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In the House of Representatives, U. S.,

September 28, 2018.

Resolved, That the House agree to the amendment of the Senate to the bill (H.R. 6) entitled ''An Act to provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.'', with the following

HOUSE AMENDMENT TO SENATE AMENDMENT:

In lieu of the matter proposed to be inserted by the Senate amendment, insert the following

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act'' or the ''SUPPORT for Patients and Communities Act''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—MEDICAID PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 1001. At-risk youth Medicaid protection.
Sec. 1002. Health insurance for former foster youth.
Sec. 1003. Demonstration project to increase substance use provider capacity under the Medicaid program.
Sec. 1004. Medicaid drug review and utilization.
Sec. 1005. Guidance to improve care for infants with neonatal abstinence syndrome and their mothers; GAO study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder.
Sec. 1006. Medicaid health homes for substance-use-disorder Medicaid enrollees.

Sec. 1007. Caring recovery for infants and babies.
Sec. 1008. Peer support enhancement and evaluation review.
Sec. 1009. Medicaid substance use disorder treatment via telehealth.
Sec. 1010. Enhancing patient access to non-opioid treatment options.
Sec. 1011. Assessing barriers to opioid use disorder treatment.
Sec. 1012. Help for moms and babies.
Sec. 1013. Securing flexibility to treat substance use disorders.
Sec. 1014. MACPAC study and report on MAT utilization controls under State Medicaid programs.
Sec. 1015. Opioid addiction treatment programs enhancement.
Sec. 1016. Better data sharing to combat the opioid crisis.
Sec. 1017. Report on innovative State initiatives and strategies to provide housing-related services and supports to individuals struggling with substance use disorders under Medicaid.
Sec. 1018. Technical assistance and support for innovative State strategies to provide housing-related supports under Medicaid.

TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID CRISIS

Sec. 2001. Expanding the use of telehealth services for the treatment of opioid use disorder and other substance use disorders.
Sec. 2002. Comprehensive screenings for seniors.
Sec. 2003. Every prescription conveyed securely.
Sec. 2004. Requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries.
Sec. 2005. Medicare coverage of certain services furnished by opioid treatment programs.
Sec. 2006. Encouraging appropriate prescribing under Medicare for victims of opioid overdose.
Sec. 2007. Automatic escalation to external review under a Medicare part D drug management program for at-risk beneficiaries.
Sec. 2008. Suspension of payments by Medicare prescription drug plans and MA–PD plans pending investigations of credible allegations of fraud by pharmacies.

TITLE III—FDA AND CONTROLLED SUBSTANCE PROVISIONS

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

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

Sec. 3011. Short title.
Sec. 3012. Notification, nondistribution, and recall of controlled substances.
Sec. 3013. Single source pattern of imported illegal drugs.
Sec. 3014. Strengthening FDA and CBP coordination and capacity.

Chapter 3—Stop Illicit Drug Importation

Sec. 3021. Short title.
Sec. 3022. Restricting entrance of illicit drugs.

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

Sec. 3031. Short title.
Sec. 3032. Safety-enhancing packaging and disposal features.

Chapter 5—Postapproval Study Requirements

Sec. 3041. Clarifying FDA postmarket authorities.

Subtitle B—Controlled Substance Provisions

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Sec. 3201. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.
Sec. 3202. Medication-assisted treatment for recovery from substance use disorder.
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Sec. 3204. Delivery of a controlled substance by a pharmacy to be administered by injection or implantation.

Chapter 2—Empowering Pharmacists in the Fight Against Opioid Abuse

Sec. 3211. Short title.
Sec. 3212. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription.

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Sec. 3221. Short title.
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Sec. 6094. Technical expert panel on reducing surgical setting opioid use; Data collection on perioperative opioid use.
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Subtitle G—Human Services

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1 ***TITLE I—MEDICAID PROVISIONS***
2 ***TO ADDRESS THE OPIOID CRISIS***

3 ***SEC. 1001. AT-RISK YOUTH MEDICAID PROTECTION.***

4 *(a) IN GENERAL.—Section 1902 of the Social Security*
5 *Act (42 U.S.C. 1396a) is amended—*
6 *(1) in subsection (a)—*

(A) by striking "and" at the end of paragraph (82);

(B) by striking the period at the end of paragraph (83) and inserting "; and"; and

(C) by inserting after paragraph (83) the following new paragraph:

"(84) provide that—

"(A) the State shall not terminate eligibility for medical assistance under the State plan for an individual who is an eligible juvenile (as defined in subsection (nn)(2)) because the juvenile is an inmate of a public institution (as defined in subsection (nn)(3)), but may suspend coverage during the period the juvenile is such an inmate;

"(B) in the case of an individual who is an eligible juvenile described in paragraph (2)(A) of subsection (nn), the State shall, prior to the individual's release from such a public institution, conduct a redetermination of eligibility for such individual with respect to such medical assistance (without requiring a new application from the individual) and, if the State determines pursuant to such redetermination that the individual continues to meet the eligibility requirements for such medical assistance, the State shall

restore coverage for such medical assistance to such an individual upon the individual's release from such public institution; and

"(C) in the case of an individual who is an eligible juvenile described in paragraph (2)(B) of subsection (nn), the State shall process any application for medical assistance submitted by, or on behalf of, such individual such that the State makes a determination of eligibility for such individual with respect to such medical assistance upon release of such individual from such public institution."; and

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

"(nn) JUVENILE; ELIGIBLE JUVENILE; PUBLIC INSTITUTION.—For purposes of subsection (a)(84) and this subsection:

"(1) JUVENILE.—The term 'juvenile' means an individual who is—

"(A) under 21 years of age; or

"(B) described in subsection (a)(10)(A)(i)(IX).

"(2) ELIGIBLE JUVENILE.—The term 'eligible juvenile' means a juvenile who is an inmate of a public institution and who—

"(A) was determined eligible for medical assistance under the State plan immediately before becoming an inmate of such a public institution; or

"(B) is determined eligible for such medical assistance while an inmate of a public institution.

"(3) INMATE OF A PUBLIC INSTITUTION.—The term 'inmate of a public institution' has the meaning given such term for purposes of applying the subdivision (A) following paragraph (30) of section 1905(a), taking into account the exception in such subdivision for a patient of a medical institution.".

(b) NO CHANGE IN EXCLUSION FROM MEDICAL ASSISTANCE FOR INMATES OF PUBLIC INSTITUTIONS.—Nothing in this section shall be construed as changing the exclusion from medical assistance under the subdivision (A) following paragraph (30) of section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)), as redesignated by section 1006(b)(2)(B) of this Act, including any applicable restrictions on a State submitting claims for Federal financial participation under title XIX of such Act for such assistance.

(c) NO CHANGE IN CONTINUITY OF ELIGIBILITY BEFORE ADJUDICATION OR SENTENCING.—Nothing in this

section shall be construed to mandate, encourage, or suggest that a State suspend or terminate coverage for individuals before they have been adjudicated or sentenced.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) shall apply to eligibility of juveniles who become inmates of public institutions on or after the date that is 1 year after the date of the enactment of this Act.

(2) RULE FOR CHANGES REQUIRING STATE LEGISLATION.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements 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 the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session,

each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1002. HEALTH INSURANCE FOR FORMER FOSTER YOUTH.

(a) COVERAGE CONTINUITY FOR FORMER FOSTER CARE CHILDREN UP TO AGE 26.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(i)(IX) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(IX)) is amended—

(A) in item (bb), by striking "are not described in or enrolled under" and inserting "are not described in and are not enrolled under";

(B) in item (cc), by striking "responsibility of the State" and inserting "responsibility of a State"; and

(C) in item (dd), by striking "the State plan under this title or under a waiver of the" and inserting "a State plan under this title or under a waiver of such a".

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect with respect to foster youth who attain 18 years of age on or after January 1, 2023.

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

Human Services shall issue guidance to States, with respect to the State Medicaid programs of such States—

(1) on best practices for—

(A) removing barriers and ensuring streamlined, timely access to Medicaid coverage for former foster youth up to age 26; and

(B) conducting outreach and raising awareness among such youth regarding Medicaid coverage options for such youth; and

(2) which shall include examples of States that have successfully extended Medicaid coverage to former foster youth up to age 26.

SEC. 1003. DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM.

Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by adding at the end the following new subsection:

"(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—

"(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this subsection, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant

Secretary for Mental Health and Substance Use, conduct a 54-month demonstration project for the purpose described in paragraph (2) under which the Secretary shall—

"(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and

"(B) for the remaining 36-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).

"(2) PURPOSE.—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:

"(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.

"(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.

"(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—

"(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder;

"(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant Secretary for Mental Health and Substance

Use for purposes of carrying out the requirements of such section 303(g); and

"(iii) are qualified under applicable State law to provide substance use disorder treatment or recovery services.

"(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—

"(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal care and infant care with respect to neonatal abstinence syndrome;

"(ii) pregnant women, postpartum women, and infants, particularly the concurrent treatment, as appropriate, and comprehensive case management of pregnant

women, postpartum women and infants, enrolled under the State plan (or a waiver of such plan);

"(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or

"(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).

"(3) PLANNING GRANTS.—

"(A) IN GENERAL.—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subparagraph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).

