of Controlled Substance of a Deceased Hospice Patient by Employees of a Qualified Hospice Program

This section amends the Controlled Substances Act to allow hospice employees to safely dispose of medications after the death of a patient.

## <u>Subtitle H—Substance Use Disorder Workforce Loan Repayment</u> Sec. 7072. Loan Repayment Program for Substance Use Disorder Treatment Employees

This section creates a loan repayment program for individuals who complete a period of service in a substance use disorder treatment job in a mental health professional shortage area or a county where the drug overdose death rate is higher than the national average. The SUD treatment job must be a full-time position where the primary intent and function is the direct care of patients with or in recovery from a substance use disorder. Individuals must enter into an agreement of service of up to six years with the Health Resources and Services Administration (HRSA). The repayment program shall pay one-sixth of the principal and interest on any eligible loan for each year of service; the maximum total amount of repayment by the program is \$250,000 per individual.

This section also requires the Sec. of HHS to submit to Congress, within 5 years of enactment of this Act, a report on the number and location of borrowers who have qualified for loan repayments, and the impact of the loan repayment program on SUD treatment employees.

This section authorizes \$25 million for each of FY 2019-2028.

#### Subtitle I—Preventing Overdoses While in Emergency Rooms (POWER)

#### Sec. 7081. Program to Support Emergency Room Discharge and Care Coordination for Drug Overdose Patients

This section authorizes the Secretary of HHS to establish a program to develop protocols for discharging patients who have presented with a drug overdose and enhance the integration and coordination of care and treatment options for individuals



with SUD after discharge from an emergency room (ER).

In carrying out the program, the Secretary shall award grants (lasting at least 2 years) on a competitive basis to no more than 20 ERs. Eligible applicants are health care sites or health care site coordinators. The ERs must be capable of providing evidence-based treatment for substance use disorders, including: medication-assisted treatment (MAT); withdrawal and detoxification services; counseling; deploying on-site peer recovery specialists to help connect patients with treatment and recovery support programs; and including the provision of overdose reversal medication in discharge protocols for opioid overdose patients.

Required uses of grant funds include: (A) To establish policies and procedures that address the provision of overdose reversal medication, prescription and dispensing of medication-assisted treatment to an emergency department patient who has had a non-fatal overdose or who is at risk of a drug overdose, and the subsequent referral to evidence-based treatment upon discharge for patients who have experienced a non-fatal drug overdose or who are at risk of a drug overdose; and (B) To develop best practices for treating non-fatal drug overdoses, including with respect to care coordination and integrated care models for long term treatment and recovery options for individuals who have experienced a non-fatal drug overdose.

Allowable uses of the grant funds include: (A) To hire emergency department peer recovery specialists; counselors; therapists; social workers; or other licensed medical professionals specializing in the treatment of substance use disorder; (B) To establish integrated models of care for individuals who have experienced a non-fatal drug overdose which may include patient assessment, follow up, and transportation to treatment facilities; (C) To provide for options for increasing the availability and access of medication-assisted treatment and other evidence-based treatment for individuals with substance use disorders; and (D) To offer consultation with and referral to other supportive services that help in treatment and recovery.

Grantees shall be required to submit to the Secretary of HHS an annual report on the number of individuals treated onsite, how grant funds were used, and the effectiveness of having an onsite health care professional to administer and begin MAT. The Secretary shall submit to Congress a report on the findings of the program.

This section authorizes \$50 million for FY 2019-2023.

# Subtitle J—Alternatives to Opioids in the Emergency Department Sec. 7092. Emergency Department Alternatives to Opioids Demonstration Program

This section authorizes the Secretary of HHS to award demonstration grants to hospitals and emergency departments to develop, implement, enhance, or study alternative pain management protocols that limit the use of opioids in emergency departments. Each recipient of a grant under this section shall submit to the Secretary annual reports on the progress of the program funded through the grant. Not later than 1 year after completion of the demonstration program, the Secretary shall submit a report to the Congress on the results of the demonstration program. This section authorizes \$10 million for each of FY 2019-2021.

