JUNE 18, 2018

**RULES COMMITTEE PRINT 115–78**

**TEXT OF AMENDMENT TO H.R. 6**

Add at the end the following:

# 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.

Section 1139B of the Social Security Act (42 U.S.C. 1320b–9b) is amended—

(1) in subsection (b)—

(A) in paragraph (3)—

(i) by striking ''Not later than January 1, 2013'' and inserting the following:

''(A) VOLUNTARY REPORTING.—Not later than January 1, 2013''; and

(ii) by adding at the end the following:

''(B) MANDATORY REPORTING WITH RESPECT TO BEHAVIORAL HEALTH MEASURES.—

Beginning with the State report required under subsection (d)(1) for 2024, the Secretary shall require States to use all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures to report information, using the standardized format for reporting information and procedures developed under subparagraph (A), regarding the quality of behavioral health care for Medicaid eligible adults.''; and

(B) in paragraph (5), by adding at the end the following new subparagraph:

''(C) BEHAVIORAL HEALTH MEASURES.—Beginning with respect to State reports required under subsection (d)(1) for 2024, the core set of adult health quality measures maintained under this paragraph (and any updates or changes to such measures) shall include behavioral health measures.''; and

(2) in subsection (d)(1)(A)—

(A) by striking ''the such plan'' and inserting ''such plan''; and

(B) by striking ''subsection (a)(5)'' and inserting ''subsection (b)(5) and, beginning with the report for 2024, all behavioral health meas-

ures included in the core set of adult health quality measures maintained under such subsection (b)(5) and any updates or changes to such measures (as required under subsection (b)(3))''.

# Subtitle B—Medicaid IMD Additional Info

**SEC. 5011. SHORT TITLE.**

This subtitle may be cited as the ''Medicaid Institutes for Mental Disease Are Decisive in Delivering Inpatient Treatment for Individuals but Opportunities for Needed Access are Limited without Information Needed about Facility Obligations Act'' or the ''Medicaid IMD ADDITIONAL INFO Act''.

**SEC. 5012. MACPAC EXPLORATORY STUDY AND REPORT ON INSTITUTIONS FOR MENTAL DISEASES REQUIREMENTS AND PRACTICES UNDER MEDICAID.**

(a) IN GENERAL.—Not later than January 1, 2020, the Medicaid and CHIP Payment and Access Commission established under section 1900 of the Social Security Act (42 U.S.C. 1396) shall conduct an exploratory study, using data from a representative sample of States, and submit to Congress a report on at least the following information, with respect to services furnished to individuals

enrolled under State plans under the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.) (or waivers of such plans) who are patients in institutions for mental diseases and for which payment is made through fee-for-service or managed care arrangements under such State plans (or waivers):

(1) A description of such institutions for mental diseases in each such State, including at a minimum—

(A) the number of such institutions in the State;

(B) the facility type of such institutions in the State; and

(C) any coverage limitations under each such State plan (or waiver) on scope, duration, or frequency of such services.

(2) With respect to each such institution for mental diseases in each such State, a description of—

(A) such services provided at such institution;

(B) the process, including any timeframe, used by such institution to clinically assess and reassess such individuals; and

(C) the discharge process used by such institution, including any care continuum of relevant services or facilities provided or used in such process.

(3) A description of—

(A) any Federal waiver that each such State has for such institutions and the Federal statutory authority for such waiver; and

(B) any other Medicaid funding sources used by each such State for funding such institutions, such as supplemental payments.

(4) A summary of State requirements (such as certification, licensure, and accreditation) applied by each such State to such institutions in order for such institutions to receive payment under the State plan (or waiver) and how each such State determines if such requirements have been met.

(5) A summary of State standards (such as quality standards, clinical standards, and facility standards) that such institutions must meet to receive payment under such State plans (or waivers) and how each such State determines if such standards have been met.

(6) Recommendations for actions by Congress and the Centers for Medicare & Medicaid Services.

such as how State Medicaid programs may improve care and improve standards and including a recommendation for how the Centers for Medicare & Medicaid Services can improve data collection from such programs to address any gaps in information.

(b) STAKEHOLDER INPUT.—In carrying out subsection (a), the Medicaid and CHIP Payment and Access Commission shall seek input from State Medicaid directors and stakeholders, including at a minimum the Substance Abuse and Mental Health Services Administration, Centers for Medicare & Medicaid Services, State Medicaid officials, State mental health authorities, Medicaid beneficiary advocates, health care providers, and Medicaid managed care organizations.

(c) DEFINITIONS.—In this section:

(1) REPRESENTATIVE SAMPLE OF STATES.—The term ''representative sample of States'' means a non-probability sample in which at least two States are selected based on the knowledge and professional judgment of the selector.

(2) STATE.—The term ''State'' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(3) INSTITUTION FOR MENTAL DISEASES.—The term ''institution for mental diseases'' has the mean-

ing given such term in section 435.1009 of title 42, Code of Federal Regulations, or any successor regulation.

# Subtitle C—CHIP Mental Health Parity

**SEC. 5021. SHORT TITLE.**

This subtitle may be cited as the ''CHIP Mental Health Parity Act''.

**SEC. 5022. ENSURING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES FOR CHILDREN AND PREGNANT WOMEN UNDER THE CHILDREN'S HEALTH INSURANCE PROGRAM.**

(a) IN GENERAL.—Section 2103(c)(1) of the Social Security Act (42 U.S.C. 1397cc(c)(1)) is amended by adding at the end the following new subparagraph:

''(E) Mental health and substance use disorder services (as defined in paragraph (5)).''.

(b) MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES.—

(1) IN GENERAL.—Section 2103(c) of the Social Security Act (42 U.S.C. 1397cc(c)) is amended—

(A) by redesignating paragraphs (5), (6), (7), and (8) as paragraphs (6), (7), (8), and (9), respectively; and

(B) by inserting after paragraph (4) the following new paragraph:

''(5) MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES.—Regardless of the type of coverage elected by a State under subsection (a), child health assistance provided under such coverage for targeted low-income children and, in the case that the State elects to provide pregnancy-related assistance under such coverage pursuant to section 2112, such pregnancy-related assistance for targeted low-income women (as defined in section 2112(d)) shall—

''(A) include coverage of mental health services (including behavioral health treatment) necessary to prevent, diagnose, and treat a broad range of mental health symptoms and disorders, including substance use disorders; and

''(B) be delivered in a culturally and linguistically appropriate manner.''.

(2) CONFORMING AMENDMENTS.—

(A) Section 2103(a) of the Social Security Act (42 U.S.C. 1397cc(a)) is amended, in the matter before paragraph (1), by striking ''paragraphs (5), (6), and (7)'' and inserting ''paragraphs (5), (6), (7), and (8)''.

(B) Section 2110(a) of the Social Security Act (42 U.S.C. 1397jj(a)) is amended—

(i) in paragraph (18), by striking ''substance abuse'' each place it appears and inserting ''substance use''; and

(ii) in paragraph (19), by striking ''substance abuse'' and inserting ''substance use''.

(C) Section 2110(b)(5)(A)(i) of the Social Security Act (42 U.S.C. 1397jj(b)(5)(A)(i)) is amended by striking ''subsection (c)(5)'' and inserting ''subsection (c)(6)''.

(c) ASSURING ACCESS TO CARE.—Section 2102(a)(7)(B) of the Social Security Act (42 U.S.C. 1397bb(c)(2)) is amended by striking ''section 2103(c)(5)'' and inserting ''paragraphs (5) and (6) of section 2103(c)''.

(d) MENTAL HEALTH SERVICES PARITY.—Subparagraph (A) of paragraph (7) of section 2103(c) of the So-

cial Security Act (42 U.S.C. 1397cc(c)) (as redesignated by subsection (b)(1)) is amended to read as follows:

''(A) IN GENERAL.—A State child health plan shall ensure that the financial requirements and treatment limitations applicable to mental health and substance use disorder services (as described in paragraph (5)) provided under such plan comply with the requirements of section 2726(a) of the Public Health Service Act in the same manner as such requirements or limitations apply to a group health plan under such section.''.

(e) EFFECTIVE DATE.—

(1) IN GENERAL.—Subject to paragraph (2), the amendments made by this section shall take effect with respect to child health assistance provided on or after the date that is one year after the date of the enactment of this Act.

(2) EXCEPTION FOR STATE LEGISLATION.—In the case of a State child health plan under title XXI of the Social Security Act (or a waiver of such plan), which the Secretary of Health and Human Services determines requires State legislation in order for the respective plan (or waiver) to meet any requirement imposed by the amendments made by this section,

the respective plan (or waiver) shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this section. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

# Subtitle D—Medicaid Reentry

**SEC. 5031. SHORT TITLE.**

This subtitle may be cited as the ''Medicaid Reentry Act''.

**SEC. 5032. PROMOTING STATE INNOVATIONS TO EASE TRANSITIONS INTEGRATION TO THE COMMUNITY FOR CERTAIN INDIVIDUALS.**

(a) STAKEHOLDER GROUP DEVELOPMENT OF BEST PRACTICES; STATE MEDICAID PROGRAM INNOVATION.—

(1) STAKEHOLDER GROUP BEST PRACTICES.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a stakeholder group of representatives of managed care organizations,

Medicaid beneficiaries, health care providers, the National Association of Medicaid Directors, and other relevant representatives from local, State, and Federal jail and prison systems to develop best practices (and submit to the Secretary and Congress a report on such best practices) for States—

(A) to ease the health care-related transition of an individual who is an inmate of a public institution from the public institution to the community, including best practices for ensuring continuity of health insurance coverage or coverage under the State Medicaid plan under title XIX of the Social Security Act, as applicable, and relevant social services; and

(B) to carry out, with respect to such an individual, such health care-related transition not later than 30 days after such individual is released from the public institution.

(2) STATE MEDICAID PROGRAM INNOVATION.—The Secretary of Health and Human Services shall work with States on innovative strategies to help individuals who are inmates of public institutions and otherwise eligible for medical assistance under the Medicaid program under title XIX of the Social Security Act transition, with respect to enrollment for

medical assistance under such program, seamlessly to the community.

(b) GUIDANCE ON INNOVATIVE SERVICE DELIVERY SYSTEMS DEMONSTRATION PROJECT OPPORTUNITIES.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, through the Administrator of the Centers for Medicare & Medicaid Services, shall issue a State Medicaid Director letter, based on best practices developed under subsection (a)(1), regarding opportunities to design demonstration projects under section 1115 of the Social Security Act (42 U.S.C. 1315) to improve care transitions for certain individuals who are soon-to-be former inmates of a public institution and who are otherwise eligible to receive medical assistance under title XIX of such Act, including systems for, with respect to a period (not to exceed 30 days) immediately prior to the day on which such individuals are expected to be released from such institution—

(1) providing assistance and education for enrollment under a State plan under the Medicaid program under title XIX of such Act for such individuals during such period; and

(2) providing health care services for such individuals during such period.

(c) RULE OF CONSTRUCTION.—Nothing under title XIX of the Social Security Act or any other provision of law precludes a State from reclassifying or suspending (rather than terminating) eligibility of an individual for medical assistance under title XIX of the Social Security Act while such individual is an inmate of a public institution.

# Subtitle E—Medicaid Partnership

**SEC. 5041. SHORT TITLE.**

This subtitle may be cited as the ''Medicaid Providers Are Required To Note Experiences in Record Systems to Help In-need Patients Act'' or the ''Medicaid PARTNERSHIP Act''.

**SEC. 5042. MEDICAID PROVIDERS ARE REQUIRED TO NOTE EXPERIENCES IN RECORD SYSTEMS TO HELP IN-NEED PATIENTS.**

(a) REQUIREMENTS UNDER THE MEDICAID PROGRAM RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS AND PRESCRIBING CERTAIN CONTROLLED SUBSTANCES.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1943 the following new section:

**"SEC. 1944. REQUIREMENTS RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS AND PRESCRIBING CERTAIN CONTROLLED SUBSTANCES.**

"(a) IN GENERAL.—Beginning October 1, 2021, a State shall, subject to subsection (d), require each covered provider to check, in accordance with such timing, manner, and form as specified by the State, the prescription drug history of a covered individual being treated by the covered provider through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance.

"(b) QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAM DESCRIBED.—A qualified prescription drug monitoring program described in this subsection is, with respect to a State, a prescription drug monitoring program administered by the State that, at a minimum, satisfies each of the following criteria:

"(1) The program facilitates access by a covered provider to, at a minimum, the following information with respect to a covered individual, in as close to real-time as possible:

"(A) Information regarding the prescription drug history of a covered individual with respect to controlled substances.

''(B) The number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period.

''(C) The name, location, and contact information (or other identifying number selected by the State, such as a national provider identifier issued by the National Plan and Provider Enumeration System of the Centers for Medicare & Medicaid Services) of each covered provider who prescribed a controlled substance to the covered individual during at least the most recent 12-month period.

''(2) The program facilitates the integration of information described in paragraph (1) into the workflow of a covered provider, which may include the electronic system the covered provider uses to prescribe controlled substances.

A qualified prescription drug monitoring program described in this subsection, with respect to a State, may have in place, in accordance with applicable State and Federal law, a data sharing agreement with the State Medicaid program that allows the medical director and pharmacy director of such program (and any designee of such a director who reports directly to such director) to

access the information described in paragraph (1) in an electronic format. The State Medicaid program under this title may facilitate reasonable and limited access, as determined by the State and ensuring documented beneficiary protections regarding the use of such data, to such qualified prescription drug monitoring program for the medical director or pharmacy director of any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under section 1903(m) or under section 1905(t)(3), or the medical director or pharmacy director of any entity has a contract to manage the pharmaceutical benefit with respect to individuals enrolled in the State plan (or waiver of the State plan). All applicable State and Federal security and privacy laws shall apply to the directors or designees of such directors of any State Medicaid program or entity accessing a qualified prescription drug monitoring program under this section.

''(c) APPLICATION OF PRIVACY RULES CLARIFICATION.—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subsection (b) in the same manner as the Secretary is required under subparagraph (J) of section 1860D–4(c)(5) to clarify pri-

vacy requirements related to the sharing of data described in such subparagraph.

''(d) ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary shall waive the application of the requirement under subsection (a), with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).

''(e) REPORTS.—

''(1) STATE REPORTS.—Each State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D), beginning with such reports submitted for 2023, information including, at a minimum, the following information for the most recent 12-month period:

''(A) The percentage of covered providers (as determined pursuant to a process established by the State) who checked the prescription drug history of a covered individual through a qualified prescription drug monitoring program described in subsection (b) before prescribing to such individual a controlled substance.

''(B) Aggregate trends with respect to prescribing controlled substances such as—

''(i) the quantity of daily morphine milligram equivalents prescribed for controlled substances;

''(ii) the number and quantity of daily morphine milligram equivalents prescribed for controlled substances per covered individual; and

''(iii) the types of controlled substances prescribed, including the dates of such prescriptions, the supplies authorized (including the duration of such supplies), and the period of validity of such prescriptions, in different populations (such as individuals who are elderly, individuals with disabilities, and individuals who are enrolled under both this title and title XVIII).

''(C) Whether or not the State requires (and a detailed explanation as to why the State does or does not require) pharmacists to check the prescription drug history of a covered individual through a qualified drug management

program before dispensing a controlled substance to such individual.

''(2) REPORT BY CMS.—Not later than October 1, 2023, the Administrator of the Centers for Medicare & Medicaid Services shall publish on the publicly available website of the Centers for Medicare & Medicaid Services a report including the following information:

''(A) Guidance for States on how States can increase the percentage of covered providers who use qualified prescription drug monitoring programs described in subsection (b).

''(B) Best practices for how States and covered providers should use such qualified prescription drug monitoring programs to reduce the occurrence of abuse of controlled substances.

''(f) INCREASE TO FEDERAL MATCHING RATE FOR CERTAIN EXPENDITURES RELATING TO QUALIFIED PRESCRIPTION DRUG MANAGEMENT PROGRAMS.—The Secretary shall increase the Federal medical assistance percentage or Federal matching rate that would otherwise apply to a State under section 1903(a) for a calendar quarter occurring during the period beginning October 1, 2018, and ending September 30, 2021, for expenditures

by the State for activities under the State plan (or waiver of the State plan) to implement a prescription drug management program that satisfies the criteria described in paragraphs (1) and (2) of subsection (b) if the State (in this subsection referred to as the 'administering State') has in place agreements with all States that are contiguous to such administering State that, when combined, enable covered providers in all such contiguous States to access, through the prescription drug management program, the information that is described in subsection (b)(1) of covered individuals of such administering State and that covered providers in such administering State are able to access through such program. In no case shall an increase under this subsection result in a Federal medical assistance percentage or Federal matching rate that exceeds 100 percent.

''(g) RULE OF CONSTRUCTION.—Nothing in this section prevents a State from requiring pharmacists to check the prescription drug history of covered individuals through a qualified drug management program before dispensing controlled substances to such individuals.

''(h) DEFINITIONS.—In this section:

''(1) CONTROLLED SUBSTANCE.—The term 'controlled substance' means a drug that is included in schedule II of section 202(c) of the Controlled

Substances Act and, at the option of the State involved, a drug included in schedule III or IV of such section.

''(2) COVERED INDIVIDUAL.—The term 'covered individual' means, with respect to a State, an individual who is enrolled in the State plan (or under a waiver of such plan). Such term does not include an individual who—

''(A) is receiving—

''(i) hospice or palliative care; or

''(ii) treatment for cancer;

''(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

''(C) the State elects to treat as exempted from such term.

''(3) COVERED PROVIDER.—

''(A) IN GENERAL.—The term 'covered provider' means, subject to subparagraph (B), with respect to a State, a health care provider who is participating under the State plan (or waiver of the State plan) and licensed, registered, or otherwise permitted by the State to

prescribe a controlled substance (or the designee of such provider).

''(B) EXCEPTIONS.—

''(i) IN GENERAL.—Beginning October 1, 2021, for purposes of this section, such term does not include a health care provider included in any type of health care provider determined by the Secretary to be exempt from application of this section under clause (ii).

''(ii) EXCEPTIONS PROCESS.—Not later than October 1, 2020, the Secretary, after consultation with the National Association of Medicaid Directors, national health care provider associations, Medicaid beneficiary advocates, and advocates for individuals with rare diseases, shall determine, based on such consultations, the types of health care providers (if any) that should be exempted from the definition of the term 'covered provider' for purposes of this section.''.

(b) GUIDANCE.—Not later than October 1, 2019, the Administrator of the Centers for Medicare & Medicaid Services, in consultation with the Director of the Centers

for Disease Control and Prevention, shall issue guidance on best practices on the uses of prescription drug monitoring programs required of prescribers and on protecting the privacy of Medicaid beneficiary information maintained in and accessed through prescription drug monitoring programs.

(c) DEVELOPMENT OF MODEL STATE PRACTICES.—

(1) IN GENERAL.—Not later than October 1, 2020, the Secretary of Health and Human Services shall develop and publish model practices to assist State Medicaid program operations in identifying and implementing strategies to utilize data sharing agreements described in the matter following paragraph (2) of section 1944(b) of the Social Security Act, as added by subsection (a), for the following purposes:

(A) Monitoring and preventing fraud, waste, and abuse.

(B) Improving health care for individuals enrolled in a State plan under title XIX of such Act (or waiver of such plan) who—

(i) transition in and out of coverage under such title;

(ii) may have sources of health care coverage in addition to coverage under such title; or

(iii) pay for prescription drugs with cash.

(C) Any other purposes specified by the Secretary.

(2) ELEMENTS OF MODEL PRACTICES.—The model practices described in paragraph (1)—

(A) shall include strategies for assisting States in allowing the medical director or pharmacy director (or designees of such a director) of managed care organizations or pharmaceutical benefit managers to access information with respect to all covered individuals served by such managed care organizations or pharmaceutical benefit managers to access as a single data set, in an electronic format; and

(B) shall include any appropriate beneficiary protections and privacy guidelines.

(3) CONSULTATION.—In developing model practices under this subsection, the Secretary shall consult with the National Association of Medicaid Directors, managed care entities (as defined in section 1932(a)(1)(B) of the Social Security Act) with con-

tracts with States pursuant to section 1903(m) of such Act, pharmaceutical benefit managers, physicians and other health care providers, beneficiary advocates, and individuals with expertise in health care technology related to prescription drug monitoring programs and electronic health records.

(d) REPORT BY COMPTROLLER GENERAL.—Not later than October 1, 2020, the Comptroller General of the United States shall issue a report examining the operation of prescription drug monitoring programs administered by States, including data security and access standards used by such programs.

# 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.

Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the end the following new clause:

"(xxv) Providing, for the adoption and use of certified EHR technology (as defined in section 1848(o)(4)) to improve the quality and coordination of care through the electronic documentation and exchange of health information, incentive payments to behavioral health providers (such as psychiatric hospitals (as defined in section 1861(f)), community mental health centers (as defined in section 1861(ff)(3)(B)), hospitals that participate in a State plan

under title XIX or a waiver of such plan, treatment facilities that participate in such a State plan or such a waiver, mental health or substance use disorder providers that participate in such a State plan or such a waiver, clinical psychologists (as defined in section 1861(ii)), nurse practitioners (as defined in section 1861(aa)(5)) with respect to the provision of psychiatric services, and clinical social workers (as defined in section 1861(hh)(1))).''.

# Subtitle B—Abuse Deterrent Access

**SEC. 6011. SHORT TITLE.**

This subtitle may be cited at the ''Abuse Deterrent Access Act of 2018''.

**SEC. 6012. STUDY ON ABUSE-DETERRENT OPIOID FORMULATIONS ACCESS BARRIERS UNDER MEDICARE.**

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall conduct a study and submit to Congress a report on the adequacy of access to abuse-deterrent opioid formulations for individuals with chronic pain enrolled in an MA–PD plan under part C of title XVIII of the Social Security Act or a prescription drug

plan under part D of such title of such Act, taking into account any barriers preventing such individuals from accessing such formulations under such MA–PD or part D plans, such as cost-sharing tiers, fail-first requirements, the price of such formulations, and prior authorization requirements.

(b) DEFINITION OF ABUSE-DETERRENT OPIOID FORMULATION.—In this section, the term ''abuse-deterrent opioid formulation'' means an opioid that is a prodrug or that has certain abuse-deterrent properties, such as physical or chemical barriers, agonist or antagonist combinations, aversion properties, delivery system mechanisms, or other features designed to prevent abuse of such opioid.

# Subtitle C—Medicare Opioid Safety Education

**SEC. 6021. SHORT TITLE.**

This subtitle may be cited as the ''Medicare Opioid Safety Education Act of 2018''.

**SEC. 6022. PROVISION OF INFORMATION REGARDING OPIOID USE AND PAIN MANAGEMENT AS PART OF MEDICARE & YOU HANDBOOK.**

(a) IN GENERAL.—Section 1804 of the Social Security Act (42 U.S.C. 1395b–2) is amended by adding at the end the following new subsection:

''(d) The notice provided under subsection (a) shall include—

''(1) educational resources, compiled by the Secretary, regarding opioid use and pain management; and

''(2) a description of alternative, non-opioid pain management treatments covered under this title.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to notices distributed prior to each Medicare open enrollment period beginning after January 1, 2019.

# Subtitle D—Opioid Addiction Action Plan

**SEC. 6031. SHORT TITLE.**

This subtitle may be cited as the ''Opioid Addiction Action Plan Act''.

**SEC. 6032. ACTION PLAN ON RECOMMENDATIONS FOR CHANGES UNDER MEDICARE AND MEDICAID TO PREVENT OPIOIDS ADDICTIONS AND ENHANCE ACCESS TO MEDICATION-ASSISTED TREATMENT.**

(a) IN GENERAL.—Not later than January 1, 2019, the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), in collaboration with

the Pain Management Best Practices Inter-Agency Task Force convened under section 101(b) of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), shall develop an action plan that provides recommendations described in subsection (b).

(b) ACTION PLAN COMPONENTS.—Recommendations described in this subsection are, based on an examination by the Secretary of potential obstacles to an effective response to the opioid crisis, recommendations, as determined appropriate by the Secretary, on the following:

(1) Recommendations on changes to the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act that would enhance coverage and payment under such programs of all medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid addiction and other therapies that manage chronic and acute pain and treat and minimize risk of opioid addiction, including recommendations on changes to the Medicare prospective payment system for hospital inpatient department services under section 1886(d) of such Act (42 U.S.C. 1395ww(d)) and the Medicare prospective payment system for hospital outpatient department services under section 1833(t) of such

Act (42 U.S.C. 1395l(t)) that would allow for separate payment for such therapies, if medically appropriate and if necessary to encourage development and adoption of such therapies.

(2) Recommendations for payment and service delivery models to be tested by the Center for Medicare and Medicaid Innovation and other federally authorized demonstration projects, including value-based models, that may encourage the use of appropriate medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid addiction and other therapies that manage chronic and acute pain and treat and minimize risk of opioid addiction.

(3) Recommendations for data collection that could facilitate research and policy making regarding prevention of opioid addiction and coverage and payment under the Medicare and Medicaid programs of appropriate opioid addiction treatments.

(4) Recommendations for policies under the Medicare program and under the Medicaid program that can expand access for rural, or medically underserved communities to the full range of medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid addiction

and other therapies that manage chronic and acute pain and treatment and minimize risk of opioid addiction.

(5) Recommendations on changes to the Medicare program and the Medicaid program to address coverage or payment barriers to patient access to medical devices that are non-opioid based treatments approved by the Food and Drug Administration for the management of acute pain and chronic pain, for monitoring substance use withdrawal and preventing overdoses of controlled substances, and for treating substance use disorder.

(c) STAKEHOLDER MEETINGS.—

(1) IN GENERAL.—Beginning not later than 3 months after the date of the enactment of this Act, the Secretary shall convene a public stakeholder meeting to solicit public comment on the components of the action plan recommendations described in subsection (b).

(2) PARTICIPANTS.—Participants of meetings described in paragraph (1) shall include representatives from the Food and Drug Administration and National Institutes of Health, biopharmaceutical industry members, medical researchers, health care providers, the medical device industry, the Medicare

program, the Medicaid program, and patient advocates.

(d) REQUEST FOR INFORMATION.—Not later than 3 months after the date of the enactment of this section, the Secretary shall issue a request for information seeking public feedback regarding ways in which the Centers for Medicare & Medicaid Services can help address the opioid crisis through the development of and application of the action plan.

(e) REPORT TO CONGRESS.—Not later than June 1, 2019, the Secretary shall submit to Congress, and make public, a report that includes—

(1) a summary of recommendations that have emerged under the action plan;

(2) the Secretary's planned next steps with respect to the action plan; and

(3) an evaluation of price trends for drugs used to reverse opioid overdoses (such as naloxone), including recommendations on ways to lower such prices for consumers.

(f) DEFINITION OF MEDICATION-ASSISTED TREATMENT.—In this section, the term ''medication-assisted treatment'' includes opioid treatment programs, behavioral therapy, and medications to treat substance abuse disorder.

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

**SEC. 6041. SHORT TITLE.**

This subtitle may be cited as the ''Advancing High Quality Treatment for Opioid Use Disorders in Medicare Act''.