"(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

"(i) select States that have a State plan (or waiver of the State plan) approved under this title;

"(ii) select States in a manner that ensures geographic diversity; and

"(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

"(C) ACTIVITIES DESCRIBED.—Activities described in this subparagraph are, with respect to a State, each of the following:

"(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under the State plan (or waiver), including the following:

"(I) An estimate of the number of individuals enrolled under the State

plan (or a waiver of such plan) who have a substance use disorder.

"(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).

"(III) Information on the gap in substance use disorder treatment or recovery services under the State plan (or waiver) based on the information described in subclauses (I) and (II).

"(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services under the State plan (or waiver) during the period of the demonstration project.

"(ii) Activities that, taking into account the results of the assessment described

in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.

"(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, $50,000,000, to remain available until expended.

"(4) POST-PLANNING STATES.—

"(A) IN GENERAL.—The Secretary shall, with respect to the remaining 36-month period of the demonstration project conducted under paragraph (1), select not more than 5 States in accordance with subparagraph (B) for purposes of carrying out the activities described in paragraph (2) and receiving payments in accordance with paragraph (5).

"(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

"(i) select States that received a planning grant under paragraph (3);

"(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;

"(iii) select States in a manner that ensures geographic diversity; and

"(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

"(C) APPLICATIONS.—

"(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:

"(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).

"(II) A review of reimbursement methodologies and other policies related to substance use disorder treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.

"(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer a continuum of care for substance use disorders. Such plan shall include the following:

"(aa) Specific activities to increase the number of providers (including providers that spe-

cialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.

"(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use disorder treatment or recovery services in the State.

"(cc) Milestones and timeliness for implementing activities set forth in the plan.

"(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).

"(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.

"(V) The expected financial impact of the demonstration project under this subsection on the State.

"(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.

"(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver

substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.

"(VIII) A description of how the State will coordinate the goals of the demonstration project with any waiver granted (or submitted by the State and pending) pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.

"(ii) CONSULTATION.—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid beneficiary advocates, and include in such application a description of such consultation.

"(5) PAYMENT.—

"(A) IN GENERAL.—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraph

(C), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.

"(B) QUALIFIED SUMS DEFINED.—For purposes of subparagraph (A), the term 'qualified sums' means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use disorder treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State during fiscal year 2018 attributable to substance use disorder treatment or recovery services.

"(C) NON-DUPLICATION OF PAYMENT.—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use disorder treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.

"(6) REPORTS.—

"(A) STATE REPORTS.—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use disorder treatment or recovery services for which payment is made to the State under this subsection, on the following:

"(i) The specific activities with respect to which payment under this subsection was provided.

"(ii) The number of providers that delivered substance use disorder treatment or recovery services in the State under the demonstration project compared to the estimated number of providers that would have otherwise delivered such services in the absence of such demonstration project.

"(iii) The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services

in the absence of such demonstration project.

"(iv) Other matters as determined by the Secretary.

"(B) CMS REPORTS.—

"(i) INITIAL REPORT.—*Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—*

"(I) the States awarded planning grants under paragraph (3);

"(II) the criteria used in such selection; and

"(III) the activities carried out by such States under such planning grants.

"(ii) INTERIM REPORT.—*Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and*

Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—

"(I) on activities carried out under the demonstration project under this subsection;

"(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;

"(III) with a description of the strengths and limitations of such demonstration project; and

"(IV) with a plan for the sustainability of such project.

"(iii) FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—

"(I) providing updates on the matters reported in the interim report under clause (ii);

"(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and

"(III) evaluating such demonstration project.

"(C) AHRQ REPORT.—Not later than 3 years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality, in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).

"(7) DATA SHARING AND BEST PRACTICES.—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.

"(8) CMS FUNDING.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, $5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.".

SEC. 1004. MEDICAID DRUG REVIEW AND UTILIZATION.

(a) MEDICAID DRUG UTILIZATION REVIEW.—

(1) STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 1001, is further amended—

(A) in paragraph (83), at the end, by striking "and";

(B) in paragraph (84), at the end, by striking the period and inserting "; and"; and

(C) by inserting after paragraph (84) the following new paragraph:

"(85) provide that the State is in compliance with the drug review and utilization requirements under subsection (oo)(1).".

(2) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 1001, is further

amended by adding at the end the following new subsection:

"(oo) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of subsection (a)(85), the drug review and utilization requirements under this subsection are, subject to paragraph (3) and beginning October 1, 2019, the following:

"(A) CLAIMS REVIEW LIMITATIONS.—

"(i) IN GENERAL.—The State has in place—

"(I) safety edits (as specified by the State) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State;

"(II) safety edits (as specified by the State) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the

State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any limitation that may be identified by the State; and

"(III) a claims review automated process (as designed and implemented by the State) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and—

"(aa) benzodiazepines; or

"(bb) antipsychotics.

"(ii) MANAGED CARE ENTITIES.—The State requires each managed care entity (as defined in section 1932(a)(1)(B)) with respect to which the State has a contract under section 1903(m) or under section 1905(t)(3) to have in place, subject to para-

graph (3), with respect to individuals who are eligible for medical assistance under the State plan (or under a waiver of the State plan) and who are enrolled with the entity, the limitations described in subclauses (I) and (II) of clause (i) and a claims review automated process described in subclause (III) of such clause.

"(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph may be construed as prohibiting a State or managed care entity from designing and implementing a claims review automated process under this subparagraph that provides for prospective or retrospective reviews of claims. Nothing in this subparagraph shall be understood as prohibiting the exercise of clinical judgment from a provider enrolled as a participating provider in a State plan (or waiver of the State plan) or contracting with a managed care entity regarding the best items and services for an individual enrolled under such State plan (or waiver).

"(B) PROGRAM TO MONITOR ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—The State has in

place a program (as designed and implemented by the State) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) and submits annually to the Secretary such information as the Secretary may require on activities carried out under such program for individuals not more than the age of 18 years generally and children in foster care specifically.

"(C) FRAUD AND ABUSE IDENTIFICATION.—The State has in place a process (as designed and implemented by the State) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

"(D) REPORTS.—The State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D) information on the limitations, requirement, program, and processes applied by the State under subparagraphs (A)

through (C) in accordance with such manner and time as specified by the Secretary.

"(E) CLARIFICATION.—Nothing shall prevent a State from satisfying the requirement—

"(i) described in subparagraph (A) by having safety edits or a claims review automated process described in such subparagraph that was in place before October 1, 2019;

"(ii) described in subparagraph (B) by having a program described in such subparagraph that was in place before such date; or

"(iii) described in subparagraph (C) by having a process described in such subparagraph that was in place before such date.

"(2) ANNUAL REPORT BY SECRETARY.—For each fiscal year beginning with fiscal year 2020, the Secretary shall submit to Congress a report on the most recent information submitted by States under paragraph (1)(D).

"(3) EXCEPTIONS.—

"(A) CERTAIN INDIVIDUALS EXEMPTED.—The drug review and utilization requirements

under this subsection shall not apply with respect to an individual who—

"(i) is receiving—

"(I) hospice or palliative care; or

"(II) treatment for cancer;

"(ii) 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

"(iii) the State elects to treat as exempted from such requirements.

"(B) EXCEPTION RELATING TO ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary shall waive the drug review and utilization requirements under this subsection, 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)).".

(3) MANAGED CARE ENTITIES.—Section 1932 of the Social Security Act (42 U.S.C. 1396u–2) is

amended by adding at the end the following new subsection:

"(i) DRUG UTILIZATION REVIEW ACTIVITIES AND REQUIREMENTS.—Beginning not later than October 1, 2019, each contract under a State plan with a managed care entity (other than a primary care case manager) under section 1903(m) shall provide that the entity is in compliance with the applicable provisions of section 438.3(s)(2) of title 42, Code of Federal Regulations, section 483.3(s)(4)) of such title, and section 483.3(s)(5) of such title, as such provisions were in effect on March 31, 2018.".

(b) IDENTIFYING AND ADDRESSING INAPPROPRIATE PRESCRIBING AND BILLING PRACTICES UNDER MEDICAID.—

(1) IN GENERAL.—Section 1927(g) of the Social Security Act (42 U.S.C. 1396r–8(g)) is amended—

(A) in paragraph (1)(A)—

(i) by striking "of section 1903(i)(10)(B)" and inserting "of section 1902(a)(54)";

(ii) by striking ", by not later than January 1, 1993,";

(iii) by inserting after "gross overuse," the following: "excessive utilization,"; and

(iv) by striking "or inappropriate or medically unnecessary care" and inserting "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization"; and

(B) in paragraph (2)(B)—

(i) by inserting after "gross overuse," the following: "excessive utilization,"; and

(ii) by striking "or inappropriate or medically unnecessary care" and inserting "inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect with respect to retrospective drug use reviews conducted on or after October 1, 2020.

SEC. 1005. GUIDANCE TO IMPROVE CARE FOR INFANTS WITH NEONATAL ABSTINENCE SYNDROME AND THEIR MOTHERS; GAO STUDY ON GAPS IN MEDICAID COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN WITH SUBSTANCE USE DISORDER.