#### <u>Subtitle K—Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now (SCREEN)</u> Sec. 7102. Detention, Refusal, and Destruction of Drugs Offered for Importation

This section provides the FDA with stronger recall and destruction authority to disrupt the entry of counterfeit and illicit drugs through International Mail Facilities (IMFs).

#### Sec. 7103. Notification, Non-Distribution, and Recall of Adulterated or Misbranded Products

This section authorizes the Secretary of HHS, upon a determination that the use or consumption of, or exposure to, a drug may present an imminent or substantial hazard to public health, to issue an order requiring any person who distributes the drug to immediately cease distribution of the drug.

#### Sec. 7104. Single Source Pattern of Shipments Adulterated or Misbranded Drugs

If the Secretary of HHS identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer, this section authorizes the Secretary to treat all drugs being offered for import from such manufacturer, distributor, or importer as adulterated or misbranded unless otherwise demonstrated.



#### Sec. 7105. Fund to Strengthen Efforts of FDA to Combat the Opioid and Substance Use Epidemic

This section authorizes the Commissioner of Food and Drug Administration (FDA) to use \$110 million for:

- (1) Obligating contract funds beginning in fiscal year 2019 for an educational campaign that will—
  - (A) educate patients and their families to differentiate opioid medications;
  - (B) raise awareness about preferred storage and disposal methods; and
  - (C) inform patients, families, and communities about medication-assisted treatment options.
- (2) Building the FDA's presence in international mail facilities, including through—
  - (A) improvements in equipment and information technology enhancements to identify unapproved, counterfeit, or other unlawful pharmaceuticals for destruction;
  - (B) increased and improved surveillance;
  - (C) renovations at international mail facility locations; and
  - (D) the purchase of laboratory equipment.
- (3) Enhancing the identification and targeting of entities offering products and products being offered by such entities for import into the United States through review and analysis of websites, import data, and other sources of intelligence for purposes of making the best use of the Food and Drug Administration's inspection and analytical resources.
- (4) Increasing the number of staff of the Food and Drug Administration to increase the number of packages being examined, ensuring the safety of the staff undertaking such examinations, and ensuring that packages identified as illegal, counterfeit, misbranded, or adulterated are removed from commerce through available authorities, including administrative destruction.
- (5) Enhancing the Food and Drug Administration's criminal investigations resources (including full-time equivalent employees and equipment), imports surveillance, and international work.
- (6) Obtaining for the Food and Drug Administration equipment and full-time equivalent employees needed to efficiently screen and analyze products offered for import, including by building data libraries of new substances and analogues to facilitate identification and evaluation of pharmaceutical based agents and by purchasing screening technologies for use at international mail facilities.
- (7) Operating the Food and Drug Administration's forensic laboratory facility to ensure adequate laboratory space and functionality for additional work and full-time equivalent employees.

This section will sunset on September 30, 2022.

#### Sec. 7106. Consideration of Potential for Misuse and Abuse Required for Drug Approval

This section authorizes the Sec. of HHS to deny approval of a new drug application if the drug is/contains a controlled substance or is unsafe due to risk of abuse or misuse or there is insufficient information to show that the drug is safe for use.

#### <u>Subtitle L—Treatment, Education, and Community Help (TEACH) to Combat Addiction</u> Sec. 7112. Establishment of Regional Centers of Excellence in Substance Use Disorder Education

This section authorizes the Secretary of HHS to designate and support Regional Centers of Excellence in SUD Education to enhance and improve how health professionals are educated in pain management and substance use disorders through the development, evaluation, and distribution of evidence-based curriculum for health profession schools.

To be eligible to receive a cooperative agreement, an entity shall:

- (A) be an entity specified by the Secretary that offers education to students in various health professions, which may include a health system; a teaching hospital; a medical school; a certified behavioral health clinic; or any other health profession school of public health, or Cooperative Extension Program at institutions of higher education engaged in an aspect of the prevention, treatment, or recovery of substance use disorders;
- (B) be accredited by the appropriate educational accreditation body;
- (C) demonstrate an existing strategy, and have in place a plan for continuing such strategy, or a proposed strategy to implement a curriculum based on best practices for substance use disorder prevention, treatment, and recovery;
- (D) demonstrate community engagement and participation through community partners, including other health profession schools, mental health counselors, social workers, peer recovery specialists, substance use treatment programs, community health centers, physicians' offices, certified behavioral health clinics, law enforcement, and the business community; and
- (E) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.