**SEC. 6042. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.**

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by inserting after section 1866E (42 U.S.C. 1395cc–5) the following new section:

**''SEC. 1866F. OPIOID USE DISORDER TREATMENT DEMONSTRATION PROGRAM.**

''(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION PROGRAM.—

''(1) IN GENERAL.—Not later than January 1, 2021, the Secretary shall implement a 4-year demonstration program under this title (in this section referred to as the 'Program') to increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce expenditures under this title. Under the Program, the Secretary shall make payments

under subsection (e) to participants (as defined in subsection (c)(1)(A)) for furnishing opioid use disorder treatment services delivered through opioid use disorder care teams, or arranging for such services to be furnished, to applicable beneficiaries participating in the Program.

''(2) OPIOID USE DISORDER TREATMENT SERVICES.—For purposes of this section, the term 'opioid use disorder treatment services'—

''(A) means, with respect to an applicable beneficiary, services that are furnished for the treatment of opioid use disorders and that utilize drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act for the treatment of opioid use disorders in an outpatient setting; and

''(B) includes—

''(i) medication assisted treatment;

''(ii) treatment planning;

''(iii) psychiatric, psychological, or counseling services (or any combination of such services), as appropriate;

''(iv) social support services, as appropriate; and

''(v) care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team.

''(b) PROGRAM DESIGN.—

''(1) IN GENERAL.—The Secretary shall design the Program in such a manner to allow for the evaluation of the extent to which the Program accomplishes the following purposes:

''(A) Reduces hospitalizations and emergency department visits.

''(B) Increases use of medication-assisted treatment for opioid use disorders.

''(C) Improves health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV).

''(D) Does not increase the total spending on items and services under this title.

''(E) Reduces deaths from opioid overdose.

''(F) Reduces the utilization of inpatient residential treatment.

''(2) CONSULTATION.—In designing the Program, including the criteria under subsection

(e)(2)(A), the Secretary shall, not later than 3 months after the date of the enactment of this section, consult with specialists in the field of addiction, clinicians in the primary care community, and beneficiary groups.

''(c) PARTICIPANTS; OPIOID USE DISORDER CARE TEAMS.—

''(1) PARTICIPANTS.—

''(A) DEFINITION.—In this section, the term 'participant' means an entity or individual—

''(i) that is otherwise enrolled under this title and that is—

''(I) a physician (as defined in section 1861(r)(1));

''(II) a group practice comprised of at least one physician described in subclause (I);

''(III) a hospital outpatient department;

''(IV) a federally qualified health center (as defined in section 1861(aa)(4));

''(V) a rural health clinic (as defined in section 1861(aa)(2));

''(VI) a community mental health center (as defined in section 1861(ff)(3)(B));

''(VII) a clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014; or

''(VIII) any other individual or entity specified by the Secretary;

''(ii) that applied for and was selected to participate in the Program pursuant to an application and selection process established by the Secretary; and

''(iii) that establishes an opioid use disorder care team (as defined in paragraph (2)) through employing or contracting with health care practitioners described in paragraph (2)(A), and uses such team to furnish or arrange for opioid use disorder treatment services in the outpatient setting under the Program.

''(B) PREFERENCE.—In selecting participants for the Program, the Secretary shall give preference to individuals and entities that are

located in areas with a prevalence of opioid use disorders that is higher than the national average prevalence.

''(2) OPIOID USE DISORDER CARE TEAMS.—

''(A) IN GENERAL.—For purposes of this section, the term 'opioid use disorder care team' means a team of health care practitioners established by a participant described in paragraph (1)(A) that—

''(i) shall include—

''(I) at least one physician (as defined in section 1861(r)(1)) furnishing primary care services or addiction treatment services to an applicable beneficiary; and

''(II) at least one eligible practitioner (as defined in paragraph (3)(A)), who may be a physician who meets the criterion in subclause (I); and

''(ii) may include other practitioners licensed under State law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries.

''(B) REQUIREMENTS FOR RECEIPT OF PAYMENT UNDER PROGRAM.—In order to receive payments under subsection (e), each participant in the Program shall—

''(i) furnish opioid use disorder treatment services through opioid use disorder care teams to applicable beneficiaries who agree to receive the services;

''(ii) meet minimum criteria, as established by the Secretary; and

''(iii) submit to the Secretary, in such form, manner, and frequency as specified by the Secretary, with respect to each applicable beneficiary for whom opioid use disorder treatment services are furnished by the opioid use disorder care team, data and such other information as the Secretary determines appropriate to—

''(I) monitor and evaluate the Program;

''(II) determine if minimum criteria are met under clause (ii); and

''(III) determine the incentive payment under subsection (e).

''(3) ELIGIBLE PRACTITIONERS; OTHER PROVIDER-RELATED DEFINITIONS AND APPLICATION PROVISIONS.—

''(A) ELIGIBLE PRACTITIONERS.—For purposes of this section, the term 'eligible practitioner' means a physician or other health care practitioner, such as a nurse practitioner, that—

''(i) is enrolled under section 1866(j)(1);

''(ii) is authorized to prescribe or dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment; and

''(iii) has in effect a waiver in accordance with section 303(g) of the Controlled Substances Act for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.

''(B) ADDICTION SPECIALISTS.—For purposes of subsection (e)(1)(B)(iv), the term 'addiction specialist' means a physician that possesses expert knowledge and skills in addiction

medicine, as evidenced by appropriate certification from a specialty body, a certificate of advanced qualification in addiction medicine, or completion of an accredited residency or fellowship in addiction medicine or addiction psychiatry, as determined by the Secretary.

''(d) PARTICIPATION OF APPLICABLE BENEFICIARIES.—

''(1) APPLICABLE BENEFICIARY DEFINED.—In this section, the term 'applicable beneficiary' means an individual who—

''(A) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B;

''(B) is not enrolled in a Medicare Advantage plan under part C;

''(C) has a current diagnosis for an opioid use disorder; and

''(D) meets such other criteria as the Secretary determines appropriate.

Such term shall include an individual who is dually eligible for benefits under this title and title XIX if such individual satisfies the criteria described in subparagraphs (A) through (D).

''(2) VOLUNTARY BENEFICIARY PARTICIPATION; LIMITATION ON NUMBER OF BENEFICIARIES.—An applicable beneficiary may participate in the Program on a voluntary basis and may terminate participation in the Program at any time. Not more than 20,000 applicable beneficiaries may participate in the Program at any time.

''(3) SERVICES.—In order to participate in the Program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participant. Participation under the Program shall not affect coverage of or payment for any other item or service under this title for the applicable beneficiary.

''(4) BENEFICIARY ACCESS TO SERVICES.—Nothing in this section shall be construed as encouraging providers to limit applicable beneficiary access to services covered under this title and applicable beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from a participant in the Program.

''(e) PAYMENTS.—

''(1) PER APPLICABLE BENEFICIARY PER MONTH CARE MANAGEMENT FEE.—

''(A) IN GENERAL.—The Secretary shall establish a schedule of per applicable beneficiary per month care management fees. Such a per applicable beneficiary per month care management fee shall be paid to a participant in addition to any other amount otherwise payable under this title to the health care practitioners in the participant's opioid use disorder care team or, if applicable, to the participant. A participant may use such per applicable beneficiary per month care management fee to deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under this title.

''(B) PAYMENT AMOUNTS.—In carrying out subparagraph (A), the Secretary shall—

''(i) consider payments otherwise payable under this title for opioid use disorder treatment services and the needs of applicable beneficiaries;

''(ii) pay a higher per applicable beneficiary per month care management fee for an applicable beneficiary who receives more intensive treatment services from a participant and for whom those services are ap-

propriate based on clinical guidelines for opioid use disorder care;

''(iii) pay a higher per applicable beneficiary per month care management fee for the month in which the applicable beneficiary begins treatment with a participant than in subsequent months, to reflect the greater time and costs required for the planning and initiation of treatment, as compared to maintenance of treatment;

''(iv) pay higher per applicable beneficiary per month care management fees for participants that have established opioid use disorder care teams that include an addiction specialist (as defined in subsection (c)(3)(B)); and

''(v) take into account whether a participant's opioid use disorder care team refers applicable beneficiaries to other suppliers or providers for any opioid use disorder treatment services.

''(C) NO DUPLICATE PAYMENT.—The Secretary shall make payments under this paragraph to only one participant for services fur-

nished to an applicable beneficiary during a calendar month.

''(2) INCENTIVE PAYMENTS.—

''(A) IN GENERAL.—Under the Program, the Secretary shall establish a performance-based incentive payment, which shall be paid (using a methodology established and at a time determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).

''(B) CRITERIA.—

''(i) IN GENERAL.—Criteria described in subparagraph (A) may include consideration of the following:

''(I) Patient engagement and retention in treatment.

''(II) Evidence-based medication-assisted treatment.

''(III) Other criteria established by the Secretary.

''(ii) REQUIRED CONSULTATION AND CONSIDERATION.—In determining criteria

described in subparagraph (A), the Secretary shall—

''(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction medicine; and

''(II) consider existing clinical guidelines for the treatment of opioid use disorders.

''(C) NO DUPLICATE PAYMENT.—The Secretary shall ensure that no duplicate payments under this paragraph are made with respect to an applicable beneficiary.

''(f) MULTIPAYER STRATEGY.—In carrying out the Program, the Secretary shall encourage other payers to provide similar payments and to use similar criteria as applied under the Program under subsection (e)(2)(C). The Secretary may enter into a memorandum of understanding with other payers to align the methodology for payment provided by such a payer related to opioid use disorder treatment services with such methodology for payment under the Program.

''(g) EVALUATION.—

''(1) IN GENERAL.—The Secretary shall conduct an intermediate and final evaluation of the pro-

gram. Each such evaluation shall determine the extent to which each of the purposes described in subsection (b) have been accomplished under the Program.

''(2) REPORTS.—The Secretary shall submit to the Secretary and Congress—

''(A) a report with respect to the intermediate evaluation under paragraph (1) not later than 3 years after the date of the implementation of the Program; and

''(B) a report with respect to the final evaluation under paragraph (1) not later than 6 years after such date.

''(h) FUNDING.—

''(1) ADMINISTRATIVE FUNDING.—For the purposes of implementing, administering, and carrying out the Program (other than for purposes described in paragraph (2)), the Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of $5,000,000 to the Centers for Medicare & Medicaid Services Program Management Account.

''(2) CARE MANAGEMENT FEES AND INCENTIVES.—For the purposes of making payments under subsection (e), the Secretary shall provide for

the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of $10,000,000 for each of fiscal years 2021 through 2024.

''(3) AVAILABILITY.—Amounts transferred under this subsection for a fiscal year shall be available until expended.

''(i) WAIVERS.—The Secretary may waive any provision of this title as may be necessary to carry out the Program under this section.''.

# Subtitle F—Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment

**SEC. 6051. SHORT TITLE.**

This subtitle may be cited as the ''Responsible Education Achieves Care and Healthy Outcomes for Users' Treatment Act of 2018'' or the ''REACH OUT Act of 2018''.

**SEC. 6052. GRANTS TO PROVIDE TECHNICAL ASSISTANCE TO OUTLIER PRESCRIBERS OF OPIOIDS.**

(a) GRANTS AUTHORIZED.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, through the Centers for Medicare & Medicaid Services, award grants, contracts, or cooperative

agreements to eligible entities for the purposes described in subsection (b).

(b) USE OF FUNDS.—Grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to support eligible entities through technical assistance—

(1) to educate and provide outreach to outlier prescribers of opioids about best practices for prescribing opioids;

(2) to educate and provide outreach to outlier prescribers of opioids about non-opioid pain management therapies; and

(3) to reduce the amount of opioid prescriptions prescribed by outlier prescribers of opioids.

(c) APPLICATION.—Each eligible entity seeking to receive a grant, contract, or cooperative agreement under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(d) GEOGRAPHIC DISTRIBUTION.—In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall prioritize establishing technical assistance resources in each State.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term ''eligible entity'' means—

(A) an organization—

(i) that has demonstrated experience providing technical assistance to health care professionals on a State or regional basis; and

(ii) that has at least—

(I) one individual who is a representative of consumers on its governing body; and

(II) one individual who is a representative of health care providers on its governing body; or

(B) an entity that is a quality improvement entity with a contract under part B of title XI of the Social Security Act (42 U.S.C. 1320c et seq.).

(2) OUTLIER PRESCRIBER OF OPIOIDS.—The term ''outlier prescriber of opioids'' means a prescriber, identified by the Secretary of Health and Human Services (through use of prescriber information provided by prescriber National Provider Identifiers included pursuant to section 1860D–4(c)(4)(A) of the Social Security Act (42 U.S.C. 1395w–

104(c)(4)(A)) on claims for covered part D drugs for part D eligible individuals enrolled in prescription drug plans under part D of title XVIII of such Act (42 U.S.C. 1395w–101 et seq.) and MA–PD plans under part C of such title (42 U.S.C. 1395w–21 et seq.)) as prescribing, as compared to other prescribers in the specialty of the prescriber and geographic area, amounts of opioids in excess of a threshold (and other criteria) specified by the Secretary, after consultation with stakeholders.

(3) PRESCRIBERS.—The term ''prescriber'' means any health care professional, including a nurse practitioner or physician assistant, who is licensed to prescribe opioids by the State or territory in which such professional practices.

(f) FUNDING.—For purposes of implementing this section, the Secretary of Health and Human Services shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of $75,000,000 for fiscal year 2019. Amounts transferred under this subparagraph shall remain available until expended.

# Subtitle G—Preventing Addiction for Susceptible Seniors

**SEC. 6061. SHORT TITLE.**

This subtitle may be cited as the ''Preventing Addiction for Susceptible Seniors Act of 2018'' or the ''PASS Act of 2018''.

**SEC. 6062. ELECTRONIC PRIOR AUTHORIZATION FOR COVERED PART D DRUGS.**

(a) INCLUSION IN ELECTRONIC PRESCRIPTION PROGRAM.—Section 1860D–4(e)(2) of the Social Security Act (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the end the following new subparagraph:

''(E) ELECTRONIC PRIOR AUTHORIZATION.—

''(i) IN GENERAL.—Not later than January 1, 2021, the program shall provide for the secure electronic transmission of—

''(I) a prior authorization request from the prescribing health care professional for coverage of a covered part D drug for a part D eligible individual enrolled in a part D plan (as defined in section 1860D–23(a)(5)) to the PDP sponsor or Medicare Advan-

tage organization offering such plan; and

''(II) a response, in accordance with this subparagraph, from such PDP sponsor or Medicare Advantage organization, respectively, to such professional.

''(ii) ELECTRONIC TRANSMISSION.—

''(I) EXCLUSIONS.—For purposes of this subparagraph, a facsimile, a proprietary payer portal that does not meet standards specified by the Secretary, or an electronic form shall not be treated as an electronic transmission described in clause (i).

''(II) STANDARDS.—In order to be treated, for purposes of this subparagraph, as an electronic transmission described in clause (i), such transmission shall comply with technical standards adopted by the Secretary in consultation with the National Council for Prescription Drug Programs, other standard setting organizations determined appropriate by

the Secretary, and stakeholders including PDP sponsors, Medicare Advantage organizations, health care professionals, and health information technology software vendors.

''(III) APPLICATION.—Notwithstanding any other provision of law, for purposes of this subparagraph, the Secretary may require the use of such standards adopted under subclause (II) in lieu of any other applicable standards for an electronic transmission described in clause (i) for a covered part D drug for a part D eligible individual.''.

(b) SENSE OF CONGRESS REGARDING ELECTRONIC PRIOR AUTHORIZATION.—It is the sense of the Congress that—

(1) there should be increased use of electronic prior authorizations for coverage of covered part D drugs for part D eligible individuals enrolled in prescription drug plans under part D of title XVIII of the Social Security Act and MA–PD plans under part C of such title to reduce access delays by re-

solving coverage issues before prescriptions for such drugs are transmitted; and

(2) greater priority should be placed on increasing the adoption of use of such electronic prior authorizations among prescribers of such drugs, pharmacies, PDP sponsors, and Medicare Advantage organizations.

**SEC. 6063. PROGRAM INTEGRITY TRANSPARENCY MEASURES UNDER MEDICARE PARTS C AND D.**

(a) IN GENERAL.—Section 1859 of the Social Security Act (42 U.S.C. 1395w–28) is amended by adding at the end the following new subsection:

''(i) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—

''(1) PROGRAM INTEGRITY PORTAL.—

''(A) IN GENERAL.—Not later than two years after the date of the enactment of this subsection, the Secretary shall, after consultation with stakeholders, establish a secure Internet website portal (or other successor technology) that would allow a secure path for communication between the Secretary, MA plans under this part, prescription drug plans under part D, and an eligible entity with a contract under section 1893 (such as a Medicare drug

integrity contractor or an entity responsible for carrying out program integrity activities under this part and part D) for the purpose of enabling through such portal (or other successor technology)—

''(i) the referral by such plans of substantiated fraud, waste, and abuse for initiating or assisting investigations conducted by the eligible entity; and

''(ii) data sharing among such MA plans, prescription drug plans, and the Secretary.

''(B) REQUIRED USES OF PORTAL.—The Secretary shall disseminate the following information to MA plans under this part and prescription drug plans under part D through the secure Internet website portal (or other successor technology) established under subparagraph (A):

''(i) Providers of services and suppliers that have been referred pursuant to subparagraph (A)(i) during the previous 12-month period.

''(ii) Providers of services and suppliers who are the subject of an active ex-

clusion under section 1128 or who are subject to a suspension of payment under this title pursuant to section 1862(o) or otherwise.

''(iii) Providers of services and suppliers who are the subject of an active revocation of participation under this title, including for not satisfying conditions of participation.

''(iv) In the case of such a plan that makes a referral under subparagraph (A)(i) through the portal (or other successor technology) with respect to activities of substantiated fraud, waste, or abuse of a provider of services or supplier, if such provider or supplier has been the subject of an administrative action under this title or title XI with respect to similar activities, a notification to such plan of such action so taken.

''(C) RULEMAKING.—For purposes of this paragraph, the Secretary shall, through rulemaking, specify what constitutes substantiated fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program In-

tegrity Manual 4.7.1. In carrying out this subsection, a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse

''(D) HIPAA COMPLIANT INFORMATION ONLY.—For purposes of this subsection, communications may only occur if the communications are permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

''(2) QUARTERLY REPORTS.—Beginning two years after the date of enactment of this subsection, the Secretary shall make available to MA plans under this part and prescription drug plans under part D in a timely manner (but no less frequently than quarterly) and using information submitted to an entity described in paragraph (1) through the portal (or other successor technology) described in such paragraph or pursuant to section 1893, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Information included in each such report shall—

''(A) include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders; and

''(B) be anonymized information submitted by plans without identifying the source of such information.

''(3) CLARIFICATION.—Nothing in this subsection shall be construed as precluding or otherwise affecting referrals described in subparagraph (A) that may otherwise be made to law enforcement entities or to the Secretary.''.

(b) CONTRACT REQUIREMENT TO COMMUNICATE PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRESCRIBERS.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

''(5) COMMUNICATING PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

''(A) IN GENERAL.—Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process estab-

lished under subparagraph (B), information on the investigations and other actions taken by such plans related to providers of services who prescribe a high volume of opioids.

''(B) PROCESS.—Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

''(C) REGULATIONS.—For purposes of this paragraph, including as applied under section 1860D–12(b)(3)(D), the Secretary shall, pursuant to rulemaking—

''(i) specify a definition for the term 'high volume of opioids' and a method for determining if a provider of services prescribes such a high volume; and

''(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.''.

(c) REFERENCE UNDER PART D TO PROGRAM INTEGRITY TRANSPARENCY MEASURES.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is

amended by adding at the end the following new subsection:

''(m) PROGRAM INTEGRITY TRANSPARENCY MEASURES.—For program integrity transparency measures applied with respect to prescription drug plan and MA plans, see section 1859(i).''.

**SEC. 6064. EXPANDING ELIGIBILITY FOR MEDICATION THERAPY MANAGEMENT PROGRAMS UNDER PART D.**

Section 1860D–4(c)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–104(c)(2)(A)(ii)) is amended—

(1) by redesignating subclauses (I) through (III) as items (aa) through (cc), respectively, and adjusting the margins accordingly;

(2) by striking ''are part D eligible individuals who—'' and inserting ''are the following:

''(I) Part D eligible individuals who—''; and

(3) by adding at the end the following new subclause:

''(II) Beginning January 1, 2021, at-risk beneficiaries for prescription drug abuse (as defined in paragraph (5)(C)).''.

**SEC. 6065. MEDICARE NOTIFICATIONS TO OUTLIER PRESCRIBERS OF OPIOIDS.**

Section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–104(c)(4)) is amended by adding at the end the following new subparagraph:

''(D) OUTLIER PRESCRIBER NOTIFICATION.—

''(i) NOTIFICATION.—Beginning not later than two years after the date of the enactment of this subparagraph, the Secretary shall, in the case of a prescriber identified by the Secretary under clause (ii) to be an outlier prescriber of opioids, provide, subject to clause (iv), an annual notification to such prescriber that such prescriber has been so identified and that includes resources on proper prescribing methods and other information specified in accordance with clause (iii).

''(ii) IDENTIFICATION OF OUTLIER PRESCRIBERS OF OPIOIDS.—

''(I) IN GENERAL.—The Secretary shall, subject to subclause (III), using the valid prescriber National Provider Identifiers included pursuant to subparagraph (A) on claims for

covered part D drugs for part D eligible individuals enrolled in prescription drug plans under this part or MA–PD plans under part C and based on the threshold established under subclause (II), conduct an analysis to identify prescribers that are outlier opioid prescribers for a period specified by the Secretary.

''(II) ESTABLISHMENT OF THRESHOLD.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish a threshold, based on prescriber specialty and geographic area, for identifying whether a prescriber in a specialty and geographic area is an outlier prescriber of opioids as compared to other prescribers of opioids within such specialty and area.

''(III) EXCLUSIONS.—The Secretary may exclude the following individuals and prescribers from the analysis under this clause:

''(aa) Individuals receiving hospice services.

''(bb) Individuals with a cancer diagnosis.

''(cc) Prescribers who are the subject of an investigation by the Centers for Medicare & Medicaid Services or the Office of Inspector General of the Department of Health and Human Services.

''(iii) CONTENTS OF NOTIFICATION.—The Secretary shall, based on input from stakeholders, specify the resources and other information to be included in notifications provided under clause (i).

''(iv) MODIFICATIONS AND EXPANSIONS.—

''(I) FREQUENCY.—Beginning 5 years after the date of the enactment of this subparagraph, the Secretary may change the frequency of the notifications described in clause (i) based on stakeholder input.

''(II) EXPANSION TO OTHER PRESCRIPTIONS.—The Secretary may expand notifications under this subparagraph to include identifications and notifications with respect to concurrent prescriptions of covered Part D drugs used in combination with opioids that are considered to have adverse side effects when so used in such combination, as determined by the Secretary.

''(v) OPIOIDS DEFINED.—For purposes of this subparagraph, the term 'opioids' has such meaning as specified by the Secretary through program instruction or otherwise.''.

**SEC. 6066. NO ADDITIONAL FUNDS AUTHORIZED.**

No additional funds are authorized to be appropriated to carry out the requirements of this subtitle and the amendments made by this subtitle. Such requirements shall be carried out using amounts otherwise authorized to be appropriated.

# Subtitle H—Expanding Oversight of Opioid Prescribing and Payment

**SEC. 6071. SHORT TITLE.**

This subtitle may be cited as the ''Expanding Oversight of Opioid Prescribing and Payment Act of 2018''.

**SEC. 6072. MEDICARE PAYMENT ADVISORY COMMISSION REPORT ON OPIOID PAYMENT, ADVERSE INCENTIVES, AND DATA UNDER THE MEDICARE PROGRAM.**

Not later than March 15, 2019, the Medicare Payment Advisory Commission shall submit to Congress a report on, with respect to the Medicare program under title XVIII of the Social Security Act, the following:

(1) A description of how the Medicare program pays for pain management treatments (both opioid and non-opioid pain management alternatives) in both inpatient and outpatient hospital settings.

(2) The identification of incentives under the hospital inpatient prospective payment system under section 1886 of the Social Security Act (42 U.S.C. 1395ww) and incentives under the hospital outpatient prospective payment system under section 1833(t) of such Act (42 U.S.C. 1395l(t)) for prescribing opioids and incentives under each such system for prescribing non-opioid treatments, and rec-

ommendations as the Commission deems appropriate for addressing any of such incentives that are adverse incentives.

(3) A description of how opioid use is tracked and monitored through Medicare claims data and other mechanisms and the identification of any areas in which further data and methods are needed for improving data and understanding of opioid use.

**SEC. 6073. NO ADDITIONAL FUNDS AUTHORIZED.**

No additional funds are authorized to be appropriated to carry out the requirements of this subtitle. Such requirements shall be carried out using amounts otherwise authorized to be appropriated.

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

**SEC. 6081. SHORT TITLE.**

This subtitle may be cited as the ''Dr. Todd Graham Pain Management, Treatment, and Recovery Act of 2018''.

**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.**

(a) OUTPATIENT PROSPECTIVE PAYMENT SYSTEM.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended by adding at the end the following new paragraph:

''(22) REVIEW AND REVISIONS OF PAYMENTS FOR NON-OPIOID ALTERNATIVE TREATMENTS.—

''(A) IN GENERAL.—With respect to payments made under this subsection for covered OPD services (or groups of services), including covered OPD services assigned to a comprehensive ambulatory payment classification, the Secretary—

''(i) shall, as soon as practicable, conduct a review (part of which may include a request for information) of payments for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not finan-

cial incentives to use opioids instead of non-opioid alternatives;

''(ii) may, as the Secretary determines appropriate, conduct subsequent reviews of such payments; and

''(iii) shall consider the extent to which revisions under this subsection to such payments (such as the creation of additional groups of covered OPD services to classify separately those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce payment incentives to use opioids instead of non-opioid alternatives for pain management.

''(B) PRIORITY.—In conducting the review under clause (i) of subparagraph (A) and considering revisions under clause (iii) of such subparagraph, the Secretary shall focus on covered OPD services (or groups of services) assigned to a comprehensive ambulatory payment classification, ambulatory payment classifications that primarily include surgical services, and other services determined by the Secretary

which generally involve treatment for pain management.

''(C) REVISIONS.—If the Secretary identifies revisions to payments pursuant to subparagraph (A)(iii), the Secretary shall, as determined appropriate, begin making such revisions for services furnished on or after January 1, 2020. Revisions under the previous sentence shall be treated as adjustments for purposes of application of paragraph (9)(B).

''(D) RULES OF CONSTRUCTION.—Nothing in this paragraph shall be construed to preclude the Secretary—

''(i) from conducting a demonstration before making the revisions described in subparagraph (C); or

''(ii) prior to implementation of this paragraph, from changing payments under this subsection for covered OPD services (or groups of services) which include opioids or non-opioid alternatives for pain management.''.

(b) AMBULATORY SURGICAL CENTERS.—Section 1833(i) of the Social Security Act (42 U.S.C. 1395l(i))

is amended by adding at the end the following new paragraph:

''(8) The Secretary shall conduct a similar type of review as required under paragraph (22) of section 1833(t)), including the second sentence of subparagraph (C) of such paragraph, to payment for services under this subsection, and make such revisions under this paragraph, in an appropriate manner (as determined by the Secretary).''.