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

Human Services shall issue guidance to improve care for infants with neonatal abstinence syndrome and their families. Such guidance shall include—

(1) best practices from States with respect to innovative or evidenced-based payment models that focus on prevention, screening, treatment, plans of safe care, and postdischarge services for mothers and fathers with substance use disorders and babies with neonatal abstinence syndrome that improve care and clinical outcomes;

(2) recommendations for States on available financing options under the Medicaid program under title XIX of such Act and under the Children's Health Insurance Program under title XXI of such Act for Children's Health Insurance Program Health Services Initiative funds for parents with substance use disorders, infants with neonatal abstinence syndrome, and home-visiting services;

(3) guidance and technical assistance to State Medicaid agencies regarding additional flexibilities and incentives related to screening, prevention, and postdischarge services, including parenting supports, and infant-caregiver bonding, including breastfeeding when it is appropriate; and

(4) guidance regarding suggested terminology and ICD codes to identify infants with neonatal abstinence syndrome and neonatal opioid withdrawal syndrome, which could include opioid-exposure, opioid withdrawal not requiring pharmacotherapy, and opioid withdrawal requiring pharmacotherapy.

(b) GAO STUDY.—Not later than 1 year 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, addressing gaps in coverage for pregnant women with substance use disorder under the Medicaid program under title XIX of the Social Security Act, and gaps in coverage for postpartum women with substance use disorder who had coverage during their pregnancy under the Medicaid program under such title.

SEC. 1006. MEDICAID HEALTH HOMES FOR SUBSTANCE-USE-DISORDER MEDICAID ENROLLEES.

(a) EXTENSION OF ENHANCED FMAP FOR CERTAIN HEALTH HOMES FOR INDIVIDUALS WITH SUBSTANCE USE DISORDERS.—Section 1945(c) of the Social Security Act (42 U.S.C. 1396w–4(c)) is amended—

(1) in paragraph (1), by inserting "subject to paragraph (4)," after "except that,"; and

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

"(4) SPECIAL RULE RELATING TO SUBSTANCE USE DISORDER HEALTH HOMES.—

"(A) IN GENERAL.—In the case of a State with an SUD-focused State plan amendment approved by the Secretary on or after October 1, 2018, the Secretary may, at the request of the State, extend the application of the Federal medical assistance percentage described in paragraph (1) to payments for the provision of health home services to SUD-eligible individuals under such State plan amendment, in addition to the first 8 fiscal year quarters the State plan amendment is in effect, for the subsequent 2 fiscal year quarters that the State plan amendment is in effect. Nothing in this section shall be construed as prohibiting a State with a State plan amendment that is approved under this section and that is not an SUD-focused State plan amendment from additionally having approved on or after such date an SUD-focused State plan amendment under this section, including for purposes of application of this paragraph.

"(B) REPORT REQUIREMENTS.—In the case of a State with an SUD-focused State plan amendment for which the application of the Fed-

eral medical assistance percentage has been extended under subparagraph (A), such State shall, at the end of the period of such State plan amendment, submit to the Secretary a report on the following, with respect to SUD-eligible individuals provided health home services under such State plan amendment:

"(i) The quality of health care provided to such individuals, with a focus on outcomes relevant to the recovery of each such individual.

"(ii) The access of such individuals to health care.

"(iii) The total expenditures of such individuals for health care.

For purposes of this subparagraph, the Secretary shall specify all applicable measures for determining quality, access, and expenditures.

"(C) BEST PRACTICES.—Not later than October 1, 2020, the Secretary shall make publicly available on the internet website of the Centers for Medicare & Medicaid Services best practices for designing and implementing an SUD-focused State plan amendment, based on the experiences of States that have State plan amendments ap-

proved under this section that include SUD-eligible individuals.

"(D) DEFINITIONS.—For purposes of this paragraph:

"(i) SUD-ELIGIBLE INDIVIDUALS.—The term 'SUD-eligible individual' means, with respect to a State, an individual who satisfies all of the following:

"(I) The individual is an eligible individual with chronic conditions.

"(II) The individual is an individual with a substance use disorder.

"(III) The individual has not previously received health home services under any other State plan amendment approved for the State under this section by the Secretary.

"(ii) SUD-FOCUSED STATE PLAN AMENDMENT.—The term 'SUD-focused State plan amendment' means a State plan amendment under this section that is designed to provide health home services primarily to SUD-eligible individuals.".

(b) REQUIREMENT FOR STATE MEDICAID PLANS TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREATMENT.—

(1) REQUIREMENT FOR STATE MEDICAID PLANS TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREATMENT.—Section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)) is amended, in the matter preceding clause (i), by striking "and (28)" and inserting "(28), and (29)".

(2) INCLUSION OF MEDICATION-ASSISTED TREATMENT AS MEDICAL ASSISTANCE.—Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended—

(A) in paragraph (28), by striking "and" at the end;

(B) by redesignating paragraph (29) as paragraph (30); and

(C) by inserting after paragraph (28) the following new paragraph:

"(29) subject to paragraph (2) of subsection (ee), for the period beginning October 1, 2020, and ending September 30, 2025, medication-assisted treatment (as defined in paragraph (1) of such subsection); and".

(3) MEDICATION-ASSISTED TREATMENT DEFINED; WAIVERS.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

"(ee) MEDICATION-ASSISTED TREATMENT.—

"(1) DEFINITION.—For purposes of subsection (a)(29), the term 'medication-assisted treatment'—

"(A) means all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and

"(B) includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

"(2) EXCEPTION.—The provisions of paragraph (29) of subsection (a) shall not apply with respect to a State for the period specified in such paragraph, if before the beginning of such period the State certifies to the satisfaction of the Secretary that implementing such provisions statewide for all individuals eligible to enroll in the State plan (or waiver of the State plan) would not be feasible by reason of a shortage of qualified providers of medication-assisted treatment,

or facilities providing such treatment, that will contract with the State or a managed care entity with which the State has a contract under section 1903(m) or under section 1905(t)(3).".

(4) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by this subsection shall apply with respect to medical assistance provided on or after October 1, 2020, and before October 1, 2025.

(B) EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) that the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet any requirement imposed by the amendments made by this subsection, the respective plan 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 the enactment of this Act. 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.

SEC. 1007. CARING RECOVERY FOR INFANTS AND BABIES.

(a) STATE PLAN AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by sections 1001 and 1004, is further amended—

(1) in paragraph (84)(C), by striking "and" after the semicolon;

(2) in paragraph (85), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (85), the following new paragraph:

"(86) provide, at the option of the State, for making medical assistance available on an inpatient or outpatient basis at a residential pediatric recovery center (as defined in subsection (pp)) to infants with neonatal abstinence syndrome.".

(b) RESIDENTIAL PEDIATRIC RECOVERY CENTER DEFINED.—Section 1902 of such Act (42 U.S.C. 1396a), as amended by sections 1001 and 1004, is further amended by adding at the end the following new subsection:

"(pp) RESIDENTIAL PEDIATRIC RECOVERY CENTER DEFINED.—

"(1) IN GENERAL.—For purposes of section 1902(a)(86), the term 'residential pediatric recovery center' means a center or facility that furnishes items and services for which medical assistance is available under the State plan to infants with the diagnosis of neonatal abstinence syndrome without any other significant medical risk factors.

"(2) COUNSELING AND SERVICES.—A residential pediatric recovery center may offer counseling and other services to mothers (and other appropriate family members and caretakers) of infants receiving treatment at such centers if such services are otherwise covered under the State plan under this title or under a waiver of such plan. Such other services may include the following:

"(A) Counseling or referrals for services.

"(B) Activities to encourage caregiver-infant bonding.

"(C) Training on caring for such infants.".

(c) EFFECTIVE DATE.—The amendments made by this section take effect on the date of enactment of this Act and shall apply to medical assistance furnished on or after that date, without regard to final regulations to carry out such amendments being promulgated as of such date.

1 ***SEC. 1008. PEER SUPPORT ENHANCEMENT AND EVALUA-***
2 ***TION REVIEW.***

3 *(a) IN GENERAL.—Not later than 2 years after the*
4 *date of the enactment of this Act, the Comptroller General*
5 *of the United States shall submit to the Committee on En-*
6 *ergy and Commerce of the House of Representatives, the*
7 *Committee on Finance of the Senate, and the Committee*
8 *on Health, Education, Labor and Pensions of the Senate*
9 *a report on the provision of peer support services under the*
10 *Medicaid program.*

11 *(b) CONTENT OF REPORT.—*

12 *(1) IN GENERAL.—The report required under*
13 *subsection (a) shall include the following information:*

14 *(A) Information on State coverage of peer*
15 *support services under Medicaid, including—*

16 *(i) the mechanisms through which*
17 *States may provide such coverage, including*
18 *through existing statutory authority or*
19 *through waivers;*

20 *(ii) the populations to which States*
21 *have provided such coverage;*

22 *(iii) the payment models, including*
23 *any alternative payment models, used by*
24 *States to pay providers of such services; and*

(iv) where available, information on Federal and State spending under Medicaid for peer support services.

(B) Information on selected State experiences in providing medical assistance for peer support services under State Medicaid plans and whether States measure the effects of providing such assistance with respect to—

(i) improving access to behavioral health services;

(ii) improving early detection, and preventing worsening, of behavioral health disorders;

(iii) reducing chronic and comorbid conditions; and

(iv) reducing overall health costs.

(2) RECOMMENDATIONS.—The report required under subsection (a) shall include recommendations, including recommendations for such legislative and administrative actions related to improving services, including peer support services, and access to peer support services under Medicaid as the Comptroller General of the United States determines appropriate.