The Secretary shall evaluate each project carried out by a Regional Center of Excellence in Substance Use Disorder Education under this section and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

This section authorizes \$4 million for each of FY 2019-2023.

#### <u>Subtitle M—Guidance from National Mental Health and Substance Use Policy Laboratory</u> Sec. 7121. Guidance from National Mental Health and Substance Use Policy Laboratory

This section authorizes the National Mental Health and Substance Use Policy Laboratory to issue and periodically update guidance for entities applying for grants from the Substance Abuse and Mental Health Services Administration (SAMHSA) in order to:

- (A) encourage the funding of evidence based practices;
- (B) encourage the replication of promising or effective practices; and
- (C) inform applicants on how to best articulate the rationale for the funding of a program or activity.

#### <u>Subtitle N—Comprehensive Opioid Recovery Centers</u> Sec. 7132. Comprehensive Opioid Recovery Centers

This section authorizes the Sec. of HHS to establish a grant program to develop at least 10 Comprehensive Opioid Recovery Centers (CORCs). Grants will last 3-5 years and may be renewed on a competitive basis. CORCs shall, at a minimum, provide, either directly or by contracting with other entities:

- Community outreach
  - Training and supervising outreach staff to work with schools, workplaces, faith-based organizations, State and local health departments, law enforcement, and first responders to ensure that such institutions are aware of the services of the Center.
  - O Disseminate and make available online evidence-based resources that educate professionals and the public on opioid use disorder and other substance use disorders.
- Intake
- Assessments
- MAT (all FDA-approved MAT medications, including methadone, to treat SUDs, including opioid and alcohol use disorders)
- Withdrawal management, including detoxification
- Counseling
- Case management
- Residential rehabilitation
- Recovery housing
- Community-based peer recovery support
- Job training and placement
- On-site pharmacy
- Establish and operate a secure and confidential electronic health information system
- Family support services (e.g. child care, family counseling, and parenting interventions)

The Centers would also conduct outreach activities, and make resources available to educate the public and professionals. This section authorizes \$10 million for each of FY 2019-2023.

#### Subtitle O—Poison Control Network Enhancement

#### Sec. 7142. Reauthorization of Poison Control Centers National Toll-Free Number

This section reauthorizes the Poison Control Centers (PCC) national toll-free number, which offers free medical advice 24/7, with the goal of serving as a resource for poisoning information and helping reduce ER visits through in-home treatment. This section calls for enhancement of communications capabilities of the PCCs, which may include text



capabilities. This section authorizes \$700,000 for each of FY 2019-2023 for the national number.

## Sec. 7143. Reauthorization of Nationwide Public Awareness Campaign to Promote Poison Control Center Utilization

This section reauthorizes a campaign carried out by the Sec. of HHS to raise awareness of poisoning and the existence of the Poison Control Centers. This section authorizes \$800,000 for each of FY 2019-2023 for the awareness campaign.

#### Sec. 7144. Reauthorization of the Poison Control Center Grant Program

This section reauthorizes the Sec. of HHS to award grants to Poison Control Centers for the purposes of: (1) preventing and providing treatment recommendations for poisonings and toxic exposures, including opioid and drug misuse; (2) assisting with public health emergencies, responses, and preparedness; and (3) complying with the operational requirements needed to sustain the accreditation of the center. This section authorizes \$28.6 million for each of FY 2019-2023 for the program.