**SEC. 6083. EXPANDING ACCESS UNDER THE MEDICARE PROGRAM TO ADDICTION TREATMENT IN FEDERALLY QUALIFIED HEALTH CENTERS AND RURAL HEALTH CLINICS.**

(a) FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1834(o) of the Social Security Act (42 U.S.C. 1395m(o)) is amended by adding at the end the following new paragraph:

''(3) ADDITIONAL PAYMENTS FOR CERTAIN FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

''(A) IN GENERAL.—In the case of a Federally qualified health center with respect to which, beginning on or after January 1, 2019, Federally-qualified health center services (as defined in section 1861(aa)(3)) are furnished for

the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in subparagraph (C) the Secretary shall, subject to availability of funds under subparagraph (D), make a payment (at such time and in such manner as specified by the Secretary) to such Federally qualified health center after receiving and approving an application submitted by such Federally qualified health center under subparagraph (B). Such a payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in subparagraph (C)(ii). Such a payment may be made only one time with respect to each such physician or practitioner.

''(B) APPLICATION.—In order to receive a payment described in subparagraph (A), a Federally-qualified health center shall submit to the Secretary an application for such a payment at such time, in such manner, and containing such information as specified by the Secretary. A Federally-qualified health center may apply for such a payment for each physician or practitioner described in subparagraph (A) furnishing

services described in such subparagraph at such center.

''(C) REQUIREMENTS.—For purposes of subparagraph (A), the requirements described in this subparagraph, with respect to a physician or practitioner, are the following:

''(i) The physician or practitioner is employed by or working under contract with a Federally qualified health center described in subparagraph (A) that submits an application under subparagraph (B).

''(ii) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Acton or after January 1, 2019.

''(D) FUNDING.—For purposes of making payments under this paragraph, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $6,000,000, which shall remain available until expended.''.

(b) RURAL HEALTH CLINIC.—Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended—

(1) by redesignating the subsection (z) relating to medical review of spinal subluxation services as subsection (aa); and

(2) by adding at the end the following new subsection:

''(bb) ADDITIONAL PAYMENTS FOR CERTAIN RURAL HEALTH CLINICS WITH PHYSICIANS OR PRACTITIONERS RECEIVING DATA 2000 WAIVERS.—

''(1) IN GENERAL.—In the case of a rural health clinic with respect to which, beginning on or after January 1, 2019, rural health clinic services (as defined in section 1861(aa)(1)) are furnished for the treatment of opioid use disorder by a physician or practitioner who meets the requirements described in paragraph (3), the Secretary shall, subject to availability of funds under paragraph (4), make a payment (at such time and in such manner as specified by the Secretary) to such rural health clinic after receiving and approving an application described in paragraph (2). Such payment shall be in an amount determined by the Secretary, based on an estimate of the average costs of training for purposes of receiving a waiver described in paragraph (3)(B). Such payment may be made only one time with respect to each such physician or practitioner.

''(2) APPLICATION.—In order to receive a payment described in paragraph (1), a rural health clinic shall submit to the Secretary an application for

such a payment at such time, in such manner, and containing such information as specified by the Secretary. A rural health clinic may apply for such a payment for each physician or practitioner described in paragraph (1) furnishing services described in such paragraph at such clinic.

''(3) REQUIREMENTS.—For purposes of paragraph (1), the requirements described in this paragraph, with respect to a physician or practitioner, are the following:

''(A) The physician or practitioner is employed by or working under contract with a rural health clinic described in paragraph (1) that submits an application under paragraph (2).

''(B) The physician or practitioner first receives a waiver under section 303(g) of the Controlled Substances Acton or after January 1, 2019.

''(4) FUNDING.—For purposes of making payments under this subsection, there are appropriated, out of amounts in the Treasury not otherwise appropriated, $2,000,000, which shall remain available until expended.''.

**SEC. 6084. STUDYING THE AVAILABILITY OF SUPPLEMENTAL BENEFITS DESIGNED TO TREAT OR PREVENT SUBSTANCE USE DISORDERS UNDER MEDICARE ADVANTAGE PLANS.**

(a) IN GENERAL.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall submit to Congress a report on the availability of supplemental health care benefits (as described in section 1852(a)(3)(A) of the Social Security Act (42 U.S.C. 1395w–22(a)(3)(A))) designed to treat or prevent substance use disorders under Medicare Advantage plans offered under part C of title XVIII of such Act. Such report shall include the analysis described in subsection (c) and any differences in the availability of such benefits under specialized MA plans for special needs individuals (as defined in section 1859(b)(6) of such Act (42 U.S.C. 1395w–28(b)(6))) offered to individuals entitled to medical assistance under title XIX of such Act and other such Medicare Advantage plans.

(b) CONSULTATION.—The Secretary shall develop the report described in subsection (a) in consultation with relevant stakeholders, including—

(1) individuals entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act;

(2) entities who advocate on behalf of such individuals;

(3) Medicare Advantage organizations;

(4) pharmacy benefit managers; and

(5) providers of services and suppliers (as such terms are defined in section 1861 of such Act (42 U.S.C. 1395x)).

(c) CONTENTS.—The report described in subsection (a) shall include an analysis on the following:

(1) The extent to which plans described in such subsection offer supplemental health care benefits relating to coverage of—

(A) medication-assisted treatments for opioid use, substance use disorder counseling, peer recovery support services, or other forms of substance use disorder treatments (whether furnished in an inpatient or outpatient setting); and

(B) non-opioid alternatives for the treatment of pain.

(2) Challenges associated with such plans offering supplemental health care benefits relating to coverage of items and services described in subparagraph (A) or (B) of paragraph (1).

(3) The impact, if any, of increasing the applicable rebate percentage determined under section 1854(b)(1)(C) of the Social Security Act (42 U.S.C. 1395w–24(b)(1)(C)) for plans offering such benefits relating to such coverage would have on the availability of such benefits relating to such coverage offered under Medicare Advantage plans.

(4) Potential ways to improve upon such coverage or to incentivize such plans to offer additional supplemental health care benefits relating to such coverage.

**SEC. 6085. CLINICAL PSYCHOLOGIST SERVICES MODELS UNDER THE CENTER FOR MEDICARE AND MEDICAID INNOVATION; GAO STUDY AND REPORT.**

(a) CMI MODELS.—Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315a(b)(2)(B) is amended by adding at the end the following new clauses:

''(xxv) Supporting ways to familiarize individuals with the availability of coverage under part B of title XVIII for qualified psychologist services (as defined in section 1861(ii)).

''(xxvi) Exploring ways to avoid unnecessary hospitalizations or emergency de-

partment visits for mental and behavioral health services (such as for treating depression) through use of a 24-hour, 7-day a week help line that may inform individuals about the availability of treatment options, including the availability of qualified psychologist services (as defined in section 1861(ii)).''.

(b) GAO STUDY AND REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study, and submit to Congress a report, on mental and behavioral health services under the Medicare program under title XVIII of the Social Security Act, including an examination of the following:

(1) Information about services furnished by psychiatrists, clinical psychologists, and other professionals.

(2) Information about ways that Medicare beneficiaries familiarize themselves about the availability of Medicare payment for qualified psychologist services (as defined in section 1861(ii) of the Social Security Act (42 U.S.C. 1395x(ii)) and ways that the provision of such information could be improved.

**SEC. 6086. PAIN MANAGEMENT STUDY.**

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a study analyzing best practices as well as payment and coverage for pain management services under title XVIII of the Social Security Act and submit to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report containing options for revising payment to providers and suppliers of services and coverage related to the use of multi-disciplinary, evidence-based, non-opioid treatments for acute and chronic pain management for individuals entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act. The Secretary shall make such report available on the public website of the Centers for Medicare & Medicaid Services.

(b) CONSULTATION.—In developing the report described in subsection (a), the Secretary shall consult with—

(1) relevant agencies within the Department of Health and Human Services;

(2) licensed and practicing osteopathic and allopathic physicians, behavioral health practitioners,

physician assistants, nurse practitioners, dentists, pharmacists, and other providers of health services;

(3) providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x));

(4) substance abuse and mental health professional organizations;

(5) pain management professional organizations and advocacy entities, including individuals who personally suffer chronic pain;

(6) medical professional organizations and medical specialty organizations;

(7) licensed health care providers who furnish alternative pain management services;

(8) organizations with expertise in the development of innovative medical technologies for pain management;

(9) beneficiary advocacy organizations; and

(10) other organizations with expertise in the assessment, diagnosis, treatment, and management of pain, as determined appropriate by the Secretary.

(c) CONTENTS.—The report described in subsection (a) shall include the following:

(1) An analysis of payment and coverage under title XVIII of the Social Security Act with respect to the following:

(A) Evidence-based treatments and technologies for chronic or acute pain, including such treatments that are covered, not covered, or have limited coverage under such title.

(B) Evidence-based treatments and technologies that monitor substance use withdrawal and prevent overdoses of opioids.

(C) Evidence-based treatments and technologies that treat substance use disorders.

(D) Items and services furnished by practitioners through a multi-disciplinary treatment model for pain management, including the patient-centered medical home.

(E) Medical devices, non-opioid based drugs, and other therapies (including interventional and integrative pain therapies) approved or cleared by the Food and Drug Administration for the treatment of pain.

(F) Items and services furnished to beneficiaries with psychiatric disorders, substance use disorders, or who are at risk of suicide, or have comorbidities and require consultation or

management of pain with one or more specialists in pain management, mental health, or addiction treatment.

(2) An evaluation of the following:

(A) Barriers inhibiting individuals entitled to benefits under part A or enrolled under part B of such title from accessing treatments and technologies described in subparagraphs (A) through (F) of paragraph (1).

(B) Costs and benefits associated with potential expansion of coverage under such title to include items and services not covered under such title that may be used for the treatment of pain, such as acupuncture, therapeutic massage, and items and services furnished by integrated pain management programs.

(C) Pain management guidance published by the Federal Government that may be relevant to coverage determinations or other coverage requirements under title XVIII of the Social Security Act.

(3) An assessment of all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids. Such assessment shall consider incor-

porating into such guidance relevant elements of the ''Va/DoD Clinical Practice Guideline for Opioid Therapy for Chronic Pain'' published in February 2017 by the Department of Veterans Affairs and Department of Defense, including adoption of elements of the Department of Defense and Department of Veterans Affairs pain rating scale.

(4) The options described in subsection (d).

(5) The impact analysis described in subsection (e).

(d) OPTIONS.—The options described in this subsection are, with respect to individuals entitled to benefits under part A or enrolled under part B of title XVIII of the Social Security Act, legislative and administrative options for accomplishing the following:

(1) Improving coverage of and payment for pain management therapies without the use of opioids, including interventional pain therapies, and options to augment opioid therapy with other clinical and complementary, integrative health services to minimize the risk of substance use disorder, including in a hospital setting.

(2) Improving coverage of and payment for medical devices and non-opioid based pharmacological and non-pharmacological therapies ap-

proved or cleared by the Food and Drug Administration for the treatment of pain as an alternative or augment to opioid therapy.

(3) Improving and disseminating treatment strategies for beneficiaries with psychiatric disorders, substance use disorders, or who are at risk of suicide, and treatment strategies to address health disparities related to opioid use and opioid abuse treatment.

(4) Improving and disseminating treatment strategies for beneficiaries with comorbidities who require a consultation or comanagement of pain with one or more specialists in pain management, mental health, or addiction treatment, including in a hospital setting.

(5) Educating providers on risks of coadministration of opioids and other drugs, particularly benzodiazepines.

(6) Ensuring appropriate case management for beneficiaries who transition between inpatient and outpatient hospital settings, or between opioid therapy to non-opioid therapy, which may include the use of care transition plans.

(7) Expanding outreach activities designed to educate providers of services and suppliers under the

Medicare program and individuals entitled to benefits under part A or under part B of such title on alternative, non-opioid therapies to manage and treat acute and chronic pain.

(8) Creating a beneficiary education tool on alternatives to opioids for chronic pain management.

(e) IMPACT ANALYSIS.—The impact analysis described in this subsection consists of an analysis of any potential effects implementing the options described in subsection (d) would have—

(1) on expenditures under the Medicare program; and

(2) on preventing or reducing opioid addiction for individuals receiving benefits under the Medicare program.

# Subtitle J—Combating Opioid Abuse for Care in Hospitals

**SEC. 6091. SHORT TITLE.**

This subtitle may be cited as the ''Combating Opioid Abuse for Care in Hospitals Act of 2018'' or the ''COACH Act of 2018''.

**SEC. 6092. DEVELOPING GUIDANCE ON PAIN MANAGEMENT AND OPIOID USE DISORDER PREVENTION FOR HOSPITALS RECEIVING PAYMENT UNDER PART A OF THE MEDICARE PROGRAM.**

(a) IN GENERAL.—Not later than January 1, 2019, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall develop and publish on the public website of the Centers for Medicare & Medicaid Services guidance for hospitals receiving payment under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) on pain management strategies and opioid use disorder prevention strategies with respect to individuals entitled to benefits under such part.

(b) CONSULTATION.—In developing the guidance described in subsection (a), the Secretary shall consult with relevant stakeholders, including—

(1) medical professional organizations;

(2) providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x));

(3) health care consumers or groups representing such consumers; and

(4) other entities determined appropriate by the Secretary.

(c) CONTENTS.—The guidance described in subsection (a) shall include, with respect to hospitals and individuals described in such subsection, the following:

(1) Best practices regarding evidence-based screening and practitioner education initiatives relating to screening and treatment protocols for opioid use disorder, including—

(A) methods to identify such individuals at-risk of opioid use disorder, including risk stratification;

(B) ways to prevent, recognize, and treat opioid overdoses; and

(C) resources available to such individuals, such as opioid treatment programs, peer support groups, and other recovery programs.

(2) Best practices for such hospitals to educate practitioners furnishing items and services at such hospital with respect to pain management and substance use disorders, including education on—

(A) the adverse effects of prolonged opioid use;

(B) non-opioid, evidence-based, non-pharmacological pain management treatments;

(C) monitoring programs for individuals who have been prescribed opioids; and

(D) the prescribing of naloxone along with an initial opioid prescription.

(3) Best practices for such hospitals to make such individuals aware of the risks associated with opioid use (which may include use of the notification template described in paragraph (4)).

(4) A notification template developed by the Secretary, for use as appropriate, for such individuals who are prescribed an opioid that—

(A) explains the risks and side effects associated with opioid use (including the risks of addiction and overdose) and the importance of adhering to the prescribed treatment regimen, avoiding medications that may have an adverse interaction with such opioid, and storing such opioid safely and securely;

(B) highlights multimodal and evidence-based non-opioid alternatives for pain management;

(C) encourages such individuals to talk to their health care providers about such alternatives;

(D) provides for a method (through signature or otherwise) for such an individual, or

person acting on such individual's behalf, to acknowledge receipt of such notification template;

(E) is worded in an easily understandable manner and made available in multiple languages determined appropriate by the Secretary; and

(F) includes any other information determined appropriate by the Secretary.

(5) Best practices for such hospital to track opioid prescribing trends by practitioners furnishing items and services at such hospital, including—

(A) ways for such hospital to establish target levels, taking into account the specialties of such practitioners and the geographic area in which such hospital is located, with respect to opioids prescribed by such practitioners;

(B) guidance on checking the medical records of such individuals against information included in prescription drug monitoring programs;

(C) strategies to reduce long-term opioid prescriptions; and

(D) methods to identify such practitioners who may be over-prescribing opioids.

(6) Other information the Secretary determines appropriate, including any such information from the Opioid Safety Initiative established by the Department of Veterans Affairs or the Opioid Overdose Prevention Toolkit published by the Substance Abuse and Mental Health Services Administration.

**SEC. 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.**

(a) IN GENERAL.—Section 1890A of the Social Security Act (42 U.S.C. 1395aaa–1) is amended by adding at the end the following new subsection:

''(g) TECHNICAL EXPERT PANEL REVIEW OF OPIOID AND OPIOID USE DISORDER QUALITY MEASURES.—

''(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this subsection, the Secretary shall establish a technical expert panel for purposes of reviewing quality measures relating to opioids and opioid use disorders, including care, prevention, diagnosis, health outcomes, and treatment furnished to individuals with opioid use disorders. The Secretary may use the entity with a contract under section 1890(a) and amend such con-

tract as necessary to provide for the establishment of such technical expert panel.

''(2) REVIEW AND ASSESSMENT.—Not later than 1 year after the date the technical expert panel described in paragraph (1) is established (and periodically thereafter as the Secretary determines appropriate), the technical expert panel shall—

''(A) review quality measures that relate to opioids and opioid use disorders, including existing measures and those under development;

''(B) identify gaps in areas of quality measurement that relate to opioids and opioid use disorders, and identify measure development priorities for such measure gaps; and

''(C) make recommendations to the Secretary on quality measures with respect to opioids and opioid use disorders for purposes of improving care, prevention, diagnosis, health outcomes, and treatment, including recommendations for revisions of such measures, need for development of new measures, and recommendations for including such measures in the Merit-Based Incentive Payment System under section 1848(q), the alternative payment models under section 1833(z)(3)(C), the shared

savings program under section 1899, the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii), and the hospital value-based purchasing program under section 1886(o).

''(3) CONSIDERATION OF MEASURES BY SECRETARY.—The Secretary shall consider—

''(A) using opioid and opioid use disorder measures (including measures used under the Merit-Based Incentive Payment System under section 1848(q), measures recommended under paragraph (2)(C), and other such measures identified by the Secretary) in alternative payment models under section 1833(z)(3)(C) and in the shared savings program under section 1899; and

''(B) using opioid measures described in subparagraph (A), as applicable, in the quality reporting requirements for inpatient hospitals under section 1886(b)(3)(B)(viii),and in the hospital value-based purchasing program under section 1886(o).

''(4) PRIORITIZATION OF MEASURE DEVELOPMENT.—The Secretary shall prioritize for measure

development the gaps in quality measures identified under paragraph (2)(B).''.

(b) EXPEDITED ENDORSEMENT PROCESS FOR OPIOID MEASURES.—Section 1890(b)(2) of the Social Security Act (42 U.S.C. 1395aaa(b)(2)) is amended by adding at the end the following new flush sentence:

''Such endorsement process shall, as determined practicable by the entity, provide for an expedited process with respect to the endorsement of such measures relating to opioids and opioid use disorders.''.

**SEC. 6094. TECHNICAL EXPERT PANEL ON REDUCING SURGICAL SETTING OPIOID USE; DATA COLLECTION ON PERIOPERATIVE OPIOID USE.**

(a) TECHNICAL EXPERT PANEL ON REDUCING SURGICAL SETTING OPIOID USE.—

(1) IN GENERAL.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall convene a technical expert panel, including medical and surgical specialty societies and hospital organizations, to provide recommendations on reducing opioid use in the inpatient and outpatient surgical settings and on best practices for pain management, including with respect to the following:

(A) Approaches that limit patient exposure to opioids during the perioperative period, including pre-surgical and post-surgical injections, and that identify such patients at risk of opioid use disorder pre-operation.

(B) Shared decision making with patients and families on pain management, including recommendations for the development of an evaluation and management code for purposes of payment under the Medicare program under title XVIII of the Social Security Act that would account for time spent on shared decision making.

(C) Education on the safe use, storage, and disposal of opioids.

(D) Prevention of opioid misuse and abuse after discharge.

(E) Development of a clinical algorithm to identify and treat at-risk, opiate-tolerant patients and reduce reliance on opioids for acute pain during the perioperative period.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress and make public a report containing the recommendations developed under

paragraph (1) and an action plan for broader implementation of pain management protocols that limit the use of opioids in the perioperative setting and upon discharge from such setting.

(b) DATA COLLECTION ON PERIOPERATIVE OPIOID USE.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that contains the following:

(1) The diagnosis-related group codes identified by the Secretary as having the highest volume of surgeries.

(2) With respect to each of such diagnosis-related group codes so identified, a determination by the Secretary of the data that is both available and reported on opioid use following such surgeries, such as with respect to—

(A) surgical volumes, practices, and opioid prescribing patterns;

(B) opioid consumption, including—

(i) perioperative days of therapy;

(ii) average daily dose at the hospital, including dosage greater than 90 milligram morphine equivalent;

(iii) post-discharge prescriptions and other combination drugs that are used before intervention and after intervention;

(iv) quantity and duration of opioid prescription at discharge; and

(v) quantity consumed and number of refills;

(C) regional anesthesia and analgesia practices, including pre-surgical and post-surgical injections;

(D) naloxone reversal;

(E) post-operative respiratory failure;

(F) information about storage and disposal; and

(G) such other information as the Secretary may specify.

(3) Recommendations for improving data collection on perioperative opioid use, including an analysis to identify and reduce barriers to collecting, reporting, and analyzing the data described in paragraph (2), including barriers related to technological availability.

**SEC. 6095. REQUIRING THE POSTING AND PERIODIC UPDATE OF OPIOID PRESCRIBING GUIDANCE FOR MEDICARE BENEFICIARIES.**

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall post on the public website of the Centers for Medicare & Medicaid Services all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids and applicable to opioid prescriptions for individuals entitled to benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.) or enrolled under part B of such title of such Act (42 U.S.C. 1395j et seq.).

(b) UPDATE OF GUIDANCE.—

(1) PERIODIC UPDATE.—The Secretary shall, in consultation with the entities specified in paragraph (2), periodically (as determined appropriate by the Secretary) update guidance described in subsection (a) and revise the posting of such guidance on the website described in such subsection.

(2) CONSULTATION.—The entities specified in this paragraph are the following:

(A) Medical professional organizations.

(B) Providers and suppliers of services (as such terms are defined in section 1861 of the Social Security Act (42 U.S.C. 1395x)).

(C) Health care consumers or groups representing such consumers.

(D) Other entities determined appropriate by the Secretary.

# Subtitle K—Stop Excessive Narcotics in Our Retirement Communities Protection

**SEC. 6101. SHORT TITLE.**

This subtitle may be cited as the ''Stop Excessive Narcotics in our Retirement Communities Protection Act of 2018'' or the ''SENIOR Communities Protection Act of 2018''.

**SEC. 6102. SUSPENSION OF PAYMENTS BY MEDICARE PRESCRIPTION DRUG PLANS AND MA–PD PLANS PENDING INVESTIGATIONS OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.**

(a) IN GENERAL.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

''(7) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—

''(A) IN GENERAL.—The provisions of section 1862(o) shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such provisions apply with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title.

''(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.''.

(b) APPLICATION TO MA–PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following new subparagraph:

''(D) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD BY PHARMACIES.—Section 1860D–12(b)(7).''.

(c) CONFORMING AMENDMENT.—Section 1862(o)(3) of the Social Security Act (42 U.S.C. 1395y(o)(3)) is amended by inserting '', section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)),'' after ''this subsection''.

(d) CLARIFICATION RELATING TO CREDIBLE ALLEGATION OF FRAUD.—Section 1862(o) of the Social Security Act (42 U.S.C. 1395y(o)) is amended by adding at the end the following new paragraph:

''(4) CREDIBLE ALLEGATION OF FRAUD.—In carrying out this subsection, section 1860D–12(b)(7) (including as applied pursuant to section 1857(f)(3)(D)), and section 1903(i)(2)(C), a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for a credible allegation of fraud.''.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after January 1, 2020.

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

**SEC. 6111. SHORT TITLE.**

This subtitle may be cited as the ''Providing Reliable Options for Patients and Educational Resources Act of 2018'' or the ''PROPER Act of 2018''.

**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 NONOPIOID MEDICATIONS OR DEVICES USED TO TREAT PAIN.**

Section 1860D–4(a)(1) of the Social Security Act (42 U.S.C. 1395w–104(a)(1)) is amended—

(1) in subparagraph (A), by inserting ", subject to subparagraph (C)," before "including";

(2) in subparagraph (B), by adding at the end the following new clause:

"(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

"(I) the risks associated with prolonged opioid use; and

"(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

"(aa) in the case of an MA-PD plan under part C, under such plan; and

''(bb) in the case of a prescription drug plan, under such plan and under parts A and B.''; and

(3) by adding at the end the following new subparagraph:

''(C) TARGETED PROVISION OF INFORMATION.—A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous two-year period.''.

**SEC. 6113. REQUIRING MEDICARE ADVANTAGE PLANS AND PRESCRIPTION DRUG PLANS TO PROVIDE INFORMATION ON THE SAFE DISPOSAL OF PRESCRIPTION DRUGS.**

(a) MEDICARE ADVANTAGE.—Section 1852 of the Social Security Act (42 U.S.C. 1395w–22) is amended by adding at the end the following new subsection:

''(n) PROVISION OF INFORMATION RELATING TO THE SAFE DISPOSAL OF CERTAIN PRESCRIPTION DRUGS.—

''(1) IN GENERAL.—In the case of an individual enrolled under an MA or MA-PD plan who is furnished an in-home health risk assessment on or after January 1, 2021, such plan shall ensure that such assessment includes information on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under paragraph (2). Such information shall include information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal.

''(2) CRITERIA.—The Secretary shall, through rulemaking, establish criteria the Secretary determines appropriate with respect to information provided to an individual to ensure that such information sufficiently educates such individual on the safe disposal of prescription drugs that are controlled substances.''.

(b) PRESCRIPTION DRUG PLANS.—Section 1860D–4(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w–104(c)(2)(B)) is amended—

(1) by striking ''may include elements that promote'';

(2) by redesignating clauses (i) through (iii) as subclauses (I) through (III) and adjusting the margins accordingly;

(3) by inserting before subclause (I), as so redesignated, the following new clause:

''(i) may include elements that promote—'';

(4) in subclause (III), as so redesignated, by striking the period at the end and inserting ''; and''; and

(5) by adding at the end the following new clause:

''(ii) with respect to plan years beginning on or after January 1, 2021, shall provide for—

''(I) the provision of information to the enrollee on the safe disposal of prescription drugs that are controlled substances that meets the criteria established under section 1852(n)(2), including information on drug takeback programs that meet such requirements determined appropriate by the Secretary and information on in-home disposal; and

''(II) cost-effective means by which an enrollee may so safely dispose of such drugs.''.

**SEC. 6114. REVISING MEASURES USED UNDER THE HOSPITAL CONSUMER ASSESSMENT OF HEALTHCARE PROVIDERS AND SYSTEMS SURVEY RELATING TO PAIN MANAGEMENT.**

(a) RESTRICTION ON THE USE OF PAIN QUESTIONS IN HCAHPS.—Section 1886(b)(3)(B)(viii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(viii)) is amended by adding at the end the following new subclause:

''(XII)(aa) With respect to a Hospital Consumer Assessment of Healthcare Providers and Systems survey (or a successor survey) conducted on or after January 1, 2019, such survey may not include questions about communication by hospital staff with an individual about such individual's pain unless such 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.

''(bb) The Secretary shall not include on the Hospital Compare Internet website any measures based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018

about communication by hospital staff with an individual about such individual's pain.''.

(b) RESTRICTION ON USE OF 2018 PAIN QUESTIONS IN THE HOSPITAL VALUE-BASED PURCHASING PROGRAM.—Section 1886(o)(2)(B) of the Social Security Act (42 U.S.C. 1395ww(o)(2)(B)) is amended by adding at the end the following new clause:

''(iii) HCAHPS PAIN QUESTIONS.—The Secretary may not include under subparagraph (A) a measure that is based on the questions appearing on the Hospital Consumer Assessment of Healthcare Providers and Systems survey in 2018 about communication by hospital staff with an individual about the individual's pain.''.