1 ***SEC. 1009. MEDICAID SUBSTANCE USE DISORDER TREAT-***
2 ***MENT VIA TELEHEALTH.***

3 *(a) DEFINITIONS.—In this section:*

4 *(1) COMPTROLLER GENERAL.—The term "Comp-*
5 *troller General" means the Comptroller General of the*
6 *United States.*

7 *(2) SCHOOL-BASED HEALTH CENTER.—The term*
8 *"school-based health center" has the meaning given*
9 *that term in section 2110(c)(9) of the Social Security*
10 *Act (42 U.S.C. 1397jj(c)(9)).*

11 *(3) SECRETARY.—The term "Secretary" means*
12 *the Secretary of Health and Human Services.*

13 *(4) UNDERSERVED AREA.—The term "under-*
14 *served area" means a health professional shortage*
15 *area (as defined in section 332(a)(1)(A) of the Public*
16 *Health Service Act (42 U.S.C. 254e(a)(1)(A))) and a*
17 *medically underserved area (according to a designa-*
18 *tion under section 330(b)(3)(A) of the Public Health*
19 *Service Act (42 U.S.C. 254b(b)(3)(A))).*

20 *(b) GUIDANCE TO STATES REGARDING FEDERAL RE-*
21 *IMBURSEMENT FOR FURNISHING SERVICES AND TREAT-*
22 *MENT FOR SUBSTANCE USE DISORDERS UNDER MEDICAID*
23 *USING SERVICES DELIVERED VIA TELEHEALTH, INCLUD-*
24 *ING IN SCHOOL-BASED HEALTH CENTERS.—Not later than*
25 *1 year after the date of enactment of this Act, the Secretary,*
26 *acting through the Administrator of the Centers for Medi-*

care & Medicaid Services, shall issue guidance to States on the following:

(1) State options for Federal reimbursement of expenditures under Medicaid for furnishing services and treatment for substance use disorders, including assessment, medication-assisted treatment, counseling, medication management, and medication adherence with prescribed medication regimes, using services delivered via telehealth. Such guidance shall also include guidance on furnishing services and treatments that address the needs of high-risk individuals, including at least the following groups:

(A) American Indians and Alaska Natives.

(B) Adults under the age of 40.

(C) Individuals with a history of non-fatal overdose.

(D) Individuals with a co-occurring serious mental illness and substance use disorder.

(2) State options for Federal reimbursement of expenditures under Medicaid for education directed to providers serving Medicaid beneficiaries with substance use disorders using the hub and spoke model, through contracts with managed care entities, through administrative claiming for disease management ac-

tivities, and under Delivery System Reform Incentive Payment ("DSRIP") programs.

(3) State options for Federal reimbursement of expenditures under Medicaid for furnishing services and treatment for substance use disorders for individuals enrolled in Medicaid in a school-based health center using services delivered via telehealth.

(c) GAO EVALUATION OF CHILDREN'S ACCESS TO SERVICES AND TREATMENT FOR SUBSTANCE USE DISORDERS UNDER MEDICAID.—

(1) STUDY.—The Comptroller General shall evaluate children's access to services and treatment for substance use disorders under Medicaid. The evaluation shall include an analysis of State options for improving children's access to such services and treatment and for improving outcomes, including by increasing the number of Medicaid providers who offer services or treatment for substance use disorders in a school-based health center using services delivered via telehealth, particularly in rural and underserved areas. The evaluation shall include an analysis of Medicaid provider reimbursement rates for services and treatment for substance use disorders.

(2) REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General

shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(d) REPORT ON REDUCING BARRIERS TO USING SERVICES DELIVERED VIA TELEHEALTH AND REMOTE PATIENT MONITORING FOR PEDIATRIC POPULATIONS UNDER MEDICAID.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall issue a report to the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives identifying best practices and potential solutions for reducing barriers to using services delivered via telehealth to furnish services and treatment for substance use disorders among pediatric populations under Medicaid. The report shall include—

(A) analyses of the best practices, barriers, and potential solutions for using services delivered via telehealth to diagnose and provide services and treatment for children with substance use disorders, including opioid use disorder; and

(B) identification and analysis of the differences, if any, in furnishing services and treatment for children with substance use disorders using services delivered via telehealth and using services delivered in person, such as, and to the extent feasible, with respect to—

(i) utilization rates;

(ii) costs;

(iii) avoidable inpatient admissions and readmissions;

(iv) quality of care; and

(v) patient, family, and provider satisfaction.

(2) PUBLICATION.—The Secretary shall publish the report required under paragraph (1) on a public internet website of the Department of Health and Human Services.

SEC. 1010. ENHANCING PATIENT ACCESS TO NON-OPIOID TREATMENT OPTIONS.

Not later than January 1, 2019, the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall issue 1 or more final guidance documents, or update existing guidance documents, to States regarding mandatory and optional items and services that may be provided

under a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), or under a waiver of such a plan, for non-opioid treatment and management of pain, including, but not limited to, evidence-based, non-opioid pharmacological therapies and non-pharmacological therapies.

SEC. 1011. ASSESSING BARRIERS TO OPIOID USE DISORDER TREATMENT.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the "Comptroller General") shall conduct a study regarding the barriers to providing medication used in the treatment of substance use disorders under Medicaid distribution models such as the "buy-and-bill" model, and options for State Medicaid programs to remove or reduce such barriers. The study shall include analyses of each of the following models of distribution of substance use disorder treatment medications, particularly buprenorphine, naltrexone, and buprenorphine-naloxone combinations:

(A) The purchasing, storage, and administration of substance use disorder treatment medications by providers.

(B) The dispensing of substance use disorder treatment medications by pharmacists.

(C) The ordering, prescribing, and obtaining substance use disorder treatment medications on demand from specialty pharmacies by providers.

(2) REQUIREMENTS.—For each model of distribution specified in paragraph (1), the Comptroller General shall evaluate how each model presents barriers or could be used by selected State Medicaid programs to reduce the barriers related to the provision of substance use disorder treatment by examining what is known about the effects of the model of distribution on—

(A) Medicaid beneficiaries' access to substance use disorder treatment medications;

(B) the differential cost to the program between each distribution model for medication-assisted treatment; and

(C) provider willingness to provide or prescribe substance use disorder treatment medications.

(b) REPORT.—Not later than 15 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the

study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

SEC. 1012. HELP FOR MOMS AND BABIES.

(a) MEDICAID STATE PLAN.—Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)), as amended by section 1006, is further amended by adding at the end the following new sentence: "In the case of a woman who is eligible for medical assistance on the basis of being pregnant (including through the end of the month in which the 60-day period beginning on the last day of her pregnancy ends), who is a patient in an institution for mental diseases for purposes of receiving treatment for a substance use disorder, and who was enrolled for medical assistance under the State plan immediately before becoming a patient in an institution for mental diseases or who becomes eligible to enroll for such medical assistance while such a patient, the exclusion from the definition of 'medical assistance' set forth in the subdivision (B) following paragraph (30) of the first sentence of this subsection shall not be construed as prohibiting Federal financial participation for medical assistance for items or services that are provided to the woman outside of the institution.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall take effect on the date of enactment of this Act.

(2) RULE FOR CHANGES REQUIRING STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendment made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements 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 the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

1 ***SEC. 1013. SECURING FLEXIBILITY TO TREAT SUBSTANCE***
2 ***USE DISORDERS.***

3 *Section 1903(m) of the Social Security Act (42 U.S.C.*
4 *1396b(m)) is amended by adding at the end the following*
5 *new paragraph:*

6 *"(7) Payment shall be made under this title to a State*
7 *for expenditures for capitation payments described in sec-*
8 *tion 438.6(e) of title 42, Code of Federal Regulations (or*
9 *any successor regulation).".*

10 ***SEC. 1014. MACPAC STUDY AND REPORT ON MAT UTILIZA-***
11 ***TION CONTROLS UNDER STATE MEDICAID***
12 ***PROGRAMS.***

13 *(a) STUDY.—The Medicaid and CHIP Payment and*
14 *Access Commission shall conduct a study and analysis of*
15 *utilization control policies applied to medication-assisted*
16 *treatment for substance use disorders under State Medicaid*
17 *programs, including policies and procedures applied both*
18 *in fee-for-service Medicaid and in risk-based managed care*
19 *Medicaid, which shall—*

20 *(1) include an inventory of such utilization con-*
21 *trol policies and related protocols for ensuring access*
22 *to medically necessary treatment;*

23 *(2) determine whether managed care utilization*
24 *control policies and procedures for medication-as-*
25 *sisted treatment for substance use disorders are con-*

sistent with section 438.210(a)(4)(ii) of title 42, Code of Federal Regulations; and

(3) identify policies that—

(A) limit an individual's access to medication-assisted treatment for a substance use disorder by limiting the quantity of medication-assisted treatment prescriptions, or the number of refills for such prescriptions, available to the individual as part of a prior authorization process or similar utilization protocols; and

(B) apply without evaluating individual instances of fraud, waste, or abuse.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Medicaid and CHIP Payment and Access Commission shall make publicly available a report containing the results of the study conducted under subsection (a).

SEC. 1015. OPIOID ADDICTION TREATMENT PROGRAMS ENHANCEMENT.

(a) T–MSIS SUBSTANCE USE DISORDER DATA BOOK.—

(1) IN GENERAL.—Not later than the date that is 12 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall publish

on the public website of the Centers for Medicare & Medicaid Services a report with comprehensive data on the prevalence of substance use disorders in the Medicaid beneficiary population and services provided for the treatment of substance use disorders under Medicaid.