#### Subtitle P—Eliminating Opioid Related Infectious Diseases

# Sec. 7152. Reauthorization and Expansion of Program of Surveillance and Education Regarding Infections Associated with Illicit Drug Use and Other Risk Factors

This section authorizes the Sec. of HHS to provide for (directly and through grants) programs foe the following:

- (1) To cooperate with the States and Indian tribes in implementing or maintaining a surveillance system to determine the incidence of infections commonly associated with illicit drug use, including infections commonly associated with injection drug use such as viral hepatitis, HIV, and infective endocarditis, and to assist the States in determining the prevalence of such infections.
- (2) To identify, counsel, and offer testing to individuals who are at risk of infections as a result of injection drug use, receiving blood transfusions prior to July 1992, or other risk factors.
- (3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals, and to ensure, to the extent practicable, the provision of appropriate follow-up services.
- (4) To develop and disseminate public information and education programs for the detection and control of infections.
- (5) To improve the education, training, and skills of health professionals in the detection and control of infections and the coordination of treatment of addiction and infectious diseases, with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, obstetrician-gynecologists, infectious diseases clinicians, and HIV clinicians.

This section authorizes \$40 million for each of FY 2019-2023.

#### Subtitle Q—Better Pain Management Through Better Data

Sec. 7162. Guidance Addressing Alternative Approaches to Data Collection and Labeling Claims for Opioid Sparing

This section directs the Food and Drug Administration (FDA) to articulate data collection methods that could be used to inform opioid-sparing labeling claims for products that may replace, delay, or reduce or the use of opioid analgesics.

#### Subtitle R— Special Registration for Telemedicine Clarification

# Sec. 7172. Deadline for Interim Final Regulation for a Special Registration to Engage in the Practice of Telemedicine

This section aims to clarify telemedicine waivers. 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. The waiver process has never been implemented through regulation, and some patients do not have the emergency access they need to treatment. This bill directs the Attorney General, within 1 year of enactment of this Act, to promulgate interim final regulations to implement the waiver.

# Subtitle S—Peer Support Communities of Recovery Sec. 7182. Building Communities of Recovery

This section amends the Building Communities of Recovery (BCOR) program that was first authorized in the Comprehensive Addiction and Recovery Act (CARA) of 2016 by allowing SAMHSA to award grants to nonprofits that focus on substance use disorders to establish regional technical assistance centers to provide assistance regarding



implementation of peer-delivered addiction recovery support services, and establishment of recovery community organizations and centers. This section authorizes \$15 million for each of FY 2019-2023.

#### Subtitle T—Stop Illicit Drug Importation

This subtitle amends the Federal Food, Drug, and Cosmetic Act to strengthen the Food and Drug Administration's (FDA) seizure powers and enhance its authority to detain, refuse, seize, or destroy illegal products offered for import.

# Subtitle U—Creating Opportunities that Necessitate New and Enhanced Connections that Improve Opioid Navigation Strategies

#### Sec. 7202. Preventing Overdoses of Controlled Substances

This section authorizes the Director of the CDC to carry out certain controlled substances overdose prevention and surveillance activities in order to improve data collection and integration into physician clinical workflow so that timely, complete, and accurate information will get into the hands of providers and dispensers so that they can make the best clinical decisions for their patients. This section authorizes \$486 million for each of FY 2019-2023.

#### Sec. 7203. Prescription Drug Monitoring Program

This section amends the Public Health Service Act's Prescription Drug Monitoring Program (PDMP). Each fiscal year, the Secretary of HHS, in consultation with the Director of the Office of National Drug Control Policy (ONDCP), acting through the Director of the Centers for Disease Control and Prevention (CDC), the Assistant Secretary for Mental Health and Substance Use, and the National Coordinator for Health Information Technology, shall support States for the purpose of improving the efficiency and use of PDMPs, including establishment of, maintenance of, and improvements to a PDMP. States must demonstrate that they have enacted legislation or regulations to provide for the implementation of the PDMP; and to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

The Secretary shall encourage a State to implement strategies that improve the reporting of dispensing in the State of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event; the consultation of the PDMP by each prescribing practitioner, or their designee, in the State before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event; the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP; the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected; the availability of data in the PDMP to other States, as allowable under State law; and the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

A State receiving support under this section shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances; and may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance.

A State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner requests information about a patient. A State shall also provide the Secretary with aggregate nonidentifiable data.