# TITLE VII—OTHER HEALTH PROVISIONS

## Subtitle A—Synthetic Drug Awareness

**SEC. 7001. SHORT TITLE.**

This subtitle may be cited as the ''Synthetic Drug Awareness Act of 2018''.

**SEC. 7002. REPORT ON EFFECTS ON PUBLIC HEALTH OF SYNTHETIC DRUG USE.**

(a) IN GENERAL.—Not later than three years after the date of the enactment of this Act, the Surgeon General of the Public Health Service shall submit to Congress a report on the health effects of new psychoactive substances (including synthetic drugs) used since January 2010 by persons who are at least 12 years of age but no more than 18 years of age.

(b) NEW PSYCHOACTIVE SUBSTANCE DEFINED.—For purposes of subsection (a), the term ''new psychoactive substance'' means a controlled substance analogue (as defined in section 102(32) of the Controlled Substances Act (21 U.S.C. 802(32)).

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

**SEC. 7011. SHORT TITLE.**

This subtitle may be cited as the ''Empowering Pharmacists in the Fight Against Opioid Abuse Act''.

**SEC. 7012. PROGRAMS AND MATERIALS FOR TRAINING ON CERTAIN CIRCUMSTANCES UNDER WHICH A PHARMACIST MAY DECLINE TO FILL A PRESCRIPTION.**

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and

Human Services, in consultation with the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Director of the Centers for Disease Control and Prevention, and the Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate programs and materials for training pharmacists, health care providers, and patients on—

(1) circumstances under which a pharmacist may, consistent with section 201 of the Controlled Substances Act (21 U.S.C. 811) and regulations thereunder, including section 1306.04 of title 21, Code of Federal Regulations, decline to fill a prescription for a controlled substance because the pharmacist suspects the prescription is fraudulent, forged, or otherwise indicative of abuse or diversion; and

(2) any Federal requirements pertaining to declining to fill a prescription under such circumstances.

(b) MATERIALS INCLUDED.—In developing materials under subsection (a), the Secretary of Health and Human Services shall include information educating—

(1) pharmacists on how to decline to fill a prescription and actions to take after declining to fill a prescription; and

(2) other health care practitioners and the public on a pharmacist's responsibility to decline to fill prescriptions in certain circumstances.

(c) STAKEHOLDER INPUT.—In developing the programs and materials required under subsection (a), the Secretary of Health and Human Services shall seek input from relevant national, State, and local associations, boards of pharmacy, medical societies, licensing boards, health care practitioners, and patients.

# Subtitle C—Indexing Narcotics, Fentanyl, and Opioids

**SEC. 7021. SHORT TITLE.**

This subtitle may be cited as the ''Indexing Narcotics, Fentanyl, and Opioids Act of 2018'' or the ''INFO Act''.

**SEC. 7022. ESTABLISHMENT OF SUBSTANCE USE DISORDER INFORMATION DASHBOARD.**

Title XVII of the Public Health Service Act (42 U.S.C. 300u et seq.) is amended by adding at the end the following new section:

**''SEC. 1711. ESTABLISHMENT OF SUBSTANCE USE DISORDER INFORMATION DASHBOARD.**

''(a) IN GENERAL.—Not later than six months after the date of the enactment of this section, the Secretary of Health and Human Services shall, in consultation with

the Director of National Drug Control Policy, establish and periodically update a public information dashboard that—

''(1) coordinates information on programs within the Department of Health and Human Services related to the reduction of opioid abuse and other substance use disorders;

''(2) provides access to publicly available data from other Federal agencies; State, local, and Tribal governments; nonprofit organizations; law enforcement; medical experts; public health educators; and research institutions regarding prevention, treatment, recovery, and other services for opioid use disorder and other substance use disorders;

''(3) provides comparable data on substance use disorder prevention and treatment strategies in different regions and population of the United States;

''(4) provides recommendations for health care providers on alternatives to controlled substances for pain management, including approaches studied by the National Institutes of Health Pain Consortium and the National Center for Complimentary and Integrative Health; and

''(5) provides guidelines and best practices for health care providers regarding treatment of substance use disorders.

''(b) CONTROLLED SUBSTANCE DEFINED.—In this section, the term 'controlled substance' has the meaning given that term in section 102 of the Controlled Substances Act (21 U.S.C. 802).''.

**SEC. 7023. INTERAGENCY SUBSTANCE USE DISORDER COORDINATING COMMITTEE.**

(a) ESTABLISHMENT.—Not later than three months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall, in consultation with the Director of National Drug Control Policy, establish a committee, to be known as the Interagency Substance Use Disorder Coordinating Committee (in this section referred to as the ''Committee'' ), to coordinate all efforts within the Department of Health and Human Services concerning substance use disorder.

(b) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The following individuals shall be the Federal members of the Committee:

(A) The Secretary, who shall service as the Chair of the Committee.

(B) The Attorney General of the United States.

(C) The Secretary of Labor.

(D) The Secretary of Housing and Urban Development.

(E) The Secretary of Education.

(F) The Secretary of Veterans Affairs.

(G) The Commissioner of Social Security.

(H) The Assistant Secretary for Mental Health and Substance Use.

(I) The Director of the Centers for Disease Control and Prevention.

(J) The Director of the National Institutes of Health and the Directors of such national research institutes of the National Institutes of Health as the Secretary determines appropriate.

(K) The Administrator of the Centers for Medicare & Medicaid Services.

(L) The Director of National Drug Control Policy.

(M) Representatives of other Federal agencies that serve individuals with substance use disorder.

(2) NON-FEDERAL MEMBERS.—The Committee shall include a minimum of 17 non-Federal members appointed by the Secretary, of which—

(A) at least two such members shall be an individual who has received treatment for a diagnosis of an opioid use disorder;

(B) at least two such members shall be an individual who has received treatment for a diagnosis of a substance use disorder other than an opioid use disorder;

(C) at least two such members shall be a State Alcohol and Substance Abuse Director;

(D) at least two such members shall be a representative of a leading research, advocacy, or service organization for adults with substance use disorder;

(E) at least two such members shall—

(i) be a physician, licensed mental health professional, advance practice registered nurse, or physician assistant; and

(ii) have experience in treating individuals with opioid use disorder or other substance use disorders;

(F) at least one such member shall be a substance use disorder treatment professional

who is employed with an opioid treatment program;

(G) at least one such member shall be a substance use disorder treatment professional who has research or clinical experience in working with racial and ethnic minority populations;

(H) at least one such member shall be a substance use disorder treatment professional who has research or clinical mental health experience in working with medically underserved populations;

(I) at least one such member shall be a State-certified substance use disorder peer support specialist;

(J) at least one such member shall be a drug court judge or a judge with experience in adjudicating cases related to substance use disorder;

(K) at least one such member shall be a law enforcement officer or correctional officer with extensive experience in interacting with adults with a substance use disorder; and

(L) at least one such member shall be an individual with experience providing services for

homeless individuals and working with adults with a substance use disorder.

(c) TERMS.—

(1) IN GENERAL.—A member of the Committee appointed under subsection (b)(2) shall be appointed for a term of three years and may be reappointed for one or more three-year terms.

(2) VACANCIES.—A vacancy on the Committee shall be filled in the same manner in which the original appointment was made. Any individual appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and may serve after the expiration of such term until a successor has been appointed.

(d) MEETINGS.—The Committee shall meet not fewer than two times each year.

(e) DUTIES.—The Committee shall—

(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.

(f) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act, and annually thereafter for the life of the Committee, the Committee shall publish on the public information dashboard established under section 7022(a) a report summarizing the activities carried out by the Committee pursuant to subsection (e), including any findings resulting from such activities.

(2) RECOMMENDATION FOR COMMITTEE EXTENSION.—After the publication of the second report of the Committee under paragraph (1), the Secretary shall submit to Congress a recommendation on whether or not the operations of the Committee should continue after the termination date described in subsection (i).

(g) WORKING GROUPS.—The Committee may establish working groups for purposes of carrying out the duties described in subsection (e). Any such working group shall be composed of members of the Committee (or the designees of such members) and may hold such meetings as are necessary to enable the working group to carry out the duties delegated to the working group.

(h) FEDERAL ADVISORY COMMITTEE ACT.—The Federal Advisory Committee Act (5 U.S.C. App.) shall

apply to the Committee only to the extent that the provisions of such Act do not conflict with the requirements of this section.

(i) SUNSET.—The Committee shall terminate on the date that is six years after the date on which the Committee is established under subsection (a).

# Subtitle D—Ensuring Access to Quality Sober Living

**SEC. 7031. SHORT TITLE.**

This subtitle may be cited as the ''Ensuring Access to Quality Sober Living Act of 2018''.

**SEC. 7032. NATIONAL RECOVERY HOUSING BEST PRACTICES.**

Part P of title III of the Public Health Service Act is amended by adding at the end the following new section:

**''SEC. 399V–7. NATIONAL RECOVERY HOUSING BEST PRACTICES.**

''(a) BEST PRACTICES.—The Secretary of Health and Human Services, in consultation with the Secretary for Housing and Urban Development, patients with a history of opioid use disorder, and other stakeholders, which may include State accrediting entities and reputable providers, analysts, and stakeholders of recovery housing services, such as the National Alliance for Recovery Residences, shall identify or facilitate the development of best

practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.

''(b) DISSEMINATION.—The Secretary shall disseminate the best practices identified or developed under subsection (a) to—

''(1) State agencies, which may include the provision of technical assistance to State agencies seeking to adopt or implement such best practices;

''(2) recovery housing entities; and

''(3) the public, as appropriate.

''(c) DEFINITIONS.—In this section:

''(1) 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.

''(2) The term 'State' includes any of the several States, the District of Columbia, each Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act), and any territory or possession of the United States.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $3,000,000 for the period of fiscal years 2019 through 2021.''.

# Subtitle E—Advancing Cutting Edge Research

**SEC. 7041. SHORT TITLE.**

This subtitle may be cited as the ''Advancing Cutting Edge Research Act'' or the ''ACE Research Act''.

**SEC. 7042. UNIQUE RESEARCH INITIATIVES.**

Section 402(n)(1) of the Public Health Service Act (42 U.S.C. 282(n)(1)) is amended—

(1) in subparagraph (A), by striking ''or'';

(2) in subparagraph (B), by striking the period and inserting ''; or''; and

(3) by adding at the end the following:

''(C) high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to 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. 7051. SHORT TITLE.**

This subtitle may be cited as ''Jessie's Law''.

**SEC. 7052. INCLUSION OF OPIOID ADDICTION HISTORY IN PATIENT RECORDS.**

(a) BEST PRACTICES.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate stakeholders, including a patient with a history of opioid use disorder, an expert in electronic health records, an expert in the confidentiality of patient health information and records, and a health care provider, shall identify or facilitate the development of best practices regarding—

(A) the circumstances under which information that a patient has provided to a health care provider regarding such patient's history of opioid use disorder should, only at the patient's request, be prominently displayed in the medical records (including electronic health records) of such patient;

(B) what constitutes the patient's request for the purpose described in subparagraph (A); and

(C) the process and methods by which the information should be so displayed.

(2) DISSEMINATION.—The Secretary shall disseminate the best practices developed under para-

graph (1) to health care providers and State agencies.

(b) REQUIREMENTS.—In identifying or facilitating the development of best practices under subsection (a), as applicable, the Secretary, in consultation with appropriate stakeholders, shall consider the following:

(1) The potential for addiction relapse or overdose, including overdose death, when opioid medications are prescribed to a patient recovering from opioid use disorder.

(2) The benefits of displaying information about a patient's opioid use disorder history in a manner similar to other potentially lethal medical concerns, including drug allergies and contraindications.

(3) The importance of prominently displaying information about a patient's opioid use disorder when a physician or medical professional is prescribing medication, including methods for avoiding alert fatigue in providers.

(4) The importance of a variety of appropriate medical professionals, including physicians, nurses, and pharmacists, to have access to information described in this section when prescribing or dis-

pensing opioid medication, consistent with Federal and State laws and regulations.

(5) The importance of protecting patient privacy, including the requirements related to consent for disclosure of substance use disorder information under all applicable laws and regulations.

(6) All applicable Federal and State laws and regulations.

**SEC. 7053. COMMUNICATION WITH FAMILIES DURING EMERGENCIES.**

(a) PROMOTING AWARENESS OF AUTHORIZED DISCLOSURES DURING EMERGENCIES.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Health Resources and Services Administration, shall annually develop and disseminate written materials (electronically or by other means) to health care providers regarding permitted disclosures under Federal health care privacy law during emergencies, including overdoses, of certain health information to families, caregivers, and health care providers.

(b) USE OF MATERIAL.—For the purposes of carrying out subsection (a), the Secretary of Health and Human Services may use material produced under section

11004 of the 21st Century Cures Act (42 U.S.C. 1320d–2 note).

# Subtitle G—Safe Disposal of Unused Medication

**SEC. 7061. SHORT TITLE.**

This subtitle may be cited as the ''Safe Disposal of Unused Medication Act''.

**SEC. 7062. DISPOSAL OF CONTROLLED SUBSTANCES OF A DECEASED HOSPICE PATIENT BY EMPLOYEES OF A QUALIFIED HOSPICE PROGRAM.**

Subsection (g) of section 302 of the Controlled Substances Act (21 U.S.C. 822) is amended by adding at the end the following:

''(5)(A) In the case of a person receiving hospice care, an employee of a qualified hospice program, acting within the scope of employment, may handle, without being registered under this section, any controlled substance that was lawfully dispensed to the person receiving hospice care, for the purpose of disposal of the controlled substance after the death of such person, so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law.

''(B) For the purposes of this paragraph:

''(i) The terms 'hospice care' and 'hospice program' have the meanings given to those terms in section 1861(dd) of the Social Security Act.

''(ii) The term 'employee of a qualified hospice program' means a physician, nurse, or other person who—

''(I) is employed by, or pursuant to arrangements made by, a qualified hospice program;

''(II)(aa) is licensed to perform medical or nursing services by the jurisdiction in which the person receiving hospice care was located; and

''(bb) is acting within the scope of such employment in accordance with applicable State law; and

''(III) has completed training through the qualified hospice program regarding the disposal of controlled substances in a secure and responsible manner so as to discourage abuse, misuse, or diversion.

''(iii) The term 'qualified hospice program' means a hospice program that—

''(I) has written policies and procedures for assisting in the disposal of the controlled sub-

stances of a person receiving hospice care after the person's death;

''(II) at the time when the controlled substances are first ordered—

''(aa) provides a copy of the written policies and procedures to the patient or patient representative and family;

''(bb) discusses the policies and procedures with the patient or representative and the family in a language and manner that they understand to ensure that these parties are educated regarding the safe disposal of controlled substances; and

''(cc) documents in the patient's clinical record that the written policies and procedures were provided and discussed; and

''(III) at the time following the disposal of the controlled substances—

''(aa) documents in the patient's clinical record the type of controlled substance, dosage, route of administration, and quantity so disposed; and

''(bb) the time, date, and manner in which that disposal occurred.''.

# Subtitle H—Substance Use Disorder Workforce Loan Repayment

**SEC. 7071. SHORT TITLE.**

This subtitle may be cited as the ''Substance Use Disorder Workforce Loan Repayment Act of 2018''.

**SEC. 7072. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT EMPLOYEES.**

Title VII of the Public Health Service Act is amended—

(1) by redesignating part F as part G; and

(2) by inserting after part E (42 U.S.C. 294n et seq.) the following:

**''PART F—SUBSTANCE USE DISORDER TREATMENT EMPLOYEES**

**''SEC. 781. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT EMPLOYEES.**

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall carry out a program under which—

''(1) the Secretary enters into agreements with individuals to make payments in accordance with subsection (b) on the principal of and interest on any eligible loan; and

''(2) the individuals each agree to complete a period of service in a substance use disorder treatment job, as described in subsection (d).

''(b) PAYMENTS.—For each year of obligated service by an individual pursuant to an agreement under subsection (a), the Secretary shall make a payment to such individual as follows:

''(1) SERVICE IN A SHORTAGE AREA.—The Secretary shall pay—

''(A) for each year of obligated service by an individual pursuant to an agreement under subsection (a), ⅙ of the principal of and interest on each eligible loan of the individual which is outstanding on the date the individual began service pursuant to the agreement; and

''(B) for completion of the sixth and final year of such service, the remainder of such principal and interest.

''(2) MAXIMUM AMOUNT.—The total amount of payments under this section to any individual shall not exceed $250,000.

''(c) ELIGIBLE LOANS.—The loans eligible for repayment under this section are each of the following:

''(1) Any loan for education or training for a substance use disorder treatment job.

''(2) Any loan under part E of title VIII (relating to nursing student loans).

''(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, or Federal Direct Unsubsidized Stafford Loan, or Federal Direct Consolidation Loan (as such terms are used in section 455 of the Higher Education Act of 1965).

''(4) Any Federal Perkins Loan under part E of title I of the Higher Education Act of 1965.

''(5) Any other Federal loan as determined appropriate by the Secretary.

''(d) PERIOD OF SERVICE.—The period of service required by an agreement under subsection (a) shall consist of up to 6 years of full-time employment, with no more than one year passing between any two years of covered employment, in a substance use disorder treatment job in the United States in—

''(1) a Mental Health Professional Shortage Area, as designated under section 332; or

''(2) a county (or a municipality, if not contained within any county) where the mean drug overdose death rate per 100,000 people over the past 3 years for which official data is available from the State, is higher than the most recent available national average overdose death rate per 100,000 peo-

ple, as reported by the Centers for Disease Control and Prevention.

''(e) INELIGIBILITY FOR DOUBLE BENEFITS.—No borrower may, for the same service, receive a reduction of loan obligations or a loan repayment under both—

''(1) this subsection; and

''(2) any Federally supported loan forgiveness program, including under section 338B, 338I, or 846 of this Act, or section 428J, 428 L, 455(m), or 460 of the Higher Education Act of 1965.

''(f) BREACH.—

''(1) LIQUIDATED DAMAGES FORMULA.—The Secretary may establish a liquidated damages formula to be used in the event of a breach of an agreement entered into under subsection (a).

''(2) LIMITATION.—The failure by an individual to complete the full period of service obligated pursuant to such an agreement, taken alone, shall not constitute a breach of the agreement, so long as the individual completed in good faith the years of service for which payments were made to the individual under this section.

''(g) ADDITIONAL CRITERIA.—The Secretary—

''(1) may establish such criteria and rules to carry out this section as the Secretary determines

are needed and in addition to the criteria and rules specified in this section; and

''(2) shall give notice to the committees specified in subsection (h) of any criteria and rules so established.

''(h) REPORT TO CONGRESS.—Not later than 5 years after the date of enactment of the Substance Use Disorder Workforce Loan Repayment Act of 2018, and every other year thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on—

''(1) the number and location of borrowers who have qualified for loan repayments under this section; and

''(2) the impact of this section on the availability of substance use disorder treatment employees nationally and in shortage areas and counties described in subsection (d).

''(i) DEFINITION.—In this section:

''(1) The term 'municipality' means a city, town, or other public body created by or pursuant to State law, or an Indian Tribe.

''(2) The term 'substance use disorder treatment job' means a full-time job (including a fellowship)—

''(A) where the primary intent and function of the job is the direct treatment or recovery support of patients with or in recovery from a substance use disorder, such as a physician, physician assistant, registered nurse, nurse practitioner, advanced practice registered nurse, social worker, recovery coach, mental health counselor, addictions counselor, psychologist or other behavioral health professional, or any other relevant professional as determine by the Secretary; and

''(B) which is located at a substance use disorder treatment program, private physician practice, hospital or health system-affiliated inpatient treatment center or outpatient clinic (including an academic medical center-affiliated treatment program), correctional facility or program, youth detention center or program, inpatient psychiatric facility, crisis stabilization unit, community health center, community mental health or other specialty community behavioral health center, recovery center, school, com-

munity-based organization, telehealth platform, migrant health center, health program or facility operated by a tribe or tribal organization, Federal medical facility, or any other facility as determined appropriate for purposes of this section by the Secretary.

''(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 2019 through 2028.''.

# Subtitle I—Preventing Overdoses While in Emergency Rooms

**SEC. 7081. SHORT TITLE.**

This subtitle may be cited as the ''Preventing Overdoses While in Emergency Rooms Act of 2018''.

**SEC. 7082. PROGRAM TO SUPPORT EMERGENCY ROOM DISCHARGE AND CARE COORDINATION FOR DRUG OVERDOSE PATIENTS.**

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a program (in this subtitle referred to as the ''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 substance use disorder after discharge.

(b) GRANT ESTABLISHMENT AND PARTICIPATION.—

(1) IN GENERAL.—In carrying out the Program, the Secretary shall award grants on a competitive basis to not more than 20 eligible entities described in paragraph (2).

(2) ELIGIBILITY.—

(A) IN GENERAL.—To be eligible for a grant under this subsection, an entity shall be—

(i) a health care site described in subparagraph (B); or

(ii) a health care site coordinator described in subparagraph (C).

(B) HEALTH CARE SITES.—To be eligible for a grant under this section, a health care site shall—

(i) submit an application to the Secretary at such time, in such manner, and containing such information as specified by the Secretary;

(ii) have an emergency department;

(iii)(I) have a licensed health care professional onsite who has a waiver under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense or prescribe covered drugs; or

(II) have a demonstrable plan to hire a sufficient number of full-time licensed health care professionals who have waivers described in subclause (I) to administer such treatment onsite;

(iv) have in place an agreement with a sufficient number and range of entities certified under applicable State and Federal law, such as pursuant to registration or a waiver under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) or certification as described in section 8.2 of title 42 of the Code of Federal Regulations, to provide treatment for substance use disorder such that the entity or the resulting network of entities with an agreement with the hospital cumulatively are capable of providing all evidence-based services for the treatment of substance use disorder, as medically appropriate for the individual involved, including—

(I) medication-assisted treatment;

(II) withdrawal and detoxification services that include patient eval-

uation, stabilization, and readiness for and entry into treatment; and

(III) counseling;

(v) deploy onsite peer recovery specialists to help connect patients with treatment and recovery support services; and

(vi) include the provision of overdose reversal medication in discharge protocols for opioid overdose patients.

(C) HEALTH CARE SITE COORDINATORS.—To be eligible for a grant under this section, a health care site coordinator shall—

(i) be an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 (and exempt from tax under section 501(a) of such Code) or a State, local, or Tribal government;

(ii) submit an application to the Secretary at such time, in such manner, and containing such information as specified by the Secretary; and

(iii) have an agreement with multiple eligible health care sites described in subparagraph (B).

(3) PREFERENCE.—In awarding grants under this section, the Secretary may give preference to eligible entities described in paragraph (2) that meet either or both of the following criteria:

(A) The eligible health care site is, or the eligible health care site coordinator has an agreement described in paragraph (2)(C)(iii) with a site that is, a critical access hospital (as defined in section 1861(mm)(1) of the Social Security Act (42 U.S.C. 1395x(mm)(1))), a low-volume hospital (as defined in section 1886(d)(12)(C)(i) of such Act (42 U.S.C. 1395ww(d)(12)(C)(i))), or a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C. 1395ww(d)(5)(D)(iii))).

(B) The eligible health care site or the eligible health care site coordinator is located in a geographic area with a drug overdose rate that is higher than the national rate, or in a geographic area with a rate of emergency department visits for overdoses that is higher than the national rate, as determined by the Secretary based on the most recent data from the Centers for Disease Control and Prevention.

(4) MEDICATION-ASSISTED TREATMENT DEFINED.—For purposes of this section, the term ''medication-assisted treatment'' means the use of a drug approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), in combination with behavioral health services, to provide an individualized approach to the treatment of substance use disorders, including opioid use disorders.

(c) PERIOD OF GRANT.—A grant awarded to an eligible entity under this section shall be for a period of at least 2 years.

(d) GRANT USES.—

(1) REQUIRED USES.—A grant awarded under this section to an eligible entity shall be used for both of the following purposes:

(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.

(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.

(2) ADDITIONAL PERMISSIBLE USES.—A grant awarded under this section to an eligible entity may be used for any of the following purposes:

(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 treat-

ment for individuals with substance use disorders.

(D) To offer consultation with and referral to other supportive services that help in treatment and recovery.

(e) REPORTING REQUIREMENTS.—

(1) REPORTS BY GRANTEES.—Each eligible entity awarded a grant under this section shall submit to the Secretary an annual report for each year for which the entity has received such grant that includes information on—

(A) the number of individuals treated at the site (or, in the case of an eligible health care site coordinator, at sites covered by the agreement referred to in subsection (b)(2)(C)(iii)) for non-fatal overdoses in the emergency department;

(B) the number of individuals administered each medication-assisted treatment at such site or sites in the emergency department;

(C) the number of individuals referred by such site or sites to other treatment facilities after a non-fatal overdose, the types of such other facilities, and the number of such individ-

uals admitted to such other facilities pursuant to such referrals;

(D) the frequency and number of patient readmissions for non-fatal overdoses and substance use disorder;

(E) for what the grant funding was used; and

(F) the effectiveness of, and any other relevant additional data regarding, having an on-site health care professional to administer and begin medication-assisted treatment for substance use disorders.

(2) REPORT BY SECRETARY.—Not less than one year after the conclusion of the Program, the Secretary shall submit to Congress a report that includes—

(A) findings of the Program;

(B) overall patient outcomes under the Program, such as with respect to hospital readmission;

(C) what percentage of patients treated by a site funded through a grant under this section were readmitted to a hospital for non-fatal or fatal overdose;

(D) an evaluation determining the effectiveness of having a practitioner onsite to administer and begin medication-assisted treatment for substance use disorder; and

(E) a compilation of voluntary guidelines and best practices from the reports submitted under paragraph (1).

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subtitle $50,000,000 for the period of fiscal years 2019 through 2023.

# Subtitle J—Alternatives to Opioids in the Emergency Department

**SEC. 7091. SHORT TITLE.**

This subtitle may be cited as the ''Alternatives to Opioids in the Emergency Department Act'' or the ''ALTO Act''.

**SEC. 7092. EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS DEMONSTRATION PROGRAM.**

(a) DEMONSTRATION PROGRAM GRANTS.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall carry out a demonstration program under which the Secretary shall award grants to hospitals and emergency departments, including freestanding emergency departments, to develop, imple-

ment, enhance, or study alternative pain management protocols and treatments that limit the use and prescription of opioids in emergency departments.

(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), a hospital or emergency department shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) GEOGRAPHIC DIVERSITY.—In awarding grants under this section, the Secretary shall seek to ensure geographical diversity among grant recipients.

(d) USE OF FUNDS.—Grants under subsection (a) shall be used to—

(1) target common painful conditions, such as renal colic, sciatica, headaches, musculoskeletal pain, and extremity fractures;

(2) train providers and other hospital personnel on protocols and the use of treatments that limit the use and prescription of opioids in the emergency department; and

(3) provide alternatives to opioids to patients with painful conditions, not including patients who present with pain related to cancer, end-of-life symptom palliation, or complex multisystem trauma.