(2) CONTENT OF REPORT.—The report required under paragraph (1) shall include, at a minimum, the following data for each State (including, to the extent available, for the District of Columbia, Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa):

(A) The number and percentage of individuals enrolled in the State Medicaid plan or waiver of such plan in each of the major enrollment categories (as defined in a public letter from the Medicaid and CHIP Payment and Access Commission to the Secretary) who have been diagnosed with a substance use disorder and whether such individuals are enrolled under the State Medicaid plan or a waiver of such plan, including the specific waiver authority under which they are enrolled, to the extent available.

(B) A list of the substance use disorder treatment services by each major type of service,

1 *such as counseling, medication-assisted treat-*
2 *ment, peer support, residential treatment, and*
3 *inpatient care, for which beneficiaries in each*
4 *State received at least 1 service under the State*
5 *Medicaid plan or a waiver of such plan.*
6 *(C) The number and percentage of individ-*
7 *uals with a substance use disorder diagnosis en-*
8 *rolled in the State Medicaid plan or waiver of*
9 *such plan who received substance use disorder*
10 *treatment services under such plan or waiver by*
11 *each major type of service under subparagraph*
12 *(B) within each major setting type, such as out-*
13 *patient, inpatient, residential, and other home-*
14 *based and community-based settings.*
15 *(D) The number of services provided under*
16 *the State Medicaid plan or waiver of such plan*
17 *per individual with a substance use disorder di-*
18 *agnosis enrolled in such plan or waiver for each*
19 *major type of service under subparagraph (B).*
20 *(E) The number and percentage of individ-*
21 *uals enrolled in the State Medicaid plan or*
22 *waiver, by major enrollment category, who re-*
23 *ceived substance use disorder treatment*
24 *through—*

(i) a medicaid managed care entity (as defined in section 1932(a)(1)(B) of the Social Security Act (42 U.S.C. 1396u–2(a)(1)(B))), including the number of such individuals who received such assistance through a prepaid inpatient health plan or a prepaid ambulatory health plan;

(ii) a fee-for-service payment model; or

(iii) an alternative payment model, to the extent available.

(F) The number and percentage of individuals with a substance use disorder who receive substance use disorder treatment services in an outpatient or home-based and community-based setting after receiving treatment in an inpatient or residential setting, and the number of services received by such individuals in the outpatient or home-based and community-based setting.

(3) ANNUAL UPDATES.—The Secretary shall issue an updated version of the report required under paragraph (1) not later than January 1 of each calendar year through 2024.

(4) USE OF T–MSIS DATA.—The report required under paragraph (1) and updates required under paragraph (3) shall—

(A) use data and definitions from the Transformed Medicaid Statistical Information System ("T–MSIS") data set that is no more than 12 months old on the date that the report or update is published; and

(B) as appropriate, include a description with respect to each State of the quality and completeness of the data and caveats describing the limitations of the data reported to the Secretary by the State that is sufficient to communicate the appropriate uses for the information.

(b) MAKING T–MSIS DATA ON SUBSTANCE USE DISORDERS AVAILABLE TO RESEARCHERS.—

(1) IN GENERAL.—The Secretary shall publish in the Federal Register a system of records notice for the data specified in paragraph (2) for the Transformed Medicaid Statistical Information System, in accordance with section 552a(e)(4) of title 5, United States Code. The notice shall outline policies that protect the security and privacy of the data that, at a minimum, meet the security and privacy policies of SORN 09–70–0541 for the Medicaid Statistical Information System.

(2) REQUIRED DATA.—The data covered by the systems of records notice required under paragraph

(1) shall be sufficient for researchers and States to analyze the prevalence of substance use disorders in the Medicaid beneficiary population and the treatment of substance use disorders under Medicaid across all States (including the District of Columbia, Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), forms of treatment, and treatment settings.

(3) INITIATION OF DATA-SHARING ACTIVITIES.—Not later than January 1, 2019, the Secretary shall initiate the data-sharing activities outlined in the notice required under paragraph (1).

SEC. 1016. BETTER DATA SHARING TO COMBAT THE OPIOID CRISIS.

(a) IN GENERAL.—Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), as amended by section 1013, is further amended by adding at the end the following new paragraph:

"(8)(A) The State agency administering the State plan under this title may have reasonable access, as determined by the State, to 1 or more prescription drug monitoring program databases administered or accessed by the State to the extent the State agency is permitted to access such databases under State law.

"(B) Such State agency may facilitate reasonable access, as determined by the State, to 1 or more prescription drug monitoring program databases administered or accessed by the State, to same extent that the State agency is permitted under State law to access such databases, for—

"(i) any provider enrolled under the State plan to provide services to Medicaid beneficiaries; and

"(ii) any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under this subsection or under section 1905(t)(3).

"(C) Such State agency may share information in such databases, to the same extent that the State agency is permitted under State law to share information in such databases, with—

"(i) any provider enrolled under the State plan to provide services to Medicaid beneficiaries; and

"(ii) any managed care entity (as defined under section 1932(a)(1)(B)) that has a contract with the State under this subsection or under section 1905(t)(3).".

(b) SECURITY AND PRIVACY.—All applicable State and Federal security and privacy protections and laws shall apply to any State agency, individual, or entity accessing 1 or more prescription drug monitoring program databases

or obtaining information in such databases in accordance with section 1903(m)(8) of the Social Security Act (as added by subsection (a)).

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of enactment of this Act.

SEC. 1017. REPORT ON INNOVATIVE STATE INITIATIVES AND STRATEGIES TO PROVIDE HOUSING-RELATED SERVICES AND SUPPORTS TO INDIVIDUALS STRUGGLING WITH SUBSTANCE USE DISORDERS UNDER MEDICAID.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue a report to Congress describing innovative State initiatives and strategies for providing housing-related services and supports under a State Medicaid program to individuals with substance use disorders who are experiencing or at risk of experiencing homelessness.

(b) CONTENT OF REPORT.—The report required under subsection (a) shall describe the following:

(1) Existing methods and innovative strategies developed and adopted by State Medicaid programs that have achieved positive outcomes in increasing housing stability among Medicaid beneficiaries with

substance use disorders who are experiencing or at risk of experiencing homelessness, including Medicaid beneficiaries with substance use disorders who are—

(A) receiving treatment for substance use disorders in inpatient, residential, outpatient, or home-based and community-based settings;

(B) transitioning between substance use disorder treatment settings; or

(C) living in supportive housing or another model of affordable housing.

(2) Strategies employed by Medicaid managed care organizations, primary care case managers, hospitals, accountable care organizations, and other care coordination providers to deliver housing-related services and supports and to coordinate services provided under State Medicaid programs across different treatment settings.

(3) Innovative strategies and lessons learned by States with Medicaid waivers approved under section 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n), including—

(A) challenges experienced by States in designing, securing, and implementing such waivers or plan amendments;

(B) how States developed partnerships with other organizations such as behavioral health agencies, State housing agencies, housing providers, health care services agencies and providers, community-based organizations, and health insurance plans to implement waivers or State plan amendments; and

(C) how and whether States plan to provide Medicaid coverage for housing-related services and supports in the future, including by covering such services and supports under State Medicaid plans or waivers.

(4) Existing opportunities for States to provide housing-related services and supports through a Medicaid waiver under sections 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n) or through a State Medicaid plan amendment, such as the Assistance in Community Integration Service pilot program, which promotes supportive housing and other housing-related supports under Medicaid for individuals with substance use disorders and for which Maryland has a waiver approved under such section 1115 to conduct the program.

(5) Innovative strategies and partnerships developed and implemented by State Medicaid programs

or other entities to identify and enroll eligible individuals with substance use disorders who are experiencing or at risk of experiencing homelessness in State Medicaid programs.

SEC. 1018. TECHNICAL ASSISTANCE AND SUPPORT FOR INNOVATIVE STATE STRATEGIES TO PROVIDE HOUSING-RELATED SUPPORTS UNDER MEDICAID.

(a) IN GENERAL.—The Secretary of Health and Human Services shall provide technical assistance and support to States regarding the development and expansion of innovative State strategies (including through State Medicaid demonstration projects) to provide housing-related supports and services and care coordination services under Medicaid to individuals with substance use disorders.

(b) REPORT.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue a report to Congress detailing a plan of action to carry out the requirements of subsection (a).

TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID CRISIS

SEC. 2001. EXPANDING THE USE OF TELEHEALTH SERVICES FOR THE TREATMENT OF OPIOID USE DISORDER AND OTHER SUBSTANCE USE DISORDERS.

(a) IN GENERAL.—Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (2)(B)—

(A) in clause (i), in the matter preceding subclause (I), by striking "clause (ii)" and inserting "clause (ii) and paragraph (6)(C)"; and

(B) in clause (ii), in the heading, by striking "FOR HOME DIALYSIS THERAPY";

(2) in paragraph (4)(C)—

(A) in clause (i), by striking "paragraph (6)" and inserting "paragraphs (5), (6), and (7)"; and

(B) in clause (ii)(X), by inserting "or telehealth services described in paragraph (7)" before the period at the end; and

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

"(7) TREATMENT OF SUBSTANCE USE DISORDER SERVICES FURNISHED THROUGH TELEHEALTH.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after July 1, 2019, to an eligible telehealth individual with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, as determined by the Secretary, at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph).".