# <u>Subtitle V—Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging</u> Sec. 7212. Improved Technologies, Controls, or Measures with Respect to the Packaging or Disposal of Certain Drugs

This section directs the FDA to work with manufacturers to establish programs for efficient return or destruction of unused Schedule II drugs, with an emphasis on opioids. These methods could include mail-back pouches to secure facilities for



incineration, or methods to immediately inactivate/render unattractive unused drugs. In addition, this bill will facilitate utilization of packaging that may reduce overprescribing of opioids. Finally, this bill will require the Government Accountability Office (GAO) to study new and innovative technologies that claim to be able to safely dispose of opioids and other unused medications. GAO would review and detail the effectiveness of these disposal methods.

#### <u>Subtitle W—Postapproval Study Requirements</u> Sec. 7221. Postapproval Study Requirements

This section aims to enhance the FDA's authorities and enforcement tools to ensure timely post-marketing studies for chronically administered opioids.

#### **TITLE VII—Miscellaneous**

#### Subtitle A—Synthetics Trafficking and Overdose Prevention

This subtitle amends the Tariff Act of 1930 to make the Postmaster General the consignee (i.e., the entity financially responsible for the receipt of a shipment) for merchandise, excluding documents, imported through the mail into the United States. The Postmaster General must designate licensed customs brokers to file required documents or information for such shipments.

The subtitle amends the Consolidated Omnibus Budget Reconciliation Act of 1985 to impose a customs user fee on postal shipments or any other item valued at \$2,000 or less arriving at an international mail facility.

The subtitle amends the Trade Act of 2002 to direct the Department of the Treasury to require the Postmaster General to provide for the advanced electronic transmission to the U.S. Customs and Border Protection of certain information for all postal shipments made by the U.S. Postal Service (USPS), including postal shipments it receives from foreign postal operators.

#### The Postmaster General:

- shall be liable for civil penalties for postal shipment violations committed by a foreign postal operator or the USPS;
- may be directly or indirectly responsible for discrepancies resulting from omissions made or false information provided by a foreign postal operator or the USPS; and
- shall ensure that all costs and penalties associated with complying with this bill are recouped from foreign shippers, foreign postal operators, or U.S. ultimate consignees.

#### <u>Subtitle B—Recognizing Early Childhood Trauma Related to Substance Abuse</u> Sec. 8012. Recognizing Early Childhood Trauma Related to Substance Abuse

This section calls for the Sec. of HHS to disseminate information, resources, and technical assistance to early child care and education providers and professionals working with young children on: (1) ways to properly recognize children who may be impacted by trauma related to substance abuse by a family member or other adult; and (2) how to respond appropriately in order to provide for the safety and well-being of young children and their families.

The information, resources, and technical assistance shall:

- (1) educate early childhood care and education providers and professionals working with young children on understanding and identifying the early signs and risk factors of children who might be impacted by trauma due to exposure to substance abuse;
- (2) suggest age-appropriate communication tools, procedures, and practices for trauma-informed care, including ways to prevent or mitigate the effects of trauma;
- (3) provide options for responding to children impacted by trauma due to exposure to substance abuse that consider the needs of the child and family, including recommending resources and referrals for evidence-based services to support such family; and
- (4) promote whole-family and multi-generational approaches to prevent separation and support re-unification of families whenever possible and in the best interest of the child.

<u>Subtitle C—Assisting States with Implementation of Plans of Safe Care</u> Sec. 8022. Assisting States with Implementation of Plans of Safe Care



This section requires the Sec. of HHS to provide written guidance and technical assistance to support States in complying with and implementing the Child Abuse Prevention and Treatment Act (CAPTA) in order to promote better protections for young children and family-centered responses. The guidance and technical assistance shall—

- (1) enhance States' understanding of requirements and flexibilities under the law, including clarifying key terms;
- (2) address State-identified challenges with developing, implementing, and monitoring plans of safe care;
- (3) disseminate best practices related to developing and implementing plans of safe care, including differential response, collaboration and coordination, and identification and delivery of services, while recognizing needs of different populations and varying community approaches across States;
- (4) support collaboration between health care providers, social service agencies, public health agencies, and the child welfare system, to promote a family-centered treatment approach;
- (5) prevent separation and support reunification of families if in the best interests of the child;
- (6) recommend treatment approaches for serving infants, pregnant women, and postpartum women whose infants may be affected by substance use that are designed to keep infants with their mothers and families whenever appropriate, including recommendations to encourage pregnant women to receive health and other support services during pregnancy;
- (7) support State efforts to develop technology systems to manage and monitor implementation of plans of safe care; and
- (8) help States improve the long-term safety and well-being of young children and their families.