(e) CONSULTATION.—The Secretary shall implement a process for recipients of grants under subsection (a) to consult (in a manner that allows for sharing of evidence-based best practices) with each other and with persons having robust knowledge, including emergency departments and physicians that have successfully deployed alternative pain management protocols, such as non-drug approaches studied through the National Center for Complimentary and Integrative Health including acupuncture that limit the use of opioids. The Secretary shall offer to each recipient of a grant under subsection (a) technical support as necessary.

(f) REPORT TO THE SECRETARY.—Each recipient of a grant under this section shall submit to the Secretary (during the period of such grant) annual reports on the progress of the program funded through the grant. These reports shall include, in accordance with State and Federal statutes and regulations regarding disclosure of patient information—

(1) a description of and specific information about the alternative pain management protocols employed;

(2) data on the alternative pain management protocols and treatments employed, including—

(A) during a baseline period before the program began, as defined by the Secretary;

(B) at various stages of the program, as determined by the Secretary; and

(C) the conditions for which the alternative pain management protocols and treatments were employed;

(3) the success of each specific alternative pain management protocol;

(4) data on the opioid prescriptions written, including—

(A) during a baseline period before the program began, as defined by the Secretary;

(B) at various stages of the program, as determined by the Secretary; and

(C) the conditions for which the opioids were prescribed;

(5) the demographic characteristics of patients who were treated with an alternative pain management protocol, including age, sex, race, ethnicity, and insurance status and type;

(6) data on patients who were eventually prescribed opioids after alternative pain management protocols and treatments were employed; and

(7) any other information the Secretary deems necessary.

(g) REPORT TO CONGRESS.—Not later than one year after completion of the demonstration program under this section, the Secretary shall submit a report to the Congress on the results of the demonstration program and include in the report—

(1) the number of applications received and the number funded;

(2) a summary of the reports described in subsection (f), including standardized data; and

(3) recommendations for broader implementation of pain management protocols that limit the use and prescription of opioids in emergency departments or other areas of the health care delivery system.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2019 through 2021.

# Subtitle K—Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now

**SEC. 7101. SHORT TITLE.**

This subtitle may be cited as the ''Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act'' or the ''SCREEN Act''.

**SEC. 7102. DETENTION, REFUSAL, AND DESTRUCTION OF DRUGS OFFERED FOR IMPORTATION.**

(a) INCREASING THE MAXIMUM DOLLAR AMOUNT OF DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''except that the Secretary'' and all that follows through the two periods at the end and inserting ''except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug refused admission under this section, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930 or such higher amount as the Commissioner of Food and Drugs may set based on a finding by the Commissioner that the higher amount is in the interest of public health), or if such drug is entering the United States by

mail, and was not brought into compliance as described under subsection (b).''.

(b) DESTRUCTION OF ARTICLES OF CONCERN.—The sixth sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended by subsection (a), is further amended by inserting before the period at the end the following: ''; and the Secretary of Health and Human Services may destroy, without the opportunity for export, any article refused admission under clause (6) of the third sentence of this subsection''.

(c) TECHNICAL AMENDMENTS.—The seventh, eighth, and ninth sentences of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amended—

(1) by striking ''a drug'' each place it appears and inserting ''an article''; and

(2) by striking ''the drug'' each place it appears and inserting ''the article''.

(d) RULE OF CONSTRUCTION.—The last sentence in section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended to read as follows: ''Clauses (2), (5), and (6) of the third sentence of this subsection shall not be construed to prohibit the admission of narcotic or nonnarcotic drugs or other substances, the

importation of which is permitted under the Controlled Substances Import and Export Act.''.

**SEC. 7103. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUG PRODUCTS.**

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(eee) The failure to comply with any order issued under section 569D.''.

(b) NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

**''SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF ADULTERATED OR MISBRANDED DRUGS.**

''(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—

''(1) IN GENERAL.—Upon a determination that the use or consumption of, or exposure to, a drug may present an imminent or substantial hazard to the public health, the Secretary shall issue an order

requiring any person who distributes the drug to immediately cease distribution of the drug.

''(2) HEARING.—An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on—

''(A) the actions required by the order; and

''(B) whether the order should be amended to require a recall of the drug.

''(3) INADEQUATE GROUNDS.—If, after providing an opportunity for a hearing under paragraph (2), the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

''(4) AMENDMENT TO ORDER TO REQUIRE RECALL.—If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the drug with respect to which the order was issued, the Secretary shall—

''(A) amend the order to require a recall; and

''(B) after consultation with the drug sponsor, specify a timetable in which the recall will occur.

''(5) NOTICE TO PERSONS AFFECTED.—An order under this subsection shall require any person who distributes the drug to provide for notice, including to individuals as appropriate, to persons who may be affected by the order to cease distribution of or recall the drug, as applicable.

''(6) ACTION FOLLOWING ORDER.—Any person who is subject to an order under paragraph (1) or (4) shall immediately cease distribution of or recall, as applicable, the drug and provide notification as required by such order.

''(b) NOTICE TO CONSUMERS AND HEALTH OFFICIALS.—The Secretary shall, as the Secretary determines to be necessary, provide notice of a recall order under this section to—

''(1) consumers to whom the drug was, or may have been, distributed; and

''(2) appropriate State and local health officials.

''(c) ORDER TO RECALL.—

''(1) CONTENTS.—An order to recall a drug under subsection (a) shall—

''(A) require periodic reports to the Secretary describing the progress of the recall; and

''(B) provide for notice, including to individuals as appropriate, to persons who may be affected by the recall.

''(2) ASSISTANCE ALLOWED.—In providing for notice under paragraph (1)(B), the Secretary may allow for the assistance of health professionals, State or local officials, or other individuals designated by the Secretary.

''(3) NONDELEGATION.—An order under this section shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research, is an official senior to such Director, or is so designated by such Director.

''(d) SAVINGS CLAUSE.—Nothing contained in this section shall be construed as limiting—

''(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, an drug under any other provision of this Act or the Public Health Service Act; or

''(2) the ability of the Secretary to request any person to perform a voluntary activity related to any

drug subject to this Act or the Public Health Service Act.''.

(c) DRUGS SUBJECT TO REFUSAL.—The third sentence of subsection (a) of section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by inserting ''or (5) in the case of a drug, such drug is subject to an order under section 568 to cease distribution of or recall the drug,'' before ''then such article shall be refused admission''.

(d) APPLICATION.—Sections 301(eee) and 569D of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall apply with respect to a drug as of such date, not later than 1 year after the date of the enactment of this Act, as the Secretary of Health and Human Services shall specify.

**SEC. 7104. SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.**

Section 801 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF ADULTERATED OR MISBRANDED DRUGS.—If the Secretary identifies a pattern of adulterated or misbranded drugs being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order choose 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.**

Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

**''SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO COMBAT THE OPIOID AND SUBSTANCE USE EPIDEMIC.**

''(a) IN GENERAL.—The Commissioner of Food and Drugs shall use any funds appropriated pursuant to the authorization of appropriations under subsection (c) to carry out the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic. Such funds shall be in addition to any funds which are otherwise available to carry out such programs and activities.

''(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC RESPONSE FUND.—

''(1) ESTABLISHMENT OF FUND.—There is established in the Treasury a fund, to be known as the FDA Opioid and Substance Use Epidemic Response

Fund (referred to in this subsection as the 'Fund'), for purposes of funding the programs and activities described in subsection (d).

''(2) TRANSFER.—For the period of fiscal years 2019 through 2023, $110,000,000 shall be transferred to the Fund from the general fund of the Treasury.

''(3) AMOUNTS DEPOSITED.—Any amounts transferred under paragraph (2) shall remain unavailable in the Fund until such amounts are appropriated pursuant to subsection (c).

''(c) APPROPRIATIONS.—

''(1) AUTHORIZATION OF APPROPRIATIONS.—For the period of fiscal years 2019 through 2023, there is authorized to be appropriated from the Fund to the Food and Drug Administration, for the purpose of carrying out the programs and activities described in subsection (d), an amount not to exceed the total amount transferred to the Fund under subsection (b)(2). Notwithstanding subsection (g), such funds shall remain available until expended.

''(2) OFFSETTING FUTURE APPROPRIATIONS.—For any of fiscal years 2019 through 2023, for any discretionary appropriation out of the Fund to the Food and Drug Administration pursuant to the au-

thorization of appropriations under paragraph (1) for the purpose of carrying out the programs and activities described in subsection (d), the total amount of such appropriations for the applicable fiscal year (not to exceed the total amount remaining in the Fund) shall be subtracted from the estimate of discretionary budget authority and the resulting outlays for any estimate under the Congressional Budget and Impoundment Control Act of 1974 or the Balanced Budget and Emergency Deficit Control Act of 1985, and the amount transferred to the Fund shall be reduced by the same amount.

''(d) FOOD AND DRUG ADMINISTRATION.—The entirety of the funds made available pursuant to subsection (c)(1) shall be for the Commissioner of Food and Drugs, pursuant to applicable authorities in the Public Health Service Act (42 U.S.C. 201 et seq.) or this Act and other applicable Federal law, to support widespread innovation in non-opioid and non-addictive medical products for pain treatment, access to opioid addiction treatments, appropriate use of approved opioids, and efforts to reduce illicit importation of opioids. Such support may include the following programs and activities:

''(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 Food and Drug Administration'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 Internet 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.

''(e) ACCOUNTABILITY AND OVERSIGHT.—

''(1) WORK PLAN.—

''(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Commissioner of Food and Drugs shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a work plan including the proposed allocation of funds appropriated pursuant to the authorization of appropriations under subsection (c) for each of fiscal years 2019 through 2023 and the contents described in subparagraph (B).

''(B) CONTENTS.—The work plan submitted under subparagraph (A) shall include—

''(i) the amount of money to be obligated or expended out of the Fund in each fiscal year for each program and activity described in subsection (d); and

''(ii) a description and justification of each such program and activity.

''(2) REPORTS.—

''(A) ANNUAL REPORTS.—Not later than October 1 of each of fiscal years 2020 through 2024, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

''(i) the amount of money obligated or expended out of the Fund in the prior fiscal year for each program and activity described in subsection (d);

''(ii) a description of all programs and activities using funds provided pursuant to the authorization of appropriations under subsection (c); and

''(iii) how the programs and activities are advancing public health.

''(B) ADDITIONAL REPORTS.—At the request of the Committee on Health, Education, Labor and Pensions of the Senate or the Committee on Energy and Commerce of the House

of Representatives, the Commissioner shall provide an update in the form of testimony and any additional reports to the respective congressional committee regarding the allocation of funding under this section or the description of the programs and activities undertaken with such funding.

''(f) LIMITATIONS.—Notwithstanding any transfer authority authorized by this section or any appropriations Act, any funds made available pursuant to the authorization of appropriations under subsection (c) may not be used for any purpose other than the programs and activities described in subsection (d) to strengthen and facilitate the Food and Drug Administration's efforts to address the opioid and substance use epidemic.

''(g) SUNSET.—This section shall expire on September 30, 2022, except that—

''(1) this subsection does not apply to reporting under subsection (e)(2); and

''(2) this section shall remain in effect until such time, and to such extent, as may be necessary for the funds transferred by subsection (b)(2) to be fully expended.''.

**SEC. 7106. CONSIDERATION OF POTENTIAL FOR MISUSE AND ABUSE REQUIRED FOR DRUG APPROVAL.**

(a) IN GENERAL.—Section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is amended—

(1) in the first sentence—

(A) by striking ''or (7)'' and inserting ''(7)''; and

(B) by inserting ''or (8) if the drug is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, the drug is unsafe for use due to the risks of abuse or misuse or there is insufficient information to show that the drug is safe for use considering such risks;'' before ''he shall issue an order refusing to approve the application''; and

(2) in the second sentence, by striking ''(6)'' and inserting ''(8)''.

(b) WITHDRAWAL AUTHORITY.—Section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) is amended in the first sentence—

(1) by striking ''or (5)'' and inserting ''(5)''; and

(2) by inserting the following: ''; or (6) that, in the case of a drug that is or contains a controlled substance for which a listing in any schedule is in effect under the Controlled Substances Act or that is permanently scheduled pursuant to section 201 of such Act, on the basis of new information before him with respect to such drug, evaluated together with the information available to him when the application was approved, that the drug is unsafe for use due to the risks of abuse or misuse'' after ''of a material fact''.

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed to limit or narrow, in any manner, the meaning or application of the provisions of paragraphs (1), (2), (3), (4), (5), and (7) of section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and (2) of section 505(e) of such Act (21 U.S.C. 355(e)).

# Subtitle L—Treatment, Education, and Community Help to Combat Addiction

**SEC. 7111. SHORT TITLE.**

This subtitle may be cited as the ''Treatment, Education, and Community Help to Combat Addiction Act of 2018'' or the ''TEACH to Combat Addiction Act of 2018''.

**SEC. 7112. ESTABLISHMENT OF REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.**

Part D of title V of the Public Health Service Act is amended by inserting after section 549 (42 U.S.C. 290ee–4) the following new section:

**''SEC. 550. REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.**

''(a) IN GENERAL.—The Secretary, in consultation with such other agencies as are appropriate, shall, subject to the availability of appropriations, establish a solicitation process and award cooperative agreements to eligible entities for the designation of such entities as Regional Centers of Excellence in Substance Use Disorder Education and support of such regional centers of excellence to enhance and improve how health professionals are educated in substance use disorder prevention, treatment, and re-

covery through development, evaluation, and distribution of evidence-based curricula for health profession schools. An eligible entity designated by the Secretary as a Regional Center of Excellence in Substance Use Disorder Education shall carry out the activities described in subsection (b).

''(b) SELECTION OF CENTERS OF EXCELLENCE.—

''(1) ELIGIBLE ENTITIES.—To be eligible to receive a cooperative agreement under subsection (a), an entity shall—

''(A) be an entity specified by the Secretary that offers education to students in various health professions, which may include—

''(i) a health system;

''(ii) a teaching hospital;

''(iii) a medical school;

''(iv) a certified behavioral health clinic; or

''(v) any other health profession school, 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.

''(2) DIVERSITY.—In awarding cooperative agreements under subsection (a), the Secretary shall take into account regional differences among eligible entities and shall make an effort to ensure geographic diversity.

''(c) DISSEMINATION OF INFORMATION.—

''(1) PUBLIC POSTING.—The Secretary shall make information provided to the Secretary under subsection (b)(1)(E) publically available on the Internet website of the Department of Health and Human Services.

''(2) EVALUATION.—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.

''(d) FUNDING.—There is authorized to be appropriated to carry out this section, $4,000,000 for each of fiscal years 2019 through 2023.''.

# Subtitle M—Guidance From National Mental Health and Substance Use Policy Laboratory

### SEC. 7121. GUIDANCE FROM NATIONAL MENTAL HEALTH AND SUBSTANCE USE POLICY LABORATORY.

Section 501A(b) of the Public Health Service Act (42 U.S.C. 290aa–0(b)) is amended—

(1) in paragraph (5), by striking ''and'' at the end;

(2) in paragraph (6), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(7) issue and periodically update guidance for entities applying for grants from the Substance Abuse and Mental Health Services Administration 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.''.

# Subtitle N—Comprehensive Opioid Recovery Centers

**SEC. 7131. SHORT TITLE.**

This subtitle may be cited as the ''Comprehensive Opioid Recovery Centers Act of 2018''.

**SEC. 7132. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

(a) IN GENERAL.—Part D of title V of the Public Health Service Act is amended by adding at the end the following new section:

**''SEC. 550. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

''(a) IN GENERAL.—The Secretary shall award grants on a competitive basis to eligible entities to estab-

lish or operate a comprehensive opioid recovery center (referred to in this section as a 'Center').

''(b) GRANT PERIOD.—

''(1) IN GENERAL.—A grant awarded under subsection (a) shall be for a period not less than three years and not more than five years.

''(2) RENEWAL.—A grant awarded under subsection (a) may be renewed, on a competitive basis, for additional periods of time, as determined by the Secretary. In determining whether to renew a grant under this paragraph, the Secretary shall consider the data submitted under subsection (h).

''(c) MINIMUM NUMBER OF CENTERS.—The Secretary shall allocate the amounts made available under subsection (i) in such amounts that not fewer than 10 Centers will be established across the United States.

''(d) APPLICATION.—In order to be eligible for a grant under subsection (a), an entity shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include—

''(1) evidence that such entity carries out, or is capable of coordinating with other entities to carry out, the activities described in subsection (g); and

''(2) such other information as the Secretary may require.

''(e) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to eligible entities located in a State or Indian country (as defined in section 1151 of title 18, United States Code)—

''(1) with a high per capita drug overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention; or

''(2) based on any other criteria or need, as determined by the Secretary.

''(f) USE OF GRANT FUNDS.—An eligible entity awarded a grant under subsection (a) shall use the grant funds to establish or operate a Center to carry out the activities described in subsection (g).

''(g) CENTER ACTIVITIES AND SERVICES.—Each Center shall, at a minimum, carry out the activities described in this subsection. In the case of a Center that determines that a service described in paragraph (2) cannot reasonably be carried out by the Center, such Center shall contract with such other entities as may be necessary to ensure that patients have access to the full range of services described in such paragraph.

''(1) COMMUNITY OUTREACH.—Each Center shall carry out the following outreach activities:

''(A) Train and supervise 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.

''(B) Disseminate and make available online evidence-based resources that educate professionals and the public on opioid use disorder and other substance use disorders.

''(2) TREATMENT AND RECOVERY SERVICES.—Each Center shall provide the following treatment and recovery services:

''(A) Ensure that intake evaluations meet the clinical needs of patients.

''(B) Periodically conduct patient assessments to ensure continued and meaningful recovery, as defined by the Assistant Secretary for Mental Health and Substance Use.

''(C) Provide the full continuum of treatment services, including—

''(i) all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act and all biological products licensed under section 351 of this Act, in-

cluding methadone, to treat substance use disorders, including opioid use disorder and alcohol use disorder;

''(ii) withdrawal management, which shall include medically supervised detoxification that includes patient evaluation, stabilization, and readiness for and entry into treatment;

''(iii) counseling and case management, including counseling and recovery services for any possible co-occurring mental illness;

''(iv) residential rehabilitation;

''(v) recovery housing;

''(vi) community-based and peer recovery support services;

''(vii) job training and placement assistance to support reintegration into the workforce; and

''(viii) other best practices, as determined by the Secretary.

''(D) Administer an onsite pharmacy and provide toxicology services.

''(E) Establish and operate a secure and confidential electronic health information system.

''(F) Offer family support services such as child care, family counseling, and parenting interventions to help stabilize families impacted by substance use disorder.

''(h) DATA REPORTING AND PROGRAM OVERSIGHT.—With respect to a grant awarded under subsection (a) to an eligible entity for a Center, not later than 90 days after the end of the first year of the grant period, and annually thereafter for the duration of the grant period (including the duration of any renewal period for such grant), the entity shall submit data, as appropriate, to the Secretary regarding—

''(1) the programs and activities funded by the grant;

''(2) health outcomes of individuals with a substance use disorder who received services from the Center;

''(3) the effectiveness of interventions designed, tested, and evaluated by the Center; and

''(4) any other information that the Secretary may require for the purpose of—

''(A) evaluating the effectiveness of the Center; and

''(B) ensuring that the Center is complying with all the requirements of the grant, including providing the full continuum of services described in subsection (g)(2)(C) and providing drugs and devices for overdose reversal under such subsection.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 for each of fiscal years 2019 through 2023 for purposes of carrying out this section.''.

(b) REPORTS TO CONGRESS.—

(1) PRELIMINARY REPORT.—Not later than three years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a preliminary report that analyzes data submitted under section 550(h) of the Public Health Service Act, as added by subsection (a).

(2) FINAL REPORT.—Not later than one year after submitting the preliminary report required under paragraph (1), the Secretary of Health and Human Services shall submit to Congress a final report that includes—

(A) an evaluation of the effectiveness of comprehensive opioid recovery centers established or operated pursuant to section 550 of the Public Health Service Act, as added by subsection (a);

(B) recommendations on whether the grant program established under such section 550 should be reauthorized and expanded; and

(C) standards and best practices for the treatment of substance use disorders, as identified through such grant program.

# Subtitle O—Poison Center Network Enhancement

**SEC. 7141. SHORT TITLE.**

This subtitle may be cited as the ''Poison Center Network Enhancement Act of 2018''.

**SEC. 7142. REAUTHORIZATION OF POISON CONTROL CENTERS NATIONAL TOLL-FREE NUMBER.**

Section 1271 of the Public Health Service Act (42 U.S.C. 300d–71) is amended to read as follows:

**''SEC. 1271. ESTABLISHMENT AND MAINTENANCE OF THE NATIONAL TOLL-FREE NUMBER AND ENHANCED COMMUNICATIONS CAPABILITIES.**

''(a) IN GENERAL.—The Secretary shall provide coordination and assistance to poison control centers for—

''(1) the development, establishment, implementation, and maintenance of a nationwide toll-free phone number; and

''(2) the enhancement of communications capabilities, which may include text capabilities.

''(b) CONSULTATION.—The Secretary may consult with nationally recognized professional organizations in the field of poison control to determine the best and most effective means of achieving the goals described in paragraphs (1) and (2) of subsection (a).

''(c) RULE OF CONSTRUCTION.—In assisting with public health emergencies, responses, or preparedness, nothing in this section shall be construed to restrict the work of poison control centers or the use of their resources by the Secretary or other governmental agencies.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $700,000 for each of fiscal years 2019 through 2023.''.

**SEC. 7143. REAUTHORIZATION OF NATIONWIDE PUBLIC AWARENESS CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION.**

Section 1272 of the Public Health Service Act (42 U.S.C. 300d–72) is amended to read as follows:

**"SEC. 1272. NATIONWIDE PUBLIC AWARENESS CAMPAIGN TO PROMOTE POISON CONTROL CENTER UTILIZATION AND THEIR PUBLIC HEALTH EMERGENCY RESPONSE CAPABILITIES.**

''(a) IN GENERAL.—The Secretary shall—

''(1) carry out, and expand upon, a national public awareness campaign to educate the public and health care providers about—

''(A) poisoning, toxic exposure, and drug misuse prevention; and

''(B) the availability of poison control center resources in local communities; and

''(2) as part of such campaign, highlight the nationwide toll-free number and enhanced communications capabilities supported under section 1271.

''(b) CONSULTATION.—In carrying out and expanding upon the national campaign under subsection (a), the Secretary may consult with nationally recognized professional organizations in the field of poison control response for the purpose of determining the best and most effective methods for achieving public awareness.

''(c) CONTRACT WITH ENTITY.—The Secretary may carry out subsection (a) by entering into contracts with one or more public or private entities, including nationally recognized professional organizations in the field of poison control and national media firms, for the development and

implementation of the awareness campaign under subsection (a), which may include—

''(1) the development and distribution of poisoning and toxic exposure prevention, poison control center, and public health emergency awareness and response materials;

''(2) television, radio, internet, and newspaper public service announcements; and

''(3) other means and activities to provide for public and professional awareness and education.

''(d) EVALUATION.—The Secretary shall—

''(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide public awareness campaign carried out under this section; and

''(2) on a biennial basis, prepare and submit to the appropriate committees of Congress an evaluation of the nationwide public awareness campaign.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $800,000 for each of fiscal years 2019 through 2023.''.

**SEC. 7144. REAUTHORIZATION OF THE POISON CONTROL CENTER GRANT PROGRAM.**

Section 1273 of the Public Health Service Act (42 U.S.C. 300d–73) is amended to read as follows:

**"SEC. 1273. MAINTENANCE OF THE POISON CONTROL CENTER GRANT PROGRAM.**

''(a) AUTHORIZATION OF PROGRAM.—The Secretary shall award grants to poison control centers accredited under subsection (c) (or granted a waiver under subsection (d)) and nationally recognized professional organizations in the field of poison control 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 under subsection (c).

''(b) ADDITIONAL USES OF FUNDS.—In addition to the purposes described in subsection (a), a poison center or professional organization awarded a grant under such subsection may also use amounts received under such grant—

''(1) to research, establish, implement, and evaluate best practices in the United States for poisoning prevention, poison control center outreach, opioid and drug misuse information and response, and public health emergency, response, and preparedness programs;

''(2) to research, develop, implement, revise, and communicate standard patient management guidelines for commonly encountered toxic exposures;

''(3) to improve national toxic exposure and opioid misuse surveillance by enhancing cooperative activities between poison control centers in the United States and the Centers for Disease Control and Prevention and other governmental agencies;

''(4) to research, improve, and enhance the communications and response capability and capacity of the Nation's network of poison control centers to facilitate increased access to the centers through the integration and modernization of the current poison control centers communications and data system, including enhancing the network's telephony, internet, data, and social networking technologies;

''(5) to develop, support, and enhance technology and capabilities of nationally recognized professional organizations in the field of poison control to collect national poisoning, toxic occurrence, and related public health data;

''(6) to develop initiatives to foster the enhanced public health utilization of national poison data collected by such organizations;

''(7) to support and expand the toxicologic expertise within poison control centers; and

''(8) to improve the capacity of poison control centers to answer high volumes of contacts and internet communications, and to sustain and enhance the poison control center's network capability to respond during times of national crisis or other public health emergencies.

''(c) ACCREDITATION.—Except as provided in subsection (d), the Secretary may award a grant to a poison control center under subsection (a) only if—

''(1) the center has been accredited by a nationally recognized professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning; or

''(2) the center has been accredited by a State government, and the Secretary has approved the State government as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning.

''(d) WAIVER OF ACCREDITATION REQUIREMENTS.—

''(1) IN GENERAL.—The Secretary may grant a waiver of the accreditation requirements of subsection (c) with respect to a nonaccredited poison control center that applies for a grant under this section if such center can reasonably demonstrate that the center will obtain such an accreditation within a reasonable period of time as determined appropriate by the Secretary.

''(2) RENEWAL.—The Secretary may renew a waiver under paragraph (1).

''(3) LIMITATION.—The Secretary may not, after the date of enactment of the Poison Control Network Enhancement Act of 2018, grant to a poison control center waivers or renewals that total more than 5 years.

''(e) SUPPLEMENT NOT SUPPLANT.—Amounts made available to a poison control center under this section shall be used to supplement and not supplant other Federal, State, or local funds provided for such center.

''(f) MAINTENANCE OF EFFORT.—A poison control center, in utilizing the proceeds of a grant under this section, shall maintain the annual recurring expenditures of the center for its activities at a level that is not less than 80 percent of the average level of such recurring expendi-

tures maintained by the center for the preceding 3 fiscal years for which a grant is received.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $28,600,000 for each of fiscal years 2019 through 2023. The Secretary may utilize an amount not to exceed 6 percent of the amount appropriated pursuant to the preceding sentence for each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions, which are determined by the Secretary to be appropriate for carrying out the program under this section.''.

# Subtitle P—Eliminating Opioid Related Infectious Diseases

**SEC. 7151. SHORT TITLE.**

This subtitle may be cited as the ''Eliminating Opioid Related Infectious Diseases Act of 2018''.