(b) IMPLEMENTATION.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") may implement the amendments made by this section by interim final rule.

(c) REPORT.—

(1) IN GENERAL.—Not later than 5 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the impact of the implementation of the amendments made by this section with respect to telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) on—

(A) the utilization of health care items and services under title XVIII of such Act (42 U.S.C. 1395 et seq.) related to substance use disorders, including emergency department visits; and

(B) health outcomes related to substance use disorders, such as opioid overdose deaths.

(2) FUNDING.—For purposes of carrying out paragraph (1), in addition to funds otherwise available, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $3,000,000 to the Centers for Medicare & Medicaid Services Program Management Account to remain available until expended.

SEC. 2002. COMPREHENSIVE SCREENINGS FOR SENIORS.

(a) INITIAL PREVENTIVE PHYSICAL EXAMINATION.—Section 1861(ww) of the Social Security Act (42 U.S.C. 1395x(ww)) is amended—

(1) in paragraph (1)—

(A) by striking "paragraph (2) and" and inserting "paragraph (2),"; and

(B) by inserting "and the furnishing of a review of any current opioid prescriptions (as defined in paragraph (4)),'' after "upon the agreement with the individual,"; and

(2) in paragraph (2)—

(A) by redesignating subparagraph (N) as subparagraph (O); and

(B) by inserting after subparagraph (M) the following new subparagraph:

"(N) Screening for potential substance use disorders."; and

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

"(4) For purposes of paragraph (1), the term 'a review of any current opioid prescriptions' means, with respect to an individual determined to have a current prescription for opioids—

"(A) a review of the potential risk factors to the individual for opioid use disorder;

"(B) an evaluation of the individual's severity of pain and current treatment plan;

"(C) the provision of information on non-opioid treatment options; and

"(D) a referral to a specialist, as appropriate.".

(b) ANNUAL WELLNESS VISIT.—Section 1861(hhh)(2) of the Social Security Act (42 U.S.C. 1395x(hhh)(2)) is amended—

(1) by redesignating subparagraph (G) as subparagraph (I); and

(2) by inserting after subparagraph (F) the following new subparagraphs:

"(G) Screening for potential substance use disorders and referral for treatment as appropriate.

"(H) The furnishing of a review of any current opioid prescriptions (as defined in subsection (ww)(4)).".

(c) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsection (a) or (b) shall be construed to prohibit separate payment for structured assessment and intervention services for substance abuse furnished to an individual on the same day as an initial preventive physical examination or an annual wellness visit.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to examinations and visits furnished on or after January 1, 2020.

SEC. 2003. EVERY PRESCRIPTION CONVEYED SECURELY.

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

"(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D

drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

"(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, through rulemaking, specify circumstances and processes by which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

"(i) a prescription issued when the practitioner and dispensing pharmacy are the same entity;

"(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

"(iii) a prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year,

from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

"(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

"(v) a prescription issued by a practitioner prescribing a drug under a research protocol;

"(vi) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such

as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

"(vii) a prescription issued by a practitioner—

"(I) for an individual who receives hospice care under this title; and

"(II) that is not covered under the hospice benefit under this title; and

"(viii) a prescription issued by a practitioner for an individual who is—

"(I) a resident of a nursing facility (as defined in section 1919(a)); and

"(II) dually eligible for benefits under this title and title XIX.

"(C) DISPENSING.—(i) Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the requirement under subparagraph (A).

"(ii) Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral, or fax prescriptions that are consistent with laws and regulations.

"(iii) Nothing in this paragraph shall be construed as affecting the ability of an individual who is being prescribed a covered part D drug to designate a particular pharmacy to dispense the covered part D drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

"(D) ENFORCEMENT.—The Secretary shall, through rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2021.

(c) UPDATE OF BIOMETRIC COMPONENT OF MULTIFACTOR AUTHENTICATION.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall update the requirements for the biometric component of

multifactor authentication with respect to electronic prescriptions of controlled substances.

SEC. 2004. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS UNDER MEDICARE TO ESTABLISH DRUG MANAGEMENT PROGRAMS FOR AT-RISK BENEFICIARIES.

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

(1) in paragraph (1), by inserting after subparagraph (E) the following new subparagraph:

"(F) With respect to plan years beginning on or after January 1, 2022, a drug management program for at-risk beneficiaries described in paragraph (5)."; and

(2) in paragraph (5)(A), by inserting "(and for plan years beginning on or after January 1, 2022, a PDP sponsor shall)" after "A PDP sponsor may".

SEC. 2005. MEDICARE COVERAGE OF CERTAIN SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (FF), by striking at the end "and";

(2) in subparagraph (GG), by inserting at the end "and"; and

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

"(HH) opioid use disorder treatment services (as defined in subsection (jjj)).".

(b) OPIOID USE DISORDER TREATMENT SERVICES AND OPIOID TREATMENT PROGRAM DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"(jjj) OPIOID USE DISORDER TREATMENT SERVICES; OPIOID TREATMENT PROGRAM.—

"(1) OPIOID USE DISORDER TREATMENT SERVICES.—The term 'opioid use disorder treatment services' means items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, including—

"(A) opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for use in the treatment of opioid use disorder;

"(B) dispensing and administration of such medications, if applicable;

"(C) substance use counseling by a professional to the extent authorized under State law to furnish such services;

"(D) individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law);

"(E) toxicology testing, and

"(F) other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

"(2) OPIOID TREATMENT PROGRAM.—The term 'opioid treatment program' means an entity that is an opioid treatment program (as defined in section 8.2 of title 42 of the Code of Federal Regulations, or any successor regulation) that—

"(A) is enrolled under section 1866(j);

"(B) has in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program;

"(C) is accredited by an accrediting body approved by the Substance Abuse and Mental Health Services Administration; and

"(D) meets such additional conditions as the Secretary may find necessary to ensure—

"(i) the health and safety of individuals being furnished services under such program; and

"(ii) the effective and efficient furnishing of such services.".

(c) PAYMENT.—

(1) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking "and (BB)" and inserting "(BB)"; and

(B) by inserting before the semicolon at the end the following ", and (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary".

(2) PAYMENT DETERMINATION.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

"(w) OPIOID USE DISORDER TREATMENT SERVICES.—

"(1) IN GENERAL.—The Secretary shall pay to an opioid treatment program (as defined in para-

graph (2) of section 1861(jjj)) an amount that is equal to 100 percent of a bundled payment under this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.

"(2) CONSIDERATIONS.—The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under title XIX or under the TRICARE program under chapter 55 of title 10 of the United States Code.

"(3) ANNUAL UPDATES.—The Secretary shall provide an update each year to the bundled payment amounts under this subsection.".

(d) INCLUDING OPIOID TREATMENT PROGRAMS AS MEDICARE PROVIDERS.—Section 1866(e) of the Social Security Act (42 U.S.C. 1395cc(e)) is amended—

(1) in paragraph (1), by striking at the end "and";

(2) in paragraph (2), by striking the period at the end and inserting "; and"; and

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

"(3) opioid treatment programs (as defined in paragraph (2) of section 1861(jjj)), but only with respect to the furnishing of opioid use disorder treatment services (as defined in paragraph (1) of such section).".

SEC. 2006. ENCOURAGING APPROPRIATE PRESCRIBING UNDER MEDICARE FOR VICTIMS OF OPIOID OVERDOSE.

Section 1860D–4(c)(5)(C) of the Social Security Act (42 U.S.C. 1395w–104(c)(5)(C)) is amended—

(1) in clause (i), in the matter preceding subclause (I), by striking "For purposes" and inserting "Except as provided in clause (v), for purposes"; and

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

"(v) TREATMENT OF ENROLLEES WITH A HISTORY OF OPIOID-RELATED OVERDOSE.—

"(I) IN GENERAL.—For plan years beginning not later than January 1, 2021, a part D eligible individual who is not an exempted individual described in clause (ii) and who is identified under this clause as a part D eligible individual with a history of opioid-related overdose (as defined by the Secretary) shall be included as a potentially at-risk beneficiary for prescription drug abuse under the drug management program under this paragraph.

"(II) IDENTIFICATION AND NOTICE.—For purposes of this clause, the Secretary shall—

"(aa) identify part D eligible individuals with a history of opioid-related overdose (as so defined); and

"(bb) notify the PDP sponsor of the prescription drug plan in which such an individual is enrolled of such identification.".

SEC. 2007. AUTOMATIC ESCALATION TO EXTERNAL REVIEW UNDER A MEDICARE PART D DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

(a) IN GENERAL.—Section 1860D–4(c)(5) of the Social Security Act (42 U.S.C. 1395ww–10(c)(5)) is amended—

(1) in subparagraph (B), in each of clauses (ii)(III) and (iii)(IV), by striking "and the option of an automatic escalation to external review" and inserting ", including notice that if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, outside entity contracted with the Secretary for review and resolution"; and

(2) in subparagraph (E), by striking "and the option" and all that follows and inserting the following: "and if on reconsideration a PDP sponsor affirms its denial, in whole or in part, the case shall be automatically forwarded to the independent, out-

side entity contracted with the Secretary for review and resolution.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply beginning not later January 1, 2021.