# <u>Subtitle D—Improving the Federal Response to Families Impacted by Substance Use Disorder</u> Sec. 8032. Interagency Task Force to Improve the Federal Response to Families Impacted by Substance Use Disorders

This section establishes an Interagency Task Force to Improve the Federal Response to Families Impacted by Substance Use Disorders. The Task Force will identify, evaluate, and recommend ways in which Federal agencies can better coordinate responses to substance use disorders and the opioid crisis. The Task Force shall be composed of 12 Federal officials having responsibility for, or administering programs related to, the duties of the Task Force. The Secretary of Health and Human Services, the Secretary of Education, the Secretary of Agriculture, and the Secretary of Labor shall each appoint two members to the Task Force from among the Federal officials employed by the Department of which they are the head. Additional Federal agency officials appointed by the Secretary of Health and Human Services shall fill the remaining positions of the Task Force.

#### The Task Force shall:

- (1) Solicit input from stakeholders, including frontline service providers, medical professionals, educators, mental health professionals, researchers, experts in infant, child, and youth trauma, child welfare professionals, and the public, in order to inform the activities of the Task Force.
- (2) Develop a strategy on how the Task Force and participating Federal agencies will collaborate, prioritize, and implement a coordinated Federal approach with regard to responding to substance use disorders, including opioid misuse.
- (3) Based off the strategy developed under number (2), evaluate and recommend opportunities for local- and Statelevel partnerships, professional development, or best practices.
- (4) In fulfilling the requirements of numbers (2) and (3), consider evidence-based, evidence-informed, and promising best practices related to identifying, referring, and supporting children and families at risk of experiencing exposure to substance abuse or experiencing substance use disorder, including opioid misuse.

The Task Force shall prepare a detailed action plan to be implemented by participating Federal agencies to create a collaborative, coordinated response to the opioid crisis, and shall disseminate the action plan to Congress, Governors, and the public.

#### <u>Subtitle E—Establishment of an Advisory Committee on Opioids and the Workplace</u> Sec. 8041. Establishment of an Advisory Committee on Opioids and the Workplace

This section requires the Secretary of Labor to establish an Advisory Committee on Opioids and the Workplace to advise the Secretary on actions the Department of Labor can take to provide informational resources and best practices on how to appropriately address the impact of opioid abuse on the workplace and support workers abusing opioids.



The Secretary of Labor shall appoint 19 individuals with expertise in employment, workplace health programs, human resources, substance use disorder, and other relevant fields to be members:

- (A) Four of the members shall be individuals representative of employers or other organizations representing employers.
- (B) Four of the members shall be individuals representative of workers or other organizations representing workers, of which at least two must be representatives designated by labor organizations.
- (C) Three of the members shall be individuals representative of health benefit plans, employee assistance plan providers, workers' compensation program administrators, and workplace safety and health professionals.
- (D) Eight of the members shall be individuals representative of substance abuse treatment and recovery experts, including medical doctors, licensed addiction therapists, and scientific and academic researchers, of which one individual may be a representative of a local or State government agency that oversees or coordinates programs that address substance use disorders.

Prior to its termination (3 years after enactment of this Act), the Advisory Committee shall issue a report to the Secretary of Labor and to the Committee on Education and the Workforce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions (HELP) of the Senate, detailing successful programs and policies involving workplace resources and benefits, including recommendations or examples of best practices for how employers can support and respond to employees impacted by opioid addiction.

#### Subtitle F—Veterans Treatment Court Improvement

#### Sec. 8051. Hiring by Department of Veterans Affairs of Additional Veterans Justice Outreach Specialists

This section requires the Secretary of Veterans Affairs to hire at least 50 Veterans Justice Outreach Specialists and place each Specialist at an eligible Department of Veterans Affairs medical center.