**SEC. 7152. REAUTHORIZATION AND EXPANSION OF PROGRAM OF SURVEILLANCE AND EDUCATION REGARDING INFECTIONS ASSOCIATED WITH ILLICIT DRUG USE AND OTHER RISK FACTORS.**

Section 317N of the Public Health Service Act (42 U.S.C. 247b–15) is amended to read as follows:

**"SEC. 317N. SURVEILLANCE AND EDUCATION REGARDING INFECTIONS ASSOCIATED WITH ILLICIT DRUG USE AND OTHER RISK FACTORS.**

''(a) IN GENERAL.—The Secretary may (directly and through grants to public and nonprofit private entities) provide for programs for 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, human immunodeficiency virus, and infective endocarditis, and to assist the States in determining the prevalence of such infections, which may include the reporting of cases 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 identified under paragraph (2) 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 described in paragraph (1), with priority given to high-risk populations as determined by the Secretary.

''(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 described in paragraph (1), with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, obstetrician-gynecologists, infectious diseases clinicians, and HIV clinicians.

''(b) LABORATORY PROCEDURES.—The Secretary may (directly or through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding infections described in subsection (a)(1).

''(c) DEFINITIONS.—In this section:

''(1) The term 'Indian tribe' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.

''(2) The term 'injection drug use' means—

''(A) intravenous administration of a substance in schedule I under section 202 of the Controlled Substances Act;

''(B) intravenous administration of a substance in schedule II, III, IV, or V under section 202 of the Controlled Substances Act that has not been approved for intravenous use under—

''(i) section 505 of the Federal Food, Drug and Cosmetic Act; or

''(ii) section 351 of the Public Health Service Act; or

''(C) intravenous administration of a substance in schedule II, III, IV, or V under section 202 of the Controlled Substances Act that has not been prescribed to the person using the substance.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for each of the fiscal years 2019 through 2023.''.

# Subtitle Q—Better Pain Management Through Better Data

**SEC. 7161. SHORT TITLE.**

This subtitle may be cited as the ''Better Pain Management Through Better Data Act of 2018''.

**SEC. 7162. GUIDANCE ADDRESSING ALTERNATIVE APPROACHES TO DATA COLLECTION AND LABELING CLAIMS FOR OPIOID SPARING.**

(a) IN GENERAL.—For purposes of assisting sponsors in collecting and incorporating opioid-sparing data in product labeling, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall conduct a public meeting and update or issue one or more guidances in accordance with subsection (b).

(b) GUIDANCE.—

(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall update or issue one or more guidances addressing—

(A) alternative methods for data collection on opioid sparing;

(B) alternative methods for inclusion of such data in product labeling; and

(C) investigations other than clinical trials, including partially controlled studies and objec-

tive trials without matched controls such as historically controlled analyses, open-label studies, and meta-analyses, on opioid sparing for inclusion in product labeling.

(2) CONTENTS.—The guidances under paragraph (1) shall address—

(A) innovative clinical trial designs for ethically and efficiently collecting data on opioid sparing for inclusion in product labeling;

(B) primary and secondary endpoints for the reduction of opioid use while maintaining adequate pain control;

(C) use of real world evidence, including patient registries, and patient reported outcomes to support inclusion of opioid-sparing data in product labeling; and

(D) how sponsors may obtain feedback from the Secretary relating to such issues prior to—

(i) commencement of such data collection; or

(ii) the submission of resulting data to the Secretary.

(3) PUBLIC MEETING.—Prior to updating or issuing the guidances required by paragraph (1), the

Secretary shall consult with stakeholders, including representatives of regulated industry, academia, patients, and provider organizations, through a public meeting to be held not later than 12 months after the date of enactment of this Act.

(4) TIMING.—The Secretary shall—

(A) not later than 12 months after the date of the public meeting required by paragraph (3), update or issue the one or more draft guidances required by paragraph (1); and

(B) not later than 12 months after the date on which the public comment period for such draft guidances closes, finalize such guidances.

(c) DEFINITION.—In this section:

(1) The terms ''opioid sparing'' and ''opioid-sparing'' refer to the use of drugs or devices (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that reduce pain while enabling the reduction, replacement, or avoidance of oral opioids.

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

# Subtitle R—Special Registration for Telemedicine Clarification

**SEC. 7171. SHORT TITLE.**

This subtitle may be cited as the ''Special Registration for Telemedicine Clarification Act of 2018''.

**SEC. 7172. DEADLINE FOR INTERIM FINAL REGULATIONS FOR A SPECIAL REGISTRATION TO ENGAGE IN THE PRACTICE OF TELEMEDICINE.**

Section 311(h)(2) of the Controlled Substances Act (21 U.S.C. 831(h)(2)) is amended by striking ''The Attorney General shall, with the concurrence of the Secretary, promulgate regulations'' and inserting ''Not later than 1 year after the date of enactment of the Special Registration for Telemedicine Clarification Act of 2018, the Attorney General shall, with the concurrence of the Secretary, promulgate interim final regulations''.

# Subtitle S—Peer Support Communities of Recovery

**SEC. 7181. SHORT TITLE.**

This subtitle may be cited as the ''Peer Support Communities of Recovery Act''.

**SEC. 7182. BUILDING COMMUNITIES OF RECOVERY.**

Section 547 of the Public Health Service Act (42 U.S.C. 290ee–2) is amended—

(1) in subsection (a)—

(A) in the heading, by striking ''DEFINITION'' and inserting ''DEFINITIONS'';

(B) in the matter preceding paragraph (1), by striking ''In this section, the term 'recovery community organization' means an independent nonprofit organization that—'' and inserting ''In this section:'';

(C) by redesignating paragraphs (1) and (2) as subparagraphs (A) and (B), respectively, and moving such subparagraphs (as so redesignated) 2 ems to the right;

(D) by inserting before subparagraph (A) (as so redesignated) the following:

''(1) RECOVERY COMMUNITY ORGANIZATION.—The term 'recovery community organization' means an independent nonprofit organization that—''; and

(E) by adding at the end the following:

''(2) ELIGIBLE ENTITY.—The term 'eligible entity' means—

''(A) a national nonprofit entity focused on substance use disorder with a network of local affiliates and partners that are geographically and organizationally diverse; or

''(B) a nonprofit organization—

''(i) focused on substance use disorder;

''(ii) established by individuals in personal or family recovery; and

''(iii) serving prevention, treatment, recovery, payor, faith-based, and criminal justice stakeholders in the implementation of local addiction and recovery initiatives.'';

(2) in subsection (b)—

(A) by striking ''The Secretary shall award grants to recovery community organizations'' and inserting ''The Secretary—

''(1) shall award grants to recovery community organizations'';

(B) by striking ''services.'' and inserting ''services and allow such organizations to use such grant funds to carry out the activities described in subparagraphs (A) through (C) of subsection (c)(2); and''; and

(C) by adding at the end the following:

''(2) may award grants to eligible entities for purposes of establishing regional technical assistance centers, in accordance with subsection (c)(2)(D).'';

(3) by striking subsection (c);

(4) by redesignating subsections (d) and (e) as subsections (c) and (d), respectively;

(5) in subsection (c) (as so redesignated)—

(A) in paragraph (1), by striking ''shall be used'' and inserting ''to a recovery community organization shall be used'';

(B) in paragraph (2)—

(i) in subparagraph (A), in the matter preceding clause (i), by inserting before ''build'' the following: ''in the case of a grant awarded to a recovery community organization,'';

(ii) in subparagraph (B)—

(I) by inserting before ''reduce'' the following: ''in the case of a grant awarded to a recovery community organization,''; and

(II) by striking ''and'' at the end;

(iii) in subparagraph (C)—

(I) by inserting before ''conduct'' the following: ''in the case of a grant awarded to a recovery community organization,''; and

(II) by striking the period at the end and inserting ''; and''; and

(iv) by adding at the end the following:

''(D) in the case of a grant awarded to an eligible entity, provide for the establishment of regional technical assistance centers to provide regional technical assistance for the following:

''(i) Implementation of regionally driven, peer-delivered addiction recovery support services before, during, after, or in conjunction with addiction treatment.

''(ii) Establishment of recovery community organizations.

''(iii) Establishment of recovery community centers.''; and

(6) in subsection (d) (as so redesignated), by inserting before the period the following: '', and $15,000,000 for each of fiscal years 2019 through 2023''.

# Subtitle T—Stop Illicit Drug Importation

**SEC. 7191. SHORT TITLE.**

This short title may be cited as the ''Stop Illicit Drug Importation Act of 2018''.

**SEC. 7192. DETENTION, REFUSAL, AND DESTRUCTION OF DRUGS OFFERED FOR IMPORTATION.**

(a) ARTICLES TREATED AS DRUGS FOR PURPOSES OF IMPORTATION.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following:

''(t) ARTICLES TREATED AS DRUGS FOR PURPOSES OF THIS SECTION.—

''(1) LABELED ARTICLES.—An article shall not be treated as a drug pursuant to this subsection if—

''(A) an electronic import entry for such article is submitted using an authorized electronic data interchange system; and

''(B) such article is designated in such system as a drug, device, dietary supplement, or other product that is regulated under this Act.

''(2) ARTICLES COVERED.—Subject to paragraph (1), for purposes of this section, an article described in this paragraph may be treated by the Secretary as a drug if it—

''(A) is or contains an ingredient that is an active ingredient that is contained within—

''(i) a drug that has been approved under section 505 of this Act; or

''(ii) a biological product that has been approved under section 351 of the Public Health Service Act;

''(B) is or contains an ingredient that is an active ingredient in a drug or biological product if—

''(i) an investigational use exemption has been authorized for such drug or biological product under section 505(i) of this Act or section 351(a) of the Public Health Service Act;

''(ii) substantial clinical investigation has been instituted for such drug or biological product; and

''(iii) the existence of such clinical investigation has been made public; or

''(C) is or contains a substance that has a chemical structure that is substantially similar to the chemical structure of an active ingredient in a drug or biological product described in subparagraph (A) or (B).

''(3) EFFECT.—Except to the extent that an article may be treated as a drug pursuant to paragraph (2), this subsection shall not be construed as bearing on or being relevant to the question of

whether any article is a drug as defined in section 201(g).''.

(b) ARTICLES OF CONCERN.—

(1) DELIVERY BY TREASURY TO HHS.—The first sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''and cosmetics'' and inserting ''cosmetics, and potential articles of concern (as defined in subsection (u))''.

(2) REFUSED ADMISSION.—The third sentence of section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by striking ''then such article shall be refused admission'' and inserting ''or (5) such article is an article of concern (as defined in subsection (u)), or (6) such article is a drug that is being imported or offered for import in violation of section 301(cc), then such article shall be refused admission''.

(3) DEFINITION OF ARTICLE OF CONCERN.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is further amended by adding at the end the following:

''(u) ARTICLE OF CONCERN DEFINED.—For purposes of subsection (a), the term 'article of concern' means an article that is or contains a drug or other substance—

''(1) for which, during the 24-month period prior to the article being imported or offered for import, the Secretary of Health and Human Services—

''(A) has requested that, based on a determination that the drug or other substance appears to meet the requirements for temporary or permanent scheduling pursuant to section 201 of the Controlled Substances Act, the Attorney General initiate the process to control the drug or other substance in accordance with such Act; or

''(B) has, following the publication by the Attorney General of a notice in the Federal Register of the intention to issue an order temporarily scheduling such drug or substance in schedule I of section 202 of the Controlled Substances Act pursuant to section 201(h) of such Act, made a determination that such article presents an imminent hazard to public safety; and

''(2) with respect to which the Attorney General has not—

''(A) scheduled the drug or other substance under such Act; or

''(B) notified the Secretary of Health and Human Services that the Attorney General has made a determination not to schedule the drug or other substance under such Act.''.

**SEC. 7193. SEIZURE.**

Section 304(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(b)) is amended by striking the first sentence and inserting the following: ''The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty rather than the procedure used for civil asset forfeiture proceedings set forth in section 983 of title 18, United States Code. On demand of either party any issue of fact joined in any such a case brought under this section shall be tried by jury. A seizure brought under this section is not governed by Rule G of the Supplemental Rules of Admiralty or Maritime Claims and Asset Forfeiture Actions. Exigent circumstances shall be deemed to exist for all seizures brought under this section, and in such cases, the summons and arrest warrant shall be issued by the clerk of the court without court review.''.

**SEC. 7194. DEBARRING VIOLATIVE INDIVIDUALS OR COMPANIES.**

(a) PROHIBITED ACT.—Section 301(cc) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc)) is amended—

(1) by inserting after ''an article of food'' the following: ''or a drug''; and

(2) by inserting after ''a person debarred'' the following: ''from such activity''.

(b) DEBARMENT.—Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended—

(1) in paragraph (1)—

(A) in the matter preceding subparagraph (A), by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(B) in subparagraph (B), by striking ''or'' at the end;

(C) in subparagraph (C), by striking the period at the end and inserting '', or''; and

(D) by adding at the end the following:

''(D) a person from importing or offering to import into the United States—

''(i) a controlled substance as defined in section 102(6) of the Controlled Substances Act; or

''(ii) any drug, if such drug is declared to be valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 498(a)(1) of the Tariff Act of 1930), or if such drug is entering the United States by mail.''; and

(2) in paragraph (3)—

(A) in the paragraph heading after ''FOOD'' by inserting ''OR DRUG'';

(B) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively, and moving the indentation of each such clause 2 ems to the right;

(C) after making the amendments required by subparagraph (B), by striking ''A person is subject'' and inserting the following:

''(A) FOOD.—A person is subject''; and

(D) by adding at the end the following:

''(B) IMPORTATION OF DRUGS.—A person is subject to debarment under paragraph (1)(D) if—

''(i) the person has been convicted of a felony for conduct relating to the importation into the United States of any drug

or controlled substance (as defined in section 102 of the Controlled Substances Act); or

''(ii) the person has engaged in a pattern of importing or offering for import articles of drug that are—

''(I)(aa) adulterated, misbranded, or in violation of section 505; and

''(bb) present a threat of serious adverse health consequences or death to humans or animals; or

''(II) controlled substances whose importation is prohibited pursuant to section 401(m) of the Tariff Act of 1930.

''(C) DEFINITION.—For purposes of subparagraph (B), the term 'pattern of importing or offering for import articles of drug' means importing or offering for import articles of drug described in subclause (I) or (II) of subparagraph (B)(ii) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.''.

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

**SEC. 7201. SHORT TITLE.**

This subtitle may be cited as the ''Creating Opportunities that Necessitate New and Enhanced Connections That Improve Opioid Navigation Strategies Act of 2018'' or the ''CONNECTIONS Act''.

**SEC. 7202. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.**

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

**''SEC. 399V–7. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.**

''(a) EVIDENCE-BASED PREVENTION GRANTS.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

''(A) to the extent practicable, carry out any evidence-based prevention activity described in paragraph (2);

''(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out any such activity; and

''(C) award grants to States, localities, and Indian tribes for purposes of carrying out any such activity.

''(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:

''(A) With respect to a State, improving the efficiency and use of the State prescription drug monitoring program by—

''(i) encouraging all authorized users (as specified by the State) to register with and use the program and making the program easier to use;

''(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;

''(iii) providing for a mechanism for the program to automatically flag any potential misuse or abuse of controlled substances and any detection of inappropriate

prescribing practices relating to such substances;

''(iv) enhancing interoperability between the program and any electronic health records system, including by integrating the use of electronic health records into the program for purposes of improving clinical decisionmaking;

''(v) continually updating program capabilities to respond to technological innovation for purposes of appropriately addressing a controlled substance overdose epidemic as such epidemic may occur and evolve;

''(vi) facilitating data sharing between the program and the prescription drug monitoring programs of neighboring States; and

''(vii) meeting the purpose of the program established under section 399O, as described in section 399O(a).

''(B) Achieving community or health system interventions through activities such as—

''(i) establishing or improving controlled substances prescribing interventions for insurers and health systems;

''(ii) enhancing the use of evidence-based controlled substances prescribing guidelines across sectors and health care settings; and

''(iii) implementing strategies to align the prescription of controlled substances with the guidelines described in clause (ii).

''(C) Evaluating interventions to better understand what works to prevent overdoses, including those involving prescription and illicit controlled substances.

''(D) Implementing projects to advance an innovative prevention approach with respect to new and emerging public health crises and opportunities to address such crises, such as enhancing public education and awareness on the risks associated with opioids.

''(b) ENHANCED SURVEILLANCE OF CONTROLLED SUBSTANCE OVERDOSE GRANTS.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention may—

''(A) to the extent practicable, carry out any controlled substance overdose surveillance activity described in paragraph (2);

''(B) provide training and technical assistance to States for purposes of carrying out any such activity;

''(C) award grants to States for purposes of carrying out any such activity; and

''(D) coordinate with the Assistant Secretary for Mental Health and Substance Use to collect data pursuant to section 505(d)(1)(A) (relating to the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs).

''(2) CONTROLLED SUBSTANCE OVERDOSE SURVEILLANCE ACTIVITIES.—A controlled substance overdose surveillance activity described in this paragraph is any of the following activities:

''(A) Enhancing the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.

''(B) Enhancing comprehensiveness of data on controlled substances overdoses by collecting information on such overdoses from appropriate sources such as toxicology reports, autopsy re-

ports, death scene investigations, and other risk factors.

''(C) Using data to help identify risk factors associated with controlled substances overdoses.

''(D) With respect to a State, supporting entities involved in providing information to inform efforts within the State, such as by coroners and medical examiners, to improve accurate testing and reporting of causes and contributing factors to controlled substances overdoses.

''(E) Working to enable information sharing regarding controlled substances overdoses among data sources.

''(c) DEFINITIONS.—In this section:

''(1) CONTROLLED SUBSTANCE.—The term 'controlled substance' has the meaning given that term in section 102 of the Controlled Substances Act.

''(2) INDIAN TRIBE.—The term 'Indian tribe' has the meaning given that term in section 4 of the Indian Self-Determination and Education Assistance Act.

''(d) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section and section 399O, there is authorized to be appropriated $486,000,000 for each of fiscal years 2019 through 2023.''.

**SEC. 7203. PRESCRIPTION DRUG MONITORING PROGRAM.**

Section 399O of the Public Health Service Act (42 U.S.C. 280g–3) is amended to read as follows:

**''SEC. 399O. PRESCRIPTION DRUG MONITORING PROGRAM.**

''(a) PROGRAM.—

''(1) IN GENERAL.—Each fiscal year, the Secretary, in consultation with the Director of National Drug Control Policy, acting through the Director of the Centers for Disease Control and Prevention, 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—

''(A) establishment and implementation of a PDMP;

''(B) maintenance of a PDMP;

''(C) improvements to a PDMP by—

''(i) enhancing functional components to work toward—

''(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow, within a State;

''(II) more timely inclusion of data within a PDMP;

''(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

''(IV) ensuring the highest level of ease in use and access of PDMPs by providers and their delegates, to the extent that State laws allow;

''(ii) improving the intrastate interoperability of PDMPs by—

''(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

''(II) linking PDMP data to other data systems within the State, including—

''(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

''(bb) worker's compensation data; and

''(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

''(iii) improving the interstate interoperability of PDMPs through—

''(I) sharing of dispensing data in near-real time across State lines; and

''(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or

''(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

''(2) STATE LEGISLATION.—As a condition on the receipt of support under this section, the Sec-

retary shall require a State to demonstrate that the State has enacted legislation or regulations—

''(A) to provide for the implementation of the PDMP; and

''(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

''(b) PDMP STRATEGIES.—The Secretary shall encourage a State, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

''(1) 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;

''(2) 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;

''(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

''(4) the proactive notification to a practitioner when patterns indicative of controlled substance misuse by a patient, including opioid misuse, are detected;

''(5) the availability of data in the PDMP to other States, as allowable under State law; and

''(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

''(c) DRUG MISUSE AND ABUSE.—In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

''(1) 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

''(2) 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.

''(d) EVALUATION AND REPORTING.—As a condition on receipt of support under this section, the 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 (or the designee of a practitioner, where permitted) requests information about such patient.

''(e) EVALUATION AND REPORTING.—A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

''(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

''(2) to prepare and submit to the Congress the report required by subsection (i)(2).

''(f) EDUCATION AND ACCESS TO THE MONITORING SYSTEM.—A State receiving support under this section shall take steps to—

''(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

''(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

''(g) ELECTRONIC FORMAT.—The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs.

''(h) RULES OF CONSTRUCTION.—

''(1) FUNCTIONS OTHERWISE AUTHORIZED BY LAW.—Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority, to perform functions otherwise authorized by law.

''(2) ADDITIONAL PRIVACY PROTECTIONS.—Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

''(3) FEDERAL PRIVACY REQUIREMENTS.—Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability

and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 543 of this Act.

''(4) NO FEDERAL PRIVATE CAUSE OF ACTION.—Nothing in this section shall be construed to create a Federal private cause of action.

''(i) PROGRESS REPORT.—Not later than 3 years after the date of enactment of the CONNECTIONS Act, the Secretary shall—

''(1) complete a study that—

''(A) determines the progress of States in establishing and implementing PDMPs consistent with this section;

''(B) provides an analysis of the extent to which the operation of PDMPs has—

''(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

''(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

''(iii) affected patient access to appropriate care in States operating PDMPs;

''(C) determine the progress of States in achieving interstate interoperability and intrastate interoperability of PDMPs, including an

assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

''(D) determines the progress of States in implementing near real-time electronic PDMPs;

''(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

''(F) determines the progress of States in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

''(G) evaluates the penalties that States have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

''(2) submit a report to the Congress on the results of the study.

''(j) ADVISORY COUNCIL.—

''(1) ESTABLISHMENT.—A State may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

''(2) LIMITATION.—A State may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

''(3) SENSE OF CONGRESS.—It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State should consult with appropriate professional boards and other interested parties.

''(k) DEFINITIONS.—For purposes of this section:

''(1) The term 'controlled substance' means a controlled substance (as defined in section 102 of the Controlled Substances Act) in schedule II, III, or IV of section 202 of such Act.

''(2) The term 'dispense' means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespec-

tive of whether the dispenser uses the internet or other means to effect such delivery.

''(3) The term 'dispenser' means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

''(4) The term 'interstate interoperability' with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

''(5) The term 'intrastate interoperability' with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

''(6) The term 'nonidentifiable information' means information that does not identify a practitioner, dispenser, or an ultimate user and with re-

spect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

''(7) The term 'PDMP' means a prescription drug monitoring program that is State-controlled.

''(8) The term 'practitioner' means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

''(9) The term 'State' means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

''(10) The term 'ultimate user' means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

''(11) The term 'clinical workflow' means the integration of automated queries for prescription

drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.''.

# Subtitle V—Securing Opioids and Unused Narcotics With Deliberate Disposal and Packaging

**SEC. 7211. SHORT TITLE.**

This subtitle may be cited as the ''Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018'' or the ''SOUND Disposal and Packaging Act''.

**SEC. 7212. IMPROVED TECHNOLOGIES, CONTROLS, OR MEASURES WITH RESPECT TO THE PACKAGING OR DISPOSAL OF CERTAIN DRUGS.**

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 505–1 (21 U.S.C. 355–1) the following new section:

**''SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.**

''(a) ORDERS.—

''(1) IN GENERAL.—The Secretary may issue an order requiring the holder of a covered applica-

tion to implement or modify one or more technologies, controls, or measures with respect to the packaging or disposal of one or more drugs identified in the covered application, if the Secretary determines such technologies, controls, or measures to be appropriate to help mitigate the risk of abuse or misuse of such drug or drugs, which may include by reducing the availability of unused drugs.

''(2) PRIOR CONSULTATION.—The Secretary may not issue an order under paragraph (1) unless the Secretary has consulted with relevant stakeholders, through a public meeting, workshop, or otherwise, about matters that are relevant to the subject of the order.

''(3) ASSURING ACCESS AND MINIMIZING BURDEN.—Technologies, controls, or measures required under paragraph (1) shall—

''(A) be commensurate with the specific risk of abuse or misuse of the drug listed in the covered application;

''(B) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular any available evidence regarding the expected or demonstrated public

health impact of such technologies, controls, or measures; and

''(C) reduce the risk of abuse or misuse of such drug.

''(4) ORDER CONTENTS.—An order issued under paragraph (1) may—

''(A) provide for a range of options for implementing or modifying the technologies, controls, or measures required to be implemented by such order; and

''(B) incorporate by reference standards regarding packaging or disposal set forth in an official compendium, established by a nationally or internationally recognized standard development organization, or described on the public website of the Food and Drug Administration, so long as the order includes the rationale for incorporation of such standard.

''(5) ORDERS APPLICABLE TO DRUG CLASS.—When a concern about the risk of abuse or misuse of a drug relates to a pharmacological class, the Secretary may, after consultation with relevant stakeholders, issue an order under paragraph (1) which applies to the pharmacological class.

''(b) COMPLIANCE.—The holder of a covered application shall—

''(1) submit a supplement containing proposed changes to the covered application to comply with an order issued under subsection (a) not later than—

''(A) 180 calendar days after the date on which the order is issued; or

''(B)(i) such longer time period as specified by the Secretary in such order; or

''(ii) if a request for an alternative date is submitted by the holder of such application not later than 60 calendar days after the date on which such order is issued—

''(I) such requested alternative date if agreed to by the Secretary; or

''(II) another date as specified by the Secretary; and

''(2) implement the changes approved pursuant to such supplement not later than the later of—

''(A) 90 calendar days after the date on which the supplement is approved; or

''(B) the end of such longer period as is—

''(i) determined to be appropriate by the Secretary; or

''(ii) approved by the Secretary pursuant to a request by the holder of the covered application that explains why such longer period is needed, including to satisfy any other applicable Federal statutory or regulatory requirements.

''(c) ALTERNATIVE MEASURES.—The holder of the covered application may propose, and the Secretary shall approve, technologies, controls, or measures regarding packaging, storage, or disposal other than those specified in the applicable order issued under subsection (a), if such technologies, controls, or measures are supported by data and information demonstrating that such alternative technologies, controls, or measures can be expected to mitigate the risk of abuse or misuse of the drug or drugs involved, including by reducing the availability of unused drugs, to at least the same extent as the technologies, controls, or measures specified in such order.

''(d) DISPUTE RESOLUTION.—If a dispute arises in connection with a supplement submitted under subsection (b), the holder of the covered application may appeal a determination made with respect to such supplement using applicable dispute resolution procedures specified by the Secretary in regulations or guidance.

''(e) DEFINITIONS.—In this section—

''(1) the term 'covered application' means an application submitted under subsection (b) or (j) of section 505 for approval under such section or an application submitted under section 351 of Public Health Service Act for approval under such section, with respect to a drug that is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act; and

''(2) the term 'relevant stakeholders' may include scientific experts within the drug manufacturing industry; brand and generic drug manufacturers; standard development organizations; wholesalers and distributors; payers; health care providers; pharmacists; pharmacies; manufacturers; poison centers; and representatives of the National Institute on Drug Abuse, the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Drug Enforcement Agency, the Consumer Product Safety Commission, individuals who specialize in treating addiction, and patient and caregiver groups.''.

(b) PROHIBITED ACTS.—Section 501 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amended by inserting after paragraph (j) the following:

''(k) If it is a drug approved under a covered application (as defined in section 505–2(e)), the holder of which does not meet the requirements of paragraphs (1) and (2) of subsection (b) of such section.''.