SEC. 2008. 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.—Section 1862(o)(1) 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 section applies with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this title. A PDP sponsor shall notify the Secretary regarding the imposition of any payment suspension pursuant to the previous sentence, such as through the secure

internet website portal (or other successor technology) established under section 1859(i).

"(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) (in-

cluding 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.

TITLE III—FDA AND CONTROLLED SUBSTANCE PROVISIONS

Subtitle A—FDA Provisions

CHAPTER 1—IN GENERAL

SEC. 3001. CLARIFYING FDA REGULATION OF NON-ADDICTIVE PAIN PRODUCTS.

(a) PUBLIC MEETINGS.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall hold not less than one public meeting to address the challenges and barriers of developing non-addictive medical products intended to treat acute or chronic pain or addiction, which may include—

(1) the manner by which the Secretary may incorporate the risks of misuse and abuse of a controlled

substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) into the risk benefit assessments under subsections (d) and (e) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), section 510(k) of such Act (21 U.S.C. 360(k)), or section 515(c) of such Act (21 U.S.C. 360e(c)), as applicable;

(2) the application of novel clinical trial designs (consistent with section 3021 of the 21st Century Cures Act (Public Law 114–255)), use of real world evidence (consistent with section 505F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g)), and use of patient experience data (consistent with section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c)) for the development of non-addictive medical products intended to treat pain or addiction;

(3) the evidentiary standards and the development of opioid-sparing data for inclusion in the labeling of medical products intended to treat acute or chronic pain; and

(4) the application of eligibility criteria under sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-

addictive medical products intended to treat pain or addiction.

(b) GUIDANCE.—Not less than one year after the public meetings are conducted under subsection (a) the Secretary shall issue one or more final guidance documents, or update existing guidance documents, to help address challenges to developing non-addictive medical products to treat pain or addiction. Such guidance documents shall include information regarding—

(1) how the Food and Drug Administration may apply sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) to non-addictive medical products intended to treat pain or addiction, including the circumstances under which the Secretary—

(A) may apply the eligibility criteria under such sections 506 and 515B to non-addictive medical products intended to treat pain or addiction;

(B) considers the risk of addiction of controlled substances approved to treat pain when establishing unmet medical need; and

(C) considers pain, pain control, or pain management in assessing whether a disease or

condition is a serious or life-threatening disease or condition;

(2) the methods by which sponsors may evaluate acute and chronic pain, endpoints for non-addictive medical products intended to treat pain, the manner in which endpoints and evaluations of efficacy will be applied across and within review divisions, taking into consideration the etiology of the underlying disease, and the manner in which sponsors may use surrogate endpoints, intermediate endpoints, and real world evidence;

(3) the manner in which the Food and Drug Administration will assess evidence to support the inclusion of opioid-sparing data in the labeling of non-addictive medical products intended to treat acute or chronic pain, including—

(A) alternative data collection methodologies, including the use of novel clinical trial designs (consistent with section 3021 of the 21st Century Cures Act (Public Law 114–255)) and real world evidence (consistent with section 505F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g)), including patient registries and patient reported outcomes, as appropriate, to support product labeling;

(B) ethical considerations of exposing subjects to controlled substances in clinical trials to develop opioid-sparing data and considerations on data collection methods that reduce harm, which may include the reduction of opioid use as a clinical benefit;

(C) endpoints, including primary, secondary, and surrogate endpoints, to evaluate the reduction of opioid use;

(D) best practices for communication between sponsors and the agency on the development of data collection methods, including the initiation of data collection; and

(E) the appropriate format in which to submit such data results to the Secretary; and

(4) the circumstances under which the Food and Drug Administration considers misuse and abuse of a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)) in making the risk benefit assessment under paragraphs (2) and (4) of subsection (d) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and in finding that a drug is unsafe under paragraph (1) or (2) of subsection (e) of such section.

(c) DEFINITIONS.—In this section—

(1) the term "medical product" means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))), or device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))); and

(2) the term "opioid-sparing" means reducing, replacing, or avoiding the use of opioids or other controlled substances intended to treat acute or chronic pain.

SEC. 3002. EVIDENCE-BASED OPIOID ANALGESIC PRESCRIBING GUIDELINES AND REPORT.

(a) GUIDELINES.—The Commissioner of Food and Drugs shall develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain only for the relevant therapeutic areas where such guidelines do not exist.

(b) PUBLIC INPUT.—In developing the guidelines under subsection (a), the Commissioner of Food and Drugs shall—

(1) consult with stakeholders, which may include conducting a public meeting of medical professional societies (including any State-based societies), health care providers, State medical boards, medical special-

ties including pain medicine specialty societies, patient groups, pharmacists, academic or medical research entities, and other entities with experience in health care, as appropriate;

(2) collaborate with the Director of the Centers for Disease Control and Prevention, as applicable and appropriate, and other Federal agencies with relevant expertise as appropriate; and

(3) provide for a notice and comment period consistent with section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)) for the submission of comments by the public.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, or, if earlier, at the time the guidelines under subsection (a) are finalized, the Commissioner of Food and Drugs shall 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, and post on the public website of the Food and Drug Administration, a report on how the Food and Drug Administration will utilize the guidelines under subsection (a) to protect the public health and a description of the public health need with respect to each such indication-specific treatment guideline.

(d) UPDATES.—The Commissioner of Food and Drugs shall periodically—

(1) update the guidelines under subsection (a), informed by public input described in subsection (b); and

(2) submit to the committees specified in subsection (c) and post on the public website of the Food and Drug Administration an updated report under such subsection.

(e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS.—The Commissioner of Food and Drugs shall ensure that opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that such guidelines or recommendations, as applicable—

(1) are intended to help inform clinical decision-making by prescribers and patients; and

(2) are not intended to be used for the purposes of restricting, limiting, delaying, or denying coverage for, or access to, a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

CHAPTER 2—STOP COUNTERFEIT DRUGS BY REGULATING AND ENHANCING ENFORCEMENT NOW

SEC. 3011. SHORT TITLE.

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

SEC. 3012. NOTIFICATION, NONDISTRIBUTION, AND RECALL OF CONTROLLED SUBSTANCES.

(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 CONTROLLED SUBSTANCES.—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 CONTROLLED SUBSTANCES.

"(a) ORDER TO CEASE DISTRIBUTION AND RECALL.—

"(1) IN GENERAL.—If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health con-

sequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

"(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 whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3).

"(3) ORDER RESOLUTION.—After an order is issued according to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)—

"(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

"(B) continue the order ceasing distribution of the controlled substance until a date specified in such order; or

"(C) amend the order to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

"(4) RISK ASSESSMENT.—If the Secretary determines that the risk of recalling a controlled substance presents a greater health risk than the health risk of not recalling such controlled substance from use, an amended order under subparagraph (B) or (C) of paragraph (3) shall not include either a recall order for, or an order to cease distribution of, such controlled substance, as applicable.

"(5) ACTION FOLLOWING ORDER.—Any person who is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the controlled substance and provide notification as required by such order.

"(b) NOTICE TO PERSONS AFFECTED.—If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to paragraph (1) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3) to provide either a notice of a recall order

for, or an order to cease distribution of, such controlled substance, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public. In providing such notice, the Secretary may use the assistance of health professionals who prescribed or dispensed such controlled substances.

"(c) NONDELEGATION.—An order described in subsection (a)(3) 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 or an official senior to 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, any 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) CONTROLLED SUBSTANCES SUBJECT TO REFUSAL.—The third sentence of section 801(a) of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)) is amended by inserting ", or is a controlled substance subject to an order under section 569D" before ", or (4)".

(d) EFFECTIVE DATE.—Sections 301(eee) and 569D of the Federal Food, Drug, and Cosmetic Act, as added by subsections (a) and (b), shall be effective beginning on the date of enactment of this Act.

SEC. 3013. SINGLE SOURCE PATTERN OF IMPORTED ILLEGAL DRUGS.

Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 3012, is further amended by adding at the end the following:

"(t) SINGLE SOURCE PATTERN OF IMPORTED ILLEGAL DRUGS.—If the Secretary determines that a person subject to debarment as a result of engaging in a pattern of importing or offering for import controlled substances or drugs as described in section 306(b)(3)(D), and such pattern is identified by the Secretary as being offered for import from the same manufacturer, distributor, or importer, the Secretary may by order determine all drugs being offered for import from such person as adulterated or misbranded, unless such person can provide evidence otherwise.".