#### <u>Subtitle G—Peer Support Counseling Program for Women Veterans</u> Sec. 8061. Peer Support Counseling Program for Women Veterans

This section calls for the Secretary of the VA to emphasize appointing peer support counselors for women veterans, and to recruit female peer support counselors who have expertise in gender-specific issues and services, the provision of information about services and benefits provided under laws administered by the VA, and employment mentoring.

#### Subtitle H—Treating Barriers to Prosperity

This subtitle allows the Appalachian Regional Commission to support projects and activities addressing substance use, including opioid use. Projects and activities may include those that:

- facilitate the sharing of best practices among states, counties, and other experts in the region with respect to reducing drug abuse;
- initiate or expand programs designed to eliminate or reduce the harm to the workforce and economic growth of the region that results from drug abuse;
- attract and retain relevant health care services, businesses, and workers; and
- develop relevant infrastructure, including broadband infrastructure that supports the use of telemedicine.

#### Subtitle I—Supporting Grandparents Raising Grandchildren

This subtitle establishes an Advisory Council to Support Grandparents Raising Grandchildren. The Advisory Council shall be composed of the following members, or their designee:

- (A) The Secretary of Health and Human Services (lead agency).
- (B) The Secretary of Education.
- (C) The Administrator of the Administration for Community Living.
- (D) The Director of the Centers for Disease Control and Prevention (CDC).
- (E) The Assistant Secretary for Mental Health and Substance Use.
- (F) The Assistant Secretary for the Administration for Children and Families (ACF).
- (G) A grandparent raising a grandchild.
- (H) An older relative caregiver of children.
- (I) As appropriate, the head of other Federal departments, or agencies, identified by the Secretary of HHS as having responsibilities, or administering programs, relating to current issues affecting grandparents or other older relatives raising children.



The Council shall identify, promote, coordinate, and publicly disseminate information and resources to help grandparents or other relatives meet the needs of the children in their care and maintain their own health and emotional well-being. The task force terminates after three years.

#### Subtitle I—Reauthorizing and Extending Grants for Recovery from Opioid Use Programs

This section reauthorizes the Comprehensive Opioid Abuse Program (COAP), which was last authorized in the Comprehensive Addiction and Recovery Act (CARA) of 2016. This section authorizes \$330 million for each of FY 2019-2023.

#### TITLE IX—SITSA (Stop the Importation and Trafficking of Synthetic Analogues)

This title creates a new schedule—schedule A—to add to the list of banned substances on the Controlled Substances Act. Schedule A drugs are defined as having: (I) a chemical structure that is substantially similar to the chemical structure of a controlled substance in schedule I, II, III, IV, or V; and (II) an actual or predicted stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I, II, III, IV, or V. Schedule A substances are not: (I) listed or otherwise included in any other schedule in this section or by regulation of the Attorney General.

This title also creates a process by which substances can be added—whether temporarily or permanently—in as little as 30 days after first being identified, rather than the years it can potentially take under current law. The the bill creates penalties for trafficking and distribution of Schedule A drugs, but does not criminalize possession of the drugs.

#### TITLE X—THRIVE (Transitional Housing for Recovery in Viable Environments) Act

This title authorizes the Sec. of Housing and Urban Development (HUD) to establish a demonstration program to set aside Section 8 housing vouchers for supportive and transitional housing for individuals recovering from substance use disorders. This bill would set aside, 10,000 vouchers or .05 percent of all vouchers for use in the five-year demonstration. Eligible voucher recipients would participate in programs that provide evidence-based treatment and workforce development training according to standards established by the HUD Secretary, in consultation with other relevant agencies.

# TITLE X—Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Execution (IMD CARE) Act

This title temporarily (from January 1, 2019 through December 31, 2023) allows States to apply to receive federal Medicaid payment for services provided in institutions for mental diseases (IMDs) and for other medically necessary services for enrollees (aged 21 to 64) with opioid or cocaine use disorders. Services may be covered for a total of up to 30 days in a 12-month period for an eligible enrollee. States must include specified information in their applications, including plans to improve access to outpatient care.