(c) REQUIRED CONTENT OF AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(2)(A)) is amended—

(1) in clause (vii)(IV), by striking ''and'' at the end;

(2) in clause (viii), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(ix) if the drug is or contains an opioid for which a listing in schedule II or III (on a temporary or permanent basis) is in effect under section 202 of the Controlled Substances Act, information to show that the applicant has proposed technologies, controls, or measures related to the packaging or disposal of the drug that provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505–2, if applicable.''.

(d) GROUNDS FOR REFUSING TO APPROVE AN ABBREVIATED NEW DRUG APPLICATION.—Section 505(j)(4)

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(4)), is amended—

(1) in subparagraph (J), by striking ''or'' at the end;

(2) in subparagraph (K), by striking the period at the end and inserting ''; or''; and

(3) by adding at the end the following:

''(L) if the drug is a drug described in paragraph (2)(A)(ix) and the applicant has not proposed technologies, controls, or measures related to the packaging or disposal of such drug that the Secretary determines provide protections comparable to those provided by the technologies, controls, or measures required for the applicable listed drug under section 505–2.''.

(e) RULES OF CONSTRUCTION.—

(1) Any labeling describing technologies, controls, or measures related to packaging or disposal intended to mitigate the risk of abuse or misuse of a drug product that is subject to an abbreviated new drug application, including labeling describing differences from the reference listed drug resulting from the application of section 505–2 of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), shall not be construed—

(A) as changes to labeling not permissible under clause (v) of section 505(j)(2)(A) of such Act (21 U.S.C. 355(j)(2)(A)), or a change in the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug under clause (i) of such section; or

(B) to preclude approval of an abbreviated new drug application under subparagraph (B) or (G) of section 505(j)(4) of such Act (21 U.S.C. 355(j)(4)).

(2) For a covered application that is an application submitted under subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), subsection (j)(2)(A) of such section 505 shall not be construed to limit the type of data or information the Secretary of Health and Human Services may request or consider in connection with making any determination under section 505–2.

(f) GAO REPORT.—Not later than 12 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to the Congress a report containing—

(1) a description of available evidence, if any, on the effectiveness of site-of-use, in-home controlled

substance disposal products and packaging technologies;

(2) identification of ways in which such disposal products intended for use by patients, consumers, and other end users that are not registrants under the Controlled Substances Act, are made available to the public and barriers to the use of such disposal products;

(3) identification of ways in which packaging technologies are made available to the public and barriers to the use of such technologies;

(4) a description of Federal oversight, if any, of site-of-use, in-home controlled substance disposal products, including—

(A) identification of the Federal agencies that oversee such products;

(B) identification of the methods of disposal of controlled substances recommended by these agencies for site-of-use, in-home disposal; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances;

(5) a description of Federal oversight, if any, of controlled substance packaging technologies, including—

(A) identification of the Federal agencies that oversee such technologies;

(B) identification of the technologies recommended by these agencies, including unit dose packaging, packaging that provides a set duration, or other packaging systems that may mitigate abuse or misuse; and

(C) a description of the effectiveness of such recommendations at preventing the diversion of legally prescribed controlled substances; and

(6) recommendations on—

(A) whether site-of-use, in-home controlled substance disposal products and packaging technologies require Federal oversight and, if so, which agencies should be responsible for such oversight and, as applicable, approval of such products or technologies; and

(B) the potential role of the Federal Government in evaluating such products to ensure product efficacy.

# Subtitle W—Postapproval Study Requirements

**SEC. 7221. POSTAPPROVAL STUDY REQUIREMENTS.**

(a) PURPOSES OF STUDY.—Section 505(o)(3)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(B)) is amended by adding at the end the following:

''(iv) To assess a potential reduction in effectiveness of the drug for the conditions of use prescribed, recommended, or suggested in the labeling thereof if—

''(I) the drug involved—

''(aa) is or contains a substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act; or

''(bb) is a drug that has not been approved under this section or licensed under section 351 of the Public Health Service Act, for which an application for such approval or licensure is pending or anticipated, and for which the

Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act; and

''(II) the potential reduction in effectiveness could result in the benefits of the drug no longer outweighing the risks.''.

(b) ESTABLISHMENT OF REQUIREMENT.—Section 505(o)(3)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)(C)) is amended by striking ''such requirement'' and all that follows through ''safety information.'' and inserting the following: ''such requirement—

''(i) in the case of a purpose described in clause (i), (ii), or (iii) of subparagraph (B), only if the Secretary becomes aware of new safety information; and

''(ii) in the case of a purpose described in clause (iv) of such subparagraph, if the Secretary determines that new effectiveness information exists.''.

(c) APPLICABILITY.—Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3)) is amended by adding at the end the following new subparagraph:

''(G) APPLICABILITY.—The conduct of a study or clinical trial required pursuant to this paragraph for the purpose specified in subparagraph (B)(iv) shall not be considered a new clinical investigation for the purpose of a period of exclusivity under clause (iii) or (iv) of subsection (c)(3)(E) or clause (iii) or (iv) of subsection (j)(5)(F).''.

(d) NEW EFFECTIVENESS INFORMATION DEFINED.—Section 505(o)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(2)) is amended by adding at the end the following new subparagraph:

''(D) NEW EFFECTIVENESS INFORMATION.—The term 'new effectiveness information', with respect to a drug that is or contains a controlled substance for which a listing in any schedule is in effect (on a temporary or permanent basis) under section 201 of the Controlled Substances Act, means new information about the effectiveness of the drug, including a new analysis of existing information, derived from—

''(i) a clinical trial; an adverse event report; a postapproval study or clinical trial (including a study or clinical trial under paragraph (3));

''(ii) peer-reviewed biomedical literature;

''(iii) data derived from the postmarket risk identification and analysis system under subsection (k); or

''(iv) other scientific data determined to be appropriate by the Secretary.''.

(e) CONFORMING AMENDMENTS WITH RESPECT TO LABELING CHANGES.—Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(4)) is amended—

(1) in subparagraph (A)—

(A) in the heading, by inserting ''OR NEW EFFECTIVENESS'' after ''SAFETY'';

(B) by striking ''safety information'' and inserting ''new safety information or new effectiveness information such''; and

(C) by striking ''believes should be'' and inserting ''believes changes should be made to'';

(2) in subparagraph (B)(i)—

(A) by striking ''new safety information'' and by inserting ''new safety information or new effectiveness information''; and

(B) by inserting ''indications,'' after ''boxed warnings,'';

(3) in subparagraph (C), by inserting ''or new effectiveness information'' after ''safety information''; and

(4) in subparagraph (E), by inserting ''or new effectiveness information'' after ''safety information''.

(f) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed to alter, in any manner, the meaning or application of the provisions of paragraph (3) of section 505(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)) with respect to the authority of the Secretary of Health and Human Services to require a postapproval study or clinical trial for a purpose specified in clauses (i) through (iii) of subparagraph (B) of such paragraph (3) or paragraph (4) of such section 505(o) with respect to the Secretary's authority to require safety labeling changes.

# TITLE VIII—MISCELLANEOUS

## Subtitle A—Synthetics Trafficking and Overdose Prevention

**SEC. 8001. SHORT TITLE; TABLE OF CONTENTS.**

This subtitle may be cited as the ''Synthetics Trafficking and Overdose Prevention Act of 2018'' or ''STOP Act of 2018''.

**SEC. 8002. CUSTOMS FEES.**

(a) IN GENERAL.—Section 13031(b)(9) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(b)(9)) is amended by adding at the end the following:

''(D)(i) With respect to the processing of items that are sent to the United States through the international postal network by 'Inbound Express Mail service' or 'Inbound EMS' (as that service is described in the mail classification schedule referred to in section 3631 of title 39, United States Code), the following payments are required:

''(I) $1 per Inbound EMS item.

''(II) If an Inbound EMS item is formally entered, the fee provided for under subsection (a)(9), if applicable.

''(ii) Notwithstanding section 451 of the Tariff Act of 1930 (19 U.S.C. 1451), the payments re-

quired by clause (i), as allocated pursuant to clause (iii)(I), shall be the only payments required for reimbursement of U.S. Customs and Border Protection for customs services provided in connection with the processing of an Inbound EMS item.

''(iii)(I) The payments required by clause (i)(I) shall be allocated as follows:

''(aa) 50 percent of the amount of the payments shall be paid on a quarterly basis by the United States Postal Service to the Commissioner of U.S. Customs and Border Protection in accordance with regulations prescribed by the Secretary of the Treasury to reimburse U.S. Customs and Border Protection for customs services provided in connection with the processing of Inbound EMS items.

''(bb) 50 percent of the amount of the payments shall be retained by the Postal Service to reimburse the Postal Service for services provided in connection with the customs processing of Inbound EMS items.

''(II) Payments received by U.S. Customs and Border Protection under subclause (I)(aa) shall, in accordance with section 524 of the Tariff Act of 1930 (19 U.S.C. 1524), be deposited in the Customs

User Fee Account and used to directly reimburse each appropriation for the amount paid out of that appropriation for the costs incurred in providing services to international mail facilities. Amounts deposited in accordance with the preceding sentence shall be available until expended for the provision of such services.

''(III) Payments retained by the Postal Service under subclause (I)(bb) shall be used to directly reimburse the Postal Service for the costs incurred in providing services in connection with the customs processing of Inbound EMS items.

''(iv) Beginning in fiscal year 2021, the Secretary, in consultation with the Postmaster General, may adjust, not more frequently than once each fiscal year, the amount described in clause (i)(I) to an amount commensurate with the costs of services provided in connection with the customs processing of Inbound EMS items, consistent with the obligations of the United States under international agreements.''.

(b) CONFORMING AMENDMENTS.—Section 13031(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (19 U.S.C. 58c(a)) is amended—

(1) in paragraph (6), by inserting ''(other than an item subject to a fee under subsection (b)(9)(D))'' after ''customs officer''; and

(2) in paragraph (10)—

(A) in subparagraph (C), in the matter preceding clause (i), by inserting ''(other than Inbound EMS items described in subsection (b)(9)(D))'' after ''release''; and

(B) in the flush at the end, by inserting ''or of Inbound EMS items described in subsection (b)(9)(D),'' after ''(C),''.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2020.

**SEC. 8003. MANDATORY ADVANCE ELECTRONIC INFORMATION FOR POSTAL SHIPMENTS.**

(a) MANDATORY ADVANCE ELECTRONIC INFORMATION.—

(1) IN GENERAL.—Section 343(a)(3)(K) of the Trade Act of 2002 (Public Law 107–210; 19 U.S.C. 2071 note) is amended to read as follows:

''(K)(i) The Secretary shall prescribe regulations requiring the United States Postal Service to transmit the information described in paragraphs (1) and (2) to the Commissioner of U.S. Customs and Border Protection for inter-

national mail shipments by the Postal Service (including shipments to the Postal Service from foreign postal operators that are transported by private carrier) consistent with the requirements of this subparagraph.

''(ii) In prescribing regulations under clause (i), the Secretary shall impose requirements for the transmission to the Commissioner of information described in paragraphs (1) and (2) for mail shipments described in clause (i) that are comparable to the requirements for the transmission of such information imposed on similar non-mail shipments of cargo, taking into account the parameters set forth in subparagraphs (A) through (J).

''(iii) The regulations prescribed under clause (i) shall require the transmission of the information described in paragraphs (1) and (2) with respect to a shipment as soon as practicable in relation to the transportation of the shipment, consistent with subparagraph (H).

''(iv) Regulations prescribed under clause (i) shall allow for the requirements for the transmission to the Commissioner of information described in paragraphs (1) and (2) for

mail shipments described in clause (i) to be implemented in phases, as appropriate, by—

''(I) setting incremental targets for increasing the percentage of such shipments for which information is required to be transmitted to the Commissioner; and

''(II) taking into consideration—

''(aa) the risk posed by such shipments;

''(bb) the volume of mail shipped to the United States by or through a particular country; and

''(cc) the capacities of foreign postal operators to provide that information to the Postal Service.

''(v)(I) Notwithstanding clause (iv), the Postal Service shall, not later than December 31, 2018, arrange for the transmission to the Commissioner of the information described in paragraphs (1) and (2) for not less than 70 percent of the aggregate number of mail shipments, including 100 percent of mail shipments from the People's Republic of China, described in clause (i).

''(II) If the requirements of subclause (I) are not met, the Comptroller General of the United States shall submit to the appropriate congressional committees, not later than June 30, 2019, a report—

''(aa) assessing the reasons for the failure to meet those requirements; and

''(bb) identifying recommendations to improve the collection by the Postal Service of the information described in paragraphs (1) and (2).

''(vi)(I) Notwithstanding clause (iv), the Postal Service shall, not later than December 31, 2020, arrange for the transmission to the Commissioner of the information described in paragraphs (1) and (2) for 100 percent of the aggregate number of mail shipments described in clause (i).

''(II) The Commissioner, in consultation with the Postmaster General, may determine to exclude a country from the requirement described in subclause (I) to transmit information for mail shipments described in clause (i) from the country if the Commissioner determines that the country—

''(aa) does not have the capacity to collect and transmit such information;

''(bb) represents a low risk for mail shipments that violate relevant United States laws and regulations; and

''(cc) accounts for low volumes of mail shipments that can be effectively screened for compliance with relevant United States laws and regulations through an alternate means.

''(III) The Commissioner shall, at a minimum on an annual basis, re-evaluate any determination made under subclause (II) to exclude a country from the requirement described in subclause (I). If, at any time, the Commissioner determines that a country no longer meets the requirements under subclause (II), the Commissioner may not further exclude the country from the requirement described in subclause (I).

''(IV) The Commissioner shall, on an annual basis, submit to the appropriate congressional committees—

''(aa) a list of countries with respect to which the Commissioner has made a de-

termination under subclause (II) to exclude the countries from the requirement described in subclause (I); and

''(bb) information used to support such determination with respect to such countries.

''(vii)(I) The Postmaster General shall, in consultation with the Commissioner, refuse any shipments received after December 31, 2020, for which the information described in paragraphs (1) and (2) is not transmitted as required under this subparagraph, except as provided in subclause (II).

''(II) If remedial action is warranted in lieu of refusal of shipments pursuant to subclause (I), the Postmaster General and the Commissioner shall take remedial action with respect to the shipments, including destruction, seizure, controlled delivery or other law enforcement initiatives, or correction of the failure to provide the information described in paragraphs (1) and (2) with respect to the shipments.

''(viii) Nothing in this subparagraph shall be construed to limit the authority of the Secretary to obtain information relating to inter-

national mail shipments from private carriers or other appropriate parties.

''(ix) In this subparagraph, the term 'appropriate congressional committees' means—

''(I) the Committee on Finance and the Committee on Homeland Security and Governmental Affairs of the Senate; and

''(II) the Committee on Ways and Means, the Committee on Oversight and Government Reform, and the Committee on Homeland Security of the House of Representatives.''.

(2) JOINT STRATEGIC PLAN ON MANDATORY ADVANCE INFORMATION.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Homeland Security and the Postmaster General shall develop and submit to the appropriate congressional committees a joint strategic plan detailing specific performance measures for achieving—

(A) the transmission of information as required by section 343(a)(3)(K) of the Trade Act of 2002, as amended by paragraph (1); and

(B) the presentation by the Postal Service to U.S. Customs and Border Protection of all

mail targeted by U.S. Customs and Border Protection for inspection.

(b) CAPACITY BUILDING.—

(1) IN GENERAL.—Section 343(a) of the Trade Act of 2002 (Public Law 107–210; 19 U.S.C. 2071 note) is amended by adding at the end the following:

''(5) CAPACITY BUILDING.—

''(A) IN GENERAL.—The Secretary, with the concurrence of the Secretary of State, and in coordination with the Postmaster General and the heads of other Federal agencies, as appropriate, may provide technical assistance, equipment, technology, and training to enhance the capacity of foreign postal operators—

''(i) to gather and provide the information required by paragraph (3)(K); and

''(ii) to otherwise gather and provide postal shipment information related to—

''(I) terrorism;

''(II) items the importation or introduction of which into the United States is prohibited or restricted, including controlled substances; and

''(III) such other concerns as the Secretary determines appropriate.

''(B) PROVISION OF EQUIPMENT AND TECHNOLOGY.—With respect to the provision of equipment and technology under subparagraph (A), the Secretary may lease, loan, provide, or otherwise assist in the deployment of such equipment and technology under such terms and conditions as the Secretary may prescribe, including nonreimbursable loans or the transfer of ownership of equipment and technology.''.

(2) JOINT STRATEGIC PLAN ON CAPACITY BUILDING.—Not later than one year after the date of the enactment of this Act, the Secretary of Homeland Security and the Postmaster General shall, in consultation with the Secretary of State, jointly develop and submit to the appropriate congressional committees a joint strategic plan—

(A) detailing the extent to which U.S. Customs and Border Protection and the United States Postal Service are engaged in capacity building efforts under section 343(a)(5) of the Trade Act of 2002, as added by paragraph (1);

(B) describing plans for future capacity building efforts; and

(C) assessing how capacity building has increased the ability of U.S. Customs and Border

Protection and the Postal Service to advance the goals of this subtitle and the amendments made by this subtitle.

(c) REPORT AND CONSULTATIONS BY SECRETARY OF HOMELAND SECURITY AND POSTMASTER GENERAL.—

(1) REPORT.—Not later than 180 days after the date of the enactment of this Act, and annually thereafter until 3 years after the Postmaster General has met the requirement under clause (vi) of subparagraph (K) of section 343(a)(3) of the Trade Act of 2002, as amended by subsection (a)(1), the Secretary of Homeland Security and the Postmaster General shall, in consultation with the Secretary of State, jointly submit to the appropriate congressional committees a report on compliance with that subparagraph that includes the following:

(A) An assessment of the status of the regulations required to be promulgated under that subparagraph.

(B) An update regarding new and existing agreements reached with foreign postal operators for the transmission of the information required by that subparagraph.

(C) A summary of deliberations between the United States Postal Service and foreign

postal operators with respect to issues relating to the transmission of that information.

(D) A summary of the progress made in achieving the transmission of that information for the percentage of shipments required by that subparagraph.

(E) An assessment of the quality of that information being received by foreign postal operators, as determined by the Secretary of Homeland Security, and actions taken to improve the quality of that information.

(F) A summary of policies established by the Universal Postal Union that may affect the ability of the Postmaster General to obtain the transmission of that information.

(G) A summary of the use of technology to detect illicit synthetic opioids and other illegal substances in international mail parcels and planned acquisitions and advancements in such technology.

(H) Such other information as the Secretary of Homeland Security and the Postmaster General consider appropriate with respect to obtaining the transmission of information required by that subparagraph.

(2) CONSULTATIONS.—Not later than 180 days after the date of the enactment of this Act, and every 180 days thereafter until the Postmaster General has met the requirement under clause (vi) of section 343(a)(3)(K) of the Trade Act of 2002, as amended by subsection (a)(1), to arrange for the transmission of information with respect to 100 percent of the aggregate number of mail shipments described in clause (i) of that section, the Secretary of Homeland Security and the Postmaster General shall provide briefings to the appropriate congressional committees on the progress made in achieving the transmission of that information for that percentage of shipments.

(d) GOVERNMENT ACCOUNTABILITY OFFICE REPORT.—Not later than June 30, 2019, the Comptroller General of the United States shall submit to the appropriate congressional committees a report—

(1) assessing the progress of the United States Postal Service in achieving the transmission of the information required by subparagraph (K) of section 343(a)(3) of the Trade Act of 2002, as amended by subsection (a)(1), for the percentage of shipments required by that subparagraph;

(2) assessing the quality of the information received from foreign postal operators for targeting purposes;

(3) assessing the specific percentage of targeted mail presented by the Postal Service to U.S. Customs and Border Protection for inspection;

(4) describing the costs of collecting the information required by such subparagraph (K) from foreign postal operators and the costs of implementing the use of that information;

(5) assessing the benefits of receiving that information with respect to international mail shipments;

(6) assessing the feasibility of assessing a customs fee under section 13031(b)(9) of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended by section 8002, on international mail shipments other than Inbound Express Mail service in a manner consistent with the obligations of the United States under international agreements; and

(7) identifying recommendations, including recommendations for legislation, to improve the compliance of the Postal Service with such subparagraph (K), including an assessment of whether the detec-

tion of illicit synthetic opioids in the international mail would be improved by—

(A) requiring the Postal Service to serve as the consignee for international mail shipments containing goods; or

(B) designating a customs broker to act as an importer of record for international mail shipments containing goods.

(e) TECHNICAL CORRECTION.—Section 343 of the Trade Act of 2002 (Public Law 107–210; 19 U.S.C. 2071 note) is amended in the section heading by striking ''**ADVANCED**'' and inserting ''**ADVANCE**''.

(f) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term ''appropriate congressional committees'' means—

(1) the Committee on Finance and the Committee on Homeland Security and Governmental Affairs of the Senate; and

(2) the Committee on Ways and Means, the Committee on Oversight and Government Reform, and the Committee on Homeland Security of the House of Representatives.

**SEC. 8004. INTERNATIONAL POSTAL AGREEMENTS.**

(a) EXISTING AGREEMENTS.—

(1) IN GENERAL.—In the event that any provision of this subtitle, or any amendment made by this Act, is determined to be in violation of obligations of the United States under any postal treaty, convention, or other international agreement related to international postal services, or any amendment to such an agreement, the Secretary of State should negotiate to amend the relevant provisions of the agreement so that the United States is no longer in violation of the agreement.

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to permit delay in the implementation of this subtitle or any amendment made by this subtitle.

(b) FUTURE AGREEMENTS.—

(1) CONSULTATIONS.—Before entering into, on or after the date of the enactment of this Act, any postal treaty, convention, or other international agreement related to international postal services, or any amendment to such an agreement, that is related to the ability of the United States to secure the provision of advance electronic information by foreign postal operators, the Secretary of State should consult with the appropriate congressional committees (as defined in section 8003(f)).

(2) EXPEDITED NEGOTIATION OF NEW AGREEMENT.—To the extent that any new postal treaty, convention, or other international agreement related to international postal services would improve the ability of the United States to secure the provision of advance electronic information by foreign postal operators as required by regulations prescribed under section 343(a)(3)(K) of the Trade Act of 2002, as amended by section 8003(a)(1), the Secretary of State should expeditiously conclude such an agreement.

**SEC. 8005. COST RECOUPMENT.**

(a) IN GENERAL.—The United States Postal Service shall, to the extent practicable and otherwise recoverable by law, ensure that all costs associated with complying with this subtitle and amendments made by this subtitle are charged directly to foreign shippers or foreign postal operators.

(b) COSTS NOT CONSIDERED REVENUE.—The recovery of costs under subsection (a) shall not be deemed revenue for purposes of subchapter I and II of chapter 36 of title 39, United States Code, or regulations prescribed under that chapter.

**SEC. 8006. DEVELOPMENT OF TECHNOLOGY TO DETECT ILLICIT NARCOTICS.**

(a) IN GENERAL.—The Postmaster General and the Commissioner of U.S. Customs and Border Protection, in coordination with the heads of other agencies as appropriate, shall collaborate to identify and develop technology for the detection of illicit fentanyl, other synthetic opioids, and other narcotics and psychoactive substances entering the United States by mail.

(b) OUTREACH TO PRIVATE SECTOR.—The Postmaster General and the Commissioner shall conduct outreach to private sector entities to gather information regarding the current state of technology to identify areas for innovation relating to the detection of illicit fentanyl, other synthetic opioids, and other narcotics and psychoactive substances entering the United States.

**SEC. 8007. CIVIL PENALTIES FOR POSTAL SHIPMENTS.**

Section 436 of the Tariff Act of 1930 (19 U.S.C. 1436) is amended by adding at the end the following new subsection:

''(e) CIVIL PENALTIES FOR POSTAL SHIPMENTS.—

''(1) CIVIL PENALTY.—A civil penalty shall be imposed against the United States Postal Service if the Postal Service accepts a shipment in violation of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002.

''(2) MODIFICATION OF CIVIL PENALTY.—

''(A) IN GENERAL.—U.S. Customs and Border Protection shall reduce or dismiss a civil penalty imposed pursuant to paragraph (1) if U.S. Customs and Border Protection determines that the United States Postal Service—

''(i) has a low error rate in compliance with section 343(a)(3)(K) of the Trade Act of 2002;

''(ii) is cooperating with U.S. Customs and Border Protection with respect to the violation of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002; or

''(iii) has taken remedial action to prevent future violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002.

''(B) WRITTEN NOTIFICATION.—U.S. Customs and Border Protection shall issue a written notification to the Postal Service with respect to each exercise of the authority of subparagraph (A) to reduce or dismiss a civil penalty imposed pursuant to paragraph (1).

''(3) ONGOING LACK OF COMPLIANCE.—If U.S. Customs and Border Protection determines that the United States Postal Service—

''(A) has repeatedly committed violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002,

''(B) has failed to cooperate with U.S. Customs and Border Protection with respect to violations of section 343(a)(3)(K)(vii)(I) of the Trade Act of 2002, and

''(C) has an increasing error rate in compliance with section 343(a)(3)(K) of the Trade Act of 2002,

civil penalties may be imposed against the United States Postal Service until corrective action, satisfactory to U.S. Customs and Border Protection, is taken.''.

**SEC. 8008. REPORT ON VIOLATIONS OF ARRIVAL, REPORTING, ENTRY, AND CLEARANCE REQUIREMENTS AND FALSITY OR LACK OF MANIFEST.**

(a) IN GENERAL.—The Commissioner of U.S. Customs and Border Protection shall submit to the appropriate congressional committees an annual report that contains the information described in subsection (b) with respect to each violation of section 436 of the Tariff Act

of 1930 (19 U.S.C. 1436), as amended by section 8007, and section 584 of such Act (19 U.S.C. 1584) that occurred during the previous year.

(b) INFORMATION DESCRIBED.—The information described in this subsection is the following:

(1) The name and address of the violator.

(2) The specific violation that was committed.

(3) The location or port of entry through which the items were transported.

(4) An inventory of the items seized, including a description of the items and the quantity seized.

(5) The location from which the items originated.

(6) The entity responsible for the apprehension or seizure, organized by location or port of entry.

(7) The amount of penalties assessed by U.S. Customs and Border Protection, organized by name of the violator and location or port of entry.

(8) The amount of penalties that U.S. Customs and Border Protection could have levied, organized by name of the violator and location or port of entry.

(9) The rationale for negotiating lower penalties, organized by name of the violator and location or port of entry.

(c) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED.—In this section, the term ''appropriate congressional committees'' means—

(1) the Committee on Finance and the Committee on Homeland Security and Governmental Affairs of the Senate; and

(2) the Committee on Ways and Means, the Committee on Oversight and Government Reform, and the Committee on Homeland Security of the House of Representatives.

**SEC. 8009. EFFECTIVE DATE; REGULATIONS.**

(a) EFFECTIVE DATE.—This subtitle and the amendments made by this subtitle (other than the amendments made by section 8002) shall take effect on the date of the enactment of this Act.

(b) REGULATIONS.—Not later than one year after the date of the enactment of this Act, such regulations as are necessary to carry out this subtitle and the amendments made by this subtitle shall be prescribed.

# Subtitle B—Recognizing Early Childhood Trauma Related to Substance Abuse

**SEC. 8011. SHORT TITLE.**

This subtitle may be cited as the ''Recognizing Early Childhood Trauma Related to Substance Abuse Act of 2018''.