1 ***SEC. 3014. STRENGTHENING FDA AND CBP COORDINATION***
2 ***AND CAPACITY.***

3 *(a) IN GENERAL.—The Secretary of Health and*
4 *Human Services (referred to in this section as the "Sec-*
5 *retary"), acting through the Commissioner of Food and*
6 *Drugs, shall coordinate with the Secretary of Homeland Se-*
7 *curity to carry out activities related to customs and border*
8 *protection and in response to illegal controlled substances*
9 *and drug imports, including at sites of import (such as*
10 *international mail facilities), that will provide improve-*
11 *ments to such facilities, technologies, and inspection capac-*
12 *ity. Such Secretaries may carry out such activities through*
13 *a memorandum of understanding between the Food and*
14 *Drug Administration and the U.S. Customs and Border*
15 *Protection.*

16 *(b) FDA IMPORT FACILITIES AND INSPECTION CAPAC-*
17 *ITY.—*

18 *(1) IN GENERAL.—In carrying out this section,*
19 *the Secretary shall, in collaboration with the Sec-*
20 *retary of Homeland Security and the Postmaster*
21 *General of the United States Postal Service, provide*
22 *that import facilities in which the Food and Drug*
23 *Administration operates or carries out activities re-*
24 *lated to drug imports within the international mail*
25 *facilities include—*

(A) facility upgrades and improved capacity in order to increase and improve inspection and detection capabilities, which may include, as the Secretary determines appropriate—

(i) improvements to facilities, such as upgrades or renovations, and support for the maintenance of existing import facilities and sites to improve coordination between Federal agencies;

(ii) improvements in equipment and information technology enhancement to identify unapproved, counterfeit, or other unlawful controlled substances for destruction;

(iii) the construction of, or upgrades to, laboratory capacity for purposes of detection and testing of imported goods;

(iv) upgrades to the security of import facilities; and

(v) innovative technology and equipment to facilitate improved and near-real-time information sharing between the Food and Drug Administration, the Department of Homeland Security, and the United States Postal Service; and

(B) innovative technology, including controlled substance detection and testing equipment and other applicable technology, in order to collaborate with the U.S. Customs and Border Protection to share near-real-time information, including information about test results, as appropriate.

(2) INNOVATIVE TECHNOLOGY.—Any technology used in accordance with paragraph (1)(B) shall be interoperable with technology used by other relevant Federal agencies, including the U.S. Customs and Border Protection, as the Secretary determines appropriate and practicable.

(c) REPORT.—Not later than 6 months after the date of enactment of this Act, the Secretary, in consultation with the Secretary of Homeland Security and the Postmaster General of the United States Postal Service, shall report to the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate on the implementation of this section, including a summary of progress made toward near-real-time information sharing and the interoperability of such technologies.

CHAPTER 3—STOP ILLICIT DRUG IMPORTATION

SEC. 3021. SHORT TITLE.

This chapter may be cited as the "Stop Illicit Drug Importation Act of 2018".

SEC. 3022. RESTRICTING ENTRANCE OF ILLICIT DRUGS.

(a) FOOD AND DRUG ADMINISTRATION AND U.S. CUSTOMS AND BORDER PROTECTION COOPERATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs and in consultation with the U.S. Customs and Border Protection, shall develop and periodically update a mutually agreed upon list of the controlled substances that the Secretary will refer to U.S. Customs and Border Protection, unless the Secretary and U.S. Customs and Border Protection agree otherwise, when such substances are offered for import via international mail and appear to violate the Controlled Substances Act (21 U.S.C. 801 et seq.), the Controlled Substances Import and Export Act (21 U.S.C. 951 et seq.), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), or any other applicable law. The Secretary shall transfer controlled substances on such list to the U.S. Customs and Border

Protection. If the Secretary identifies additional packages that appear to be the same as such package containing a controlled substance, such additional packages may also be transferred to U.S. Customs and Border Protection. The U.S. Customs and Border Protection shall receive such packages consistent with the requirements of the Controlled Substances Act (21 U.S.C. 801 et seq.).

(2) REPORT.—Not later than 9 months after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Secretary of Homeland Security, shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the implementation of this section.

(b) DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION.—

(1) PROHIBITED ACT.—Section 301(cc) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc)) is amended—

(A) by inserting "or a drug" after "food"; and

(B) by inserting "from such activity" after "person debarred".

(2) DEBARMENT.—Section 306(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(b)) is amended—

(A) in paragraph (1)—

(i) in the matter preceding subparagraph (A), by inserting "or (3)" after "paragraph (2)";

(ii) in subparagraph (A), by striking the comma at the end and inserting a semicolon;

(iii) in subparagraph (B), by striking ", or" and inserting a semicolon;

(iv) in subparagraph (C), by striking the period and inserting "; or"; and

(v) by adding at the end the following: "(D) a person from importing or offering for import into the United States a drug.";

(B) in paragraph (3)—

(i) in the heading, by inserting "OR DRUG" after "FOOD";

(ii) in subparagraph (A), by striking "; or" and inserting a semicolon;

(iii) in subparagraph (B), by striking the period and inserting a semicolon; and

(iv) by adding at the end the following:

"(C) 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);

"(D) the person has engaged in a pattern of importing or offering for import—

"(i) controlled substances that are prohibited from importation under section 401(m) of the Tariff Act of 1930 (19 U.S.C. 1401(m)); or

"(ii) adulterated or misbranded drugs that are—

"(I) not designated in an authorized electronic data interchange system as a product that is regulated by the Secretary; or

"(II) knowingly or intentionally falsely designated in an authorized electronic data interchange system as a product that is regulated by the Secretary."; and

(C) by adding at the end the following:

"(5) DEFINITION.—For purposes of paragraph (3)(D), the term 'pattern of importing or offering for import' means importing or offering for import a drug described in clause (i) or (ii) of paragraph (3)(D) in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer.".

(c) IMPORTS AND EXPORTS.—Section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a)), as amended, is further amended—

(1) by striking ", then such article shall be refused admission" inserting "or (5) such article is being imported or offered for import in violation of section 301(cc), then any such article described in any of clauses (1) through (5) shall be refused admission";

(2) by inserting "If it appears from the examination of such samples or otherwise that the article is a counterfeit drug, such article shall be refused admission." before "With respect to an article of food, if importation"; and

(3) by striking "Clause (2) of the third sentence" and all that follows through the period at the end and inserting the following: "Neither clause (2) nor clause

(5) of the third sentence of this subsection shall be construed to prohibit the admission of narcotic drugs, the importation of which is permitted under the Controlled Substances Import and Export Act.".

(d) CERTAIN ILLICIT ARTICLES.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended, is amended by adding at the end the following—

"(u) ILLICIT ARTICLES CONTAINING ACTIVE PHARMACEUTICAL INGREDIENTS.—

"(1) IN GENERAL.—For purposes of this section, an article that is being imported or offered for import into the United States may be treated by the Secretary as a drug if the article—

"(A) is not—

"(i) accompanied by an electronic import entry for such article submitted using an authorized electronic data interchange system; and

"(ii) designated in such a system as an article regulated by the Secretary (which may include regulation as a drug, a device, a dietary supplement, or other product that is regulated under this Act); and

"(B) is an ingredient that presents significant public health concern and is, or contains—

"(i) an active ingredient in a drug—

"(I) that is approved under section 505 or licensed under section 351 of the Public Health Service Act; or

"(II) for which—

"(aa) an investigational use exemption has been authorized under section 505(i) of this Act or section 351(a) of the Public Health Service Act; and

"(bb) a substantial clinical investigation has been instituted, and such investigation has been made public; or

"(ii) 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 subclause (I) or (II) of clause (i).

"(2) EFFECT.—This subsection shall not be construed to bear upon any determination of whether an article is a drug within the meaning of section 201(g), other than for the purposes described in paragraph (1).".

CHAPTER 4—SECURING OPIOIDS AND UNUSED NARCOTICS WITH DELIBERATE DISPOSAL AND PACKAGING

SEC. 3031. SHORT TITLE.

This chapter 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. 3032. SAFETY-ENHANCING PACKAGING AND DISPOSAL FEATURES.

(a) DELIBERATE DISPOSAL AND PACKAGING ELEMENTS OF STRATEGY.—Section 505–1(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(e)) is amended by adding at the end the following:

"(4) PACKAGING AND DISPOSAL.—The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience described in subparagraph (B) or (C) of subsection (b)(1), taking into consideration the factors described in subparagraphs (C) and (D) of subsection (f)(2) and in consultation with other relevant Federal agencies with authorities over drug disposal packaging, which may include requiring that—

"(A) the drug be made available for dispensing to certain patients in unit dose pack-

aging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate such serious risk; or

"(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system for purposes of rendering drugs nonretrievable (as defined in section 1300.05 of title 21, Code of Federal Regulations (or any successor regulation)) if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available.".

(b) ASSURING ACCESS AND MINIMIZING BURDEN.—Section 505–1(f)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(f)(2)(C)) is amended—

(1) in clause (i) by striking "and" at the end; and

(2) by adding at the end the following:

"(iii) patients with functional limitations; and".

(c) APPLICATION TO ABBREVIATED NEW DRUG APPLICATIONS.—Section 505–1(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(i)) is amended—

(1) in paragraph (1)—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) inserting after subparagraph (A) the following:

"(B) A packaging or disposal requirement, if required under subsection (e)(4) for the applicable listed drug."; and

(2) in paragraph (2)—

(A) in subparagraph (A), by striking "and" at the end;

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

"(B) shall permit packaging systems and safe disposal packaging or safe disposal systems that are different from those required for the applicable listed drug under subsection (e)(4); and".

(d) 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 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) an evaluation of existing reference standards with respect to controlled substance disposal products and packaging technologies, including any such standards established by a standards development organization, and how such standards should be considered in ensuring effectiveness of such products and technologies;

(3) 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 (21 U.S.C. 801 et seq.), are made available to the public and any barriers to the use of such disposal products;

(4) identification of ways in which packaging technologies are made available to the public and any barriers to the use of such technologies;

(5) a description of current 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 such 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;

(6) a description of current 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 such agencies, including unit dose packaging, packaging that provides a set duration, and 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

(7) recommendations, as appropriate, on—

(A) whether site-of-use, in-home controlled substance disposal products and packaging technologies require Federal oversight and, if so, which agency or agencies