**SEC. 8012. RECOGNIZING EARLY CHILDHOOD TRAUMA RELATED TO SUBSTANCE ABUSE.**

(a) DISSEMINATION OF INFORMATION.—The Secretary of Health and Human Services shall disseminate information, resources, and, if requested, technical assistance to early childhood 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.

(b) GOALS.—The information, resources, and technical assistance provided under subsection (a) 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.

(c) RULE OF CONSTRUCTION.—Such information, resources, and if applicable, technical assistance, shall not be construed to amend the requirements under—

(1) the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.);

(2) the Head Start Act (42 U.S.C. 9831 et seq.); or

(3) the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

# Subtitle C—Assisting States' Implementation of Plans of Safe Care

**SEC. 8021. SHORT TITLE.**

This subtitle may be cited as the ''Assisting States' Implementation of Plans of Safe Care Act''.

**SEC. 8022. ASSISTING STATES WITH IMPLEMENTATION OF PLANS OF SAFE CARE.**

(a) IN GENERAL.—The Secretary of Health and Human Services shall provide written guidance and, if appropriate, technical assistance to support States in complying with, and implementing, subsections (b)(2)(B)(iii) and (d)(18) of section 106 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a) in order to promote better protections for young children and family-centered responses.

(b) REQUIREMENTS.—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.

(c) CONSTRUCTION.—The guidance and technical assistance shall not be construed to amend the requirements of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 et seq.).

(d) DEFINITION.—For purposes of this section, the term ''State'' has the meaning given such term in section 3 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 note).

# Subtitle D—Improving the Federal Response to Families Impacted by Substance Use Disorder

**SEC. 8031. SHORT TITLE.**

This subtitle may be cited as the ''Improving the Federal Response to Families Impacted by Substance Use Disorder Act''.

**SEC. 8032. INTERAGENCY TASK FORCE TO IMPROVE THE FEDERAL RESPONSE TO FAMILIES IMPACTED BY SUBSTANCE USE DISORDERS.**

(a) ESTABLISHMENT.—There is established a task force, to be known as the ''Interagency Task Force to Improve the Federal Response to Families Impacted by Substance Use Disorders'' (in this section referred to as ''Task Force'').

(b) RESPONSIBILITIES.—The Task Force—

(1) shall identify, evaluate, and recommend ways in which Federal agencies can better coordinate responses to substance use disorders and the opioid crisis; and

(2) shall carry out the additional duties described in subsection (d).

(c) MEMBERSHIP.—

(1) NUMBER AND APPOINTMENT.—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.

(2) CHAIRPERSON.—The Secretary of Health and Human Services shall designate a Federal official employed by the Department of Health and Human Services to serve as the chairperson of the Task Force.

(3) DEADLINE FOR APPOINTMENT.—Each member shall be appointed to the Task Force not later than 60 days after the date of the enactment of this Act.

(4) ADDITIONAL AGENCY INPUT.—The Task Force may seek input from other Federal agencies and offices with experience, expertise, or information relevant in responding to the opioid crisis.

(5) VACANCIES.—A vacancy in the Task Force shall be filled in the manner in which the original appointment was made.

(6) PROHIBITION OF COMPENSATION.—Members of the Task Force may not receive pay, allowances, or benefits by reason of their service on the Task Force.

(d) DUTIES.—The Task Force shall carry out the following duties:

(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, that shall include—

(A) identifying options for the coordination of existing grants that support infants, children, and youth, and their families as appropriate, who have experienced, or are at risk of experiencing, exposure to substance abuse disorders, including opioid misuse; and

(B) other ways to improve coordination, planning, and communication within and across Federal agencies, offices, and programs, to better serve children and families impacted by substance use disorders, including opioid misuse.

(3) Based off the strategy developed under paragraph (2), evaluate and recommend opportunities for local- and State-level partnerships, professional development, or best practices that—

(A) are designed to quickly identify and refer children and families, as appropriate, who have experienced or are at risk of experiencing exposure to substance abuse;

(B) utilize and develop partnerships with early childhood education programs, local social

services organizations, and health care services aimed at preventing or mitigating the effects of exposure to substance use disorders, including opioid misuse;

(C) offer community-based prevention activities, including educating families and children on the effects of exposure to substance use disorders, including opioid misuse, and how to build resilience and coping skills to mitigate those effects;

(D) in accordance with Federal privacy protections, utilize non-personally identifiable data from screenings, referrals, or the provision of services and supports to evaluate and improve processes addressing exposure to substance use disorders, including opioid misuse; and

(E) are designed to prevent separation and support reunification of families if in the best interest of the child.

(4) In fulfilling the requirements of paragraphs (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, including—

(A) prevention strategies for those at risk of experiencing or being exposed to substance abuse, including misuse of opioids;

(B) whole-family and multi-generational approaches;

(C) community-based initiatives;

(D) referral to, and implementation of, trauma-informed practices and supports; and

(E) multi-generational practices that assist parents, foster parents, and kinship and other caregivers

(e) FACA.—The Federal Advisory Committee Act (5 U.S.C. App. 2) shall not apply to the Task Force.

(f) ACTION PLAN; REPORTS.—The Task Force—

(1) shall prepare a detailed action plan to be implemented by participating Federal agencies to create a collaborative, coordinated response to the opioid crisis, which shall include—

(A) relevant information identified and collected under subsection (d);

(B) a proposed timeline for implementing recommendations and efforts identified under subsection (d); and

(C) a description of how other Federal agencies and offices with experience, expertise, or information relevant in responding to the opioid crisis that have provided input under subsection (c)(4) will be participating in the coordinated approach;

(2) shall submit to the Congress a report describing the action plan prepared under paragraph (1), including, where applicable, identification of any recommendations included in such plan that require additional legislative authority to implement; and

(3) shall submit a report to the Governors describing the opportunities for local- and State-level partnerships, professional development, or best practices recommended under subsection (d)(3).

(g) DISSEMINATION.—

(1) IN GENERAL.—The action plan and reports required under subsection (f) shall be—

(A) disseminated widely, including among the participating Federal agencies and the Governors; and

(B) be made publicly available online in an accessible format.

(2) DEADLINE.—The action plan and reports required under subsection (f) may be released on

separate dates but shall be released not later than 9 months after the date of the enactment of this Act.

(h) TERMINATION.—The Task Force shall terminate 30 days after the dissemination of the action plan and reports under subsection (g).

(i) FUNDING.—The administrative expenses of the Task Force shall be paid out of existing Department of Health and Human Services funds or appropriations.

(j) DEFINITIONS.—For purposes of this section:

(1) The term ''Governor'' means the chief executive officer of a State.

(2) The term ''participating Federal agencies'' means all the Executive agencies (as defined in section 105 of title 5, United States Code) whose officials have been appointed to the Task Force.

(3) The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

# Subtitle E—Establishment of an Advisory Committee on Opioids and the Workplace

**SEC. 8041. ESTABLISHMENT OF AN ADVISORY COMMITTEE ON OPIOIDS AND THE WORKPLACE.**

(a) ESTABLISHMENT.—Not later than 90 days after enactment of this Act, the Secretary of Labor shall establish an Advisory Committee on Opioids and the Workplace (referred to in this subtitle as the ''Advisory Committee'') 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.

(b) MEMBERSHIP.—

(1) COMPOSITION.—The Secretary of Labor shall appoint as members of the Advisory Committee 19 individuals with expertise in employment, workplace health programs, human resources, substance use disorder, and other relevant fields. The Advisory Committee shall be composed as follows:

(A) 4 of the members shall be individuals representative of employers or other organizations representing employers.

(B) 4 of the members shall be individuals representative of workers or other organizations representing workers, of which at least 2 must be representatives designated by labor organizations.

(C) 3 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) 8 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 1 individual may be a representative of a local or State government agency that oversees or coordinates programs that address substance use disorder.

(2) CHAIR.—From the members appointed under paragraph (1), the Secretary of Labor shall appoint a chairperson.

(3) TERMS.—Each member of the Advisory Committee shall serve for a term of three years. A member appointed to fill a vacancy shall be appointed only for the remainder of such term.

(4) QUORUM.—A majority of members of the Advisory Committee shall constitute a quorum and action shall be taken only by a majority vote of the members.

(5) VOTING.—The Advisory Committee shall establish voting procedures.

(6) NO COMPENSATION.—Members of the Advisory Committee shall serve without compensation.

(7) DISCLOSURE.—Every member of the Advisory Committee must disclose the entity, if applicable, that he or she is representing.

(c) DUTIES.—

(1) ADVISEMENT.—

(A) IN GENERAL.—The Advisory Committee established under subsection (a) shall advise the Secretary of Labor 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.

(B) CONSIDERATIONS.—In providing such advice, the Advisory Committee shall take into account—

(i) evidence-based and other employer substance abuse policies and best practices regarding opioid use or abuse, including benefits provided by employee assistance programs or other employer-provided benefits, programs, or resources;

(ii) the effect of opioid use or abuse on the safety of the workplace as well as policies and procedures addressing workplace safety and health;

(iii) the impact of opioid abuse on productivity and absenteeism, and assessments of model human resources policies that support workers abusing opioids, such as policies that facilitate seeking and receiving treatment and returning to work;

(iv) the extent to which alternative pain management treatments other than opioids are or should be covered by employer-sponsored health plans;

(v) the legal requirements protecting employee privacy and health information in the workplace, as well as the legal requirements related to nondiscrimination;

(vi) potential interactions of opioid abuse with other substance use disorders;

(vii) any additional benefits or resources available to an employee abusing opioids that promote retaining employment or reentering the workforce;

(viii) evidence-based initiatives that engage employers, employees, and community leaders to promote early identification of opioid abuse, intervention, treatment, and recovery;

(ix) workplace policies regarding opioid abuse that reduce stigmatization among fellow employees and management; and

(x) the legal requirements of the Mental Health Parity and Addiction Equity Act and other laws related to health coverage of substance abuse and mental health services and medications.

(2) REPORT.—Prior to its termination as provided in subsection (j), 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 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 abuse.

(d) MEETINGS.—The Advisory Committee shall meet at least twice a year at the call of the chairperson.

(e) STAFF SUPPORT.—The Secretary of Labor shall make available staff necessary for the Advisory Committee to carry out its responsibilities.

(f) FEDERAL ADVISORY COMMITTEE ACT.—The Federal Advisory Committee Act shall apply to the Advisory Committee established under this subtitle.

(g) NO APPROPRIATED FUNDS.—No additional funds are authorized to be appropriated to carry out this subtitle. Expenses of the Advisory Committee shall be paid with funds otherwise appropriated to Departmental Management within the Department of Labor.

(h) EX OFFICIO.—Three nonvoting representatives from agencies within the Department of Health and Human Services whose responsibilities include opioid prescribing guidelines, workplace safety, and monitoring of substance abuse and prevention programs shall be ap-

pointed by the Secretary of Labor and designated as ex officio members.

(i) AGENDA.—The Secretary of Labor or a representative of the Secretary shall consult with the Chair in establishing the agenda for Committee meetings.

(j) TERMINATION.—The Advisory Committee established under this subtitle shall terminate three years after the date of enactment of this Act.

# Subtitle F—Veterans Treatment Court Improvement

**SEC. 8051. SHORT TITLE.**

This subtitle may be cited as the ''Veterans Treatment Court Improvement Act of 2018''.

**SEC. 8052. HIRING BY DEPARTMENT OF VETERANS AFFAIRS OF ADDITIONAL VETERANS JUSTICE OUTREACH SPECIALISTS.**

(a) HIRING OF ADDITIONAL VETERANS JUSTICE OUTREACH SPECIALISTS.—

(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Veterans Affairs shall hire not fewer than 50 Veterans Justice Outreach Specialists and place each such Veterans Justice Outreach Specialist at an eligible Department of Veterans Affairs medical center in accordance with this section.

(2) REQUIREMENTS.—The Secretary shall ensure that each Veterans Justice Outreach Specialist employed under paragraph (1)—

(A) serves, either exclusively or in addition to other duties, as part of a justice team in a veterans treatment court or other veteran-focused court; and

(B) otherwise meets Department hiring guidelines for Veterans Justice Outreach Specialists.

(b) ELIGIBLE DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTERS.—For purposes of this section, an eligible Department of Veterans Affairs medical center is any Department of Veterans Affairs medical center that—

(1) complies with all Department guidelines and regulations for placement of a Veterans Justice Outreach Specialist;

(2) works within a local criminal justice system with justice-involved veterans;

(3) maintains an affiliation with one or more veterans treatment courts or other veteran-focused courts; and

(4) either—

(A) routinely provides Veterans Justice Outreach Specialists to serve as part of a jus-

tice team in a veterans treatment court or other veteran-focused court; or

(B) establishes a plan that is approved by the Secretary to provide Veterans Justice Outreach Specialists employed under subsection (a)(1) to serve as part of a justice team in a veterans treatment court or other veteran-focused court.

(c) PLACEMENT PRIORITY.—The Secretary shall prioritize the placement of Veterans Justice Outreach Specialists employed under subsection (a)(1) at eligible Department of Veterans Affairs medical centers that have or intend to establish an affiliation, for the purpose of carrying out the Veterans Justice Outreach Program, with a veterans treatment court, or other veteran-focused court, that—

(1) was established on or after the date of the enactment of this Act; or

(2)(A) was established before the date of the enactment of this Act; and

(B) is not fully staffed with Veterans Justice Outreach Specialists.

(d) REPORTS.—

(1) REPORT BY SECRETARY OF VETERANS AFFAIRS.—

(A) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Secretary of Veterans Affairs shall submit to Congress a report on the implementation of this section and its effect on the Veterans Justice Outreach Program.

(B) CONTENTS.—The report submitted under paragraph (1) shall include the following:

(i) The status of the efforts of the Secretary to hire Veterans Justice Outreach Specialists pursuant to subsection (a)(1), including the total number of Veterans Justice Outreach Specialists hired by the Secretary pursuant to such subsection and the number that the Secretary expects to hire pursuant to such subsection.

(ii) The total number of Veterans Justice Outreach Specialists assigned to each Department of Veterans Affairs medical center that participates in the Veterans Justice Outreach Program, including the number of Veterans Justice Outreach Specialists hired under subsection (a)(1) disaggregated by Department of Veterans Affairs medical center.

(iii) The total number of eligible Department of Veterans Affairs medical centers that sought placement of a Veterans Justice Outreach Specialist under subsection (a)(1), how many Veterans Justice Outreach Specialists each such center sought, and how many of such medical centers received no placement of a Veterans Justice Outreach Specialist under subsection (a)(1).

(iv) For each eligible Department of Veterans Affairs medical center—

(I) the number of justice-involved veterans who were served or are expected to be served by a Veterans Justice Outreach Specialist hired under subsection (a)(1); and

(II) the number of justice-involved veterans who do not have access to a Veterans Justice Outreach Specialist.

(2) REPORT BY COMPTROLLER GENERAL OF THE UNITED STATES.—

(A) IN GENERAL.—Not later than three years after the date of the enactment of this

Act, the Comptroller General of the United States shall submit to Congress a report on the implementation of this section and the effectiveness of the Veterans Justice Outreach Program.

(B) CONTENTS.—The report required by subparagraph (A) shall include the following:

(i) An assessment of whether the Secretary has fulfilled the Secretary's obligations under this section.

(ii) The number of veterans who are served by Veterans Justice Outreach Specialists hired under subsection (a)(1), disaggregated by demographics (including discharge status).

(iii) An identification of any subgroups of veterans who underutilize services provided under laws administered by the Secretary, including an assessment of whether these veterans have access to Veterans Justice Outreach Specialists under the Veterans Justice Outreach Program.

(iv) Such recommendations as the Comptroller General may have for the Secretary to improve the effectiveness of the Veterans Justice Outreach Program.

(e) DEFINITIONS.—In this section:

(1) JUSTICE TEAM.—The term ''justice team'' means the group of individuals, which may include a judge, court coordinator, prosecutor, public defender, treatment provider, probation or other law enforcement officer, program mentor, and Veterans Justice Outreach Specialist, who assist justice-involved veterans in a veterans treatment court or other veteran-focused court.

(2) JUSTICE-INVOLVED VETERAN.—The term ''justice-involved veteran'' means a veteran with active, ongoing, or recent contact with some component of a local criminal justice system.

(3) LOCAL CRIMINAL JUSTICE SYSTEM.—The term ''local criminal justice system'' means law enforcement, jails, prisons, and Federal, State, and local courts.

(4) VETERANS JUSTICE OUTREACH PROGRAM.—The term ''Veterans Justice Outreach Program'' means the program through which the Department of Veterans Affairs identifies justice-involved veterans and provides such veterans with access to Department services.

(5) VETERANS JUSTICE OUTREACH SPECIALIST.—The term ''Veterans Justice Outreach

Specialist'' means an employee of the Department of Veterans Affairs who serves as a liaison between the Department and the local criminal justice system on behalf of a justice-involved veteran.

(6) VETERANS TREATMENT COURT.—The term ''veterans treatment court'' means a State or local court that is participating in the veterans treatment court program (as defined in section 2991(i)(1) of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3797aa(i)(1))).

# Subtitle G—Peer Support Counseling Program for Women Veterans

## SEC. 8061. PEER SUPPORT COUNSELING PROGRAM FOR WOMEN VETERANS.

(a) IN GENERAL.—Section 1720F(j) of title 38, United States Code, is amended by adding at the end the following new paragraph:

''(4)(A) As part of the counseling program under this subsection, the Secretary shall emphasize appointing peer support counselors for women veterans. To the degree practicable, the Secretary shall seek to recruit women peer support counselors with expertise in—

''(i) female gender-specific issues and services;

''(ii) the provision of information about services and benefits provided under laws administered by the Secretary; or

''(iii) employment mentoring.

''(B) To the degree practicable, the Secretary shall emphasize facilitating peer support counseling for women veterans who are eligible for counseling and services under section 1720D of this title, have post-traumatic stress disorder or suffer from another mental health condition, are homeless or at risk of becoming homeless, or are otherwise at increased risk of suicide, as determined by the Secretary.

''(C) The Secretary shall conduct outreach to inform women veterans about the program and the assistance available under this paragraph.

''(D) In carrying out this paragraph, the Secretary shall coordinate with such community organizations, State and local governments, institutions of higher education, chambers of commerce, local business organizations, organizations that provide legal assistance, and other organizations as the Secretary considers appropriate.

''(E) In carrying out this paragraph, the Secretary shall provide adequate training for peer support counselors, including training carried out under the national program of training required by section 304(c) of the

Caregivers and Veterans Omnibus Health Services Act of 2010 (38 U.S.C. 1712A note).''.

(b) FUNDING.—The Secretary of Veterans Affairs shall carry out paragraph (4) of section 1720F(j) of title 38, United States Code, as added by subsection (a), using funds otherwise made available to the Secretary. No additional funds are authorized to be appropriated by reason of such paragraph.

(c) REPORT TO CONGRESS.—Not later than two years after the date of the enactment of this Act, the Secretary of Veterans Affairs shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives a report on the peer support counseling program under section 1720F(j) of title 38, United States Code, as amended by this section. Such report shall include—

(1) the number of peer support counselors in the program;

(2) an assessment of the effectiveness of the program; and

(3) a description of the oversight of the program.

# Subtitle H—Treating Barriers to Prosperity

**SEC. 8071. SHORT TITLE.**

This subtitle may be cited as the ''Treating Barriers to Prosperity Act of 2018''.

**SEC. 8072. DRUG ABUSE MITIGATION INITIATIVE.**

(a) IN GENERAL.—Chapter 145 of title 40, United States Code, is amended by inserting after section 14509 the following:

**''§ 14510. Drug abuse mitigation initiative**

''(a) IN GENERAL.—The Appalachian Regional Commission may provide technical assistance to, make grants to, enter into contracts with, or otherwise provide amounts to individuals or entities in the Appalachian region for projects and activities to address drug abuse, including opioid abuse, in the region, including projects and activities—

''(1) to facilitate the sharing of best practices among States, counties, and other experts in the region with respect to reducing such abuse;

''(2) to initiate or expand programs designed to eliminate or reduce the harm to the workforce and economic growth of the region that results from such abuse;

''(3) to attract and retain relevant health care services, businesses, and workers; and

''(4) to develop relevant infrastructure, including broadband infrastructure that supports the use of telemedicine.

''(b) LIMITATION ON AVAILABLE AMOUNTS.—Of the cost of any activity eligible for a grant under this section—

''(1) not more than 50 percent may be provided from amounts appropriated to carry out this section; and

''(2) notwithstanding paragraph (1)—

''(A) in the case of a project to be carried out in a county for which a distressed county designation is in effect under section 14526, not more than 80 percent may be provided from amounts appropriated to carry out this section; and

''(B) in the case of a project to be carried out in a county for which an at-risk designation is in effect under section 14526, not more than 70 percent may be provided from amounts appropriated to carry out this section.

''(c) SOURCES OF ASSISTANCE.—Subject to subsection (b), a grant provided under this section may be

provided from amounts made available to carry out this section in combination with amounts made available—

''(1) under any other Federal program (subject to the availability of subsequent appropriations); or

''(2) from any other source.

''(d) FEDERAL SHARE.—Notwithstanding any provision of law limiting the Federal share under any other Federal program, amounts made available to carry out this section may be used to increase that Federal share, as the Appalachian Regional Commission determines to be appropriate.''.

(b) CLERICAL AMENDMENT.—The analysis for chapter 145 of title 40, United States Code, is amended by inserting after the item relating to section 14509 the following:

''14510. Drug abuse mitigation initiative.''.

# Subtitle I—Supporting Grandparents Raising Grandchildren

**SEC. 8081. SHORT TITLE.**

This subtitle may be cited as the ''Supporting Grandparents Raising Grandchildren Act''.

**SEC. 8082. FINDINGS.**

Congress finds the following:

(1) More than 2,500,000 grandparents in the United States are the primary caretaker of their

grandchildren, and experts report that such numbers are increasing as the opioid epidemic expands.

(2) Between 2009 and 2016, the incidence of parental alcohol or other drug use as a contributing factor for children's out-of-home placement rose from 25.4 to 37.4 percent.

(3) When children cannot remain safely with their parents, placement with relatives is preferred over placement in foster care with nonrelatives because placement with relatives provides stability for children and helps them maintain family connections.

(4) The number of foster children placed with a grandparent or other relative increased from 24 percent in 2006 to 32 percent in 2016, according to data from the Department of Health and Human Services.

(5) Grandparents' lives are enhanced by caring for their grandchildren; the overwhelming majority of grandparents report experiencing significant benefits in serving as their grandchildren's primary caregivers.

(6) Providing full-time care to their grandchildren may decrease grandparents' ability to ad-

dress their own physical and mental health needs and personal well-being.

(7) Grandparents would benefit from better coordination and dissemination of information and resources available to support them in their caregiving responsibilities.

**SEC. 8083. ADVISORY COUNCIL TO SUPPORT GRANDPARENTS RAISING GRANDCHILDREN.**

(a) ESTABLISHMENT.—There is established an Advisory Council to Support Grandparents Raising Grandchildren.

(b) MEMBERSHIP.—

(1) IN GENERAL.—The Advisory Council shall be composed of the following members, or their designee:

(A) The Secretary of Health and Human Services.

(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.

(E) The Assistant Secretary for Mental Health and Substance Use.

(F) The Assistant Secretary for the Administration for Children and Families.

(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 Health and Human Services as having responsibilities, or administering programs, relating to current issues affecting grandparents or other older relatives raising children.

(2) LEAD AGENCY.—The Department of Health and Human Services shall be the lead agency for the Advisory Council.

(c) DUTIES.—

(1) IN GENERAL.—

(A) INFORMATION.—The Advisory Council shall identify, promote, coordinate, and disseminate to the public information, resources, and the best practices available to help grandparents and other older relatives—

(i) meet the health, educational, nutritional, and other needs of the children in their care; and

(ii) maintain their own physical and mental health and emotional well-being.

(B) OPIOIDS.—In carrying out the duties described in subparagraph (A), the Advisory Council shall consider the needs of those affected by the opioid crisis.

(C) NATIVE AMERICANS.—In carrying out the duties described in subparagraph (A), the Advisory Council shall consider the needs of members of Native American tribes.

(2) REPORT.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Advisory Council shall submit a report to—

(i) the appropriate committees;

(ii) the State agencies that are responsible for carrying out family caregiver programs; and

(iii) the public online in an accessible format.

(B) REPORT FORMAT.—The report shall include—

(i) best practices, resources, and other useful information for grandparents and other older relatives raising children identi-

fied under paragraph (1)(A) including, if applicable, any information related to the needs of children who have been impacted by the opioid epidemic;

(ii) an identification of any gaps in items under clause (i); and

(iii) where applicable, identification of any additional Federal legislative authority necessary to implement the activities described in clause (i) and (ii).

(3) FOLLOW-UP REPORT.—Not later than 2 years after the date on which the report required under paragraph (2)(A) is submitted, the Advisory Council shall submit a follow-up report that includes the information identified in paragraph (2)(B) to—

(A) the appropriate committees;

(B) the State agencies that are responsible for carrying out family caregiver programs; and

(C) the public online in an accessible format.

(4) PUBLIC INPUT.—

(A) IN GENERAL.—The Advisory Council shall establish a process for public input to inform the development of, and provide updates to, the best practices, resources, and other in-

formation described in paragraph (1) that shall include—

(i) outreach to States, local entities, and organizations that provide information to, or support for, grandparents or other older relatives raising children; and

(ii) outreach to grandparents and other older relatives with experience raising children.

(B) NATURE OF OUTREACH.—Such outreach shall ask individuals to provide input on—

(i) information, resources, and best practices available, including identification of any gaps and unmet needs; and

(ii) recommendations that would help grandparents and other older relatives better meet the health, educational, nutritional, and other needs of the children in their care, as well as maintain their own physical and mental health and emotional well-being.

(d) FACA.—The Advisory Council shall be exempt from the requirements of the Federal Advisory Committee Act (5 U.S.C. App.).

(e) FUNDING.—No additional funds are authorized to be appropriated to carry out this subtitle.

(f) SUNSET.—The Advisory Council shall terminate on the date that is 3 years after the date of enactment of this Act.

**SEC. 8084. DEFINITIONS.**

In this subtitle:

(1) ADVISORY COUNCIL.—In this subtitle, the term ''Advisory Council'' means the Advisory Council to Support Grandparents Raising Grandchildren that is established under section 8083.

(2) APPROPRIATE COMMITTEES.—In this subtitle, the term ''appropriate committees'' means the following:

(A) The Special Committee on Aging of the Senate.

(B) The Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Committee on Education and the Workforce of the House of Representatives.

(D) The Committee on Energy and Commerce of the House of Representatives.

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

**SEC. 8091. SHORT TITLE.**

This subtitle may be cited as the ''Reauthorizing and Extending Grants for Recovery from Opioid Use Programs Act of 2018'' or the ''REGROUP Act of 2018''.

**SEC. 8092. REAUTHORIZATION OF THE COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.**

Section 1001(a)(27) of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10261(a)(27)) is amended by striking ''through 2021'' and inserting ''and 2018, and $330,000,000 for each of fiscal years 2019 through 2023''.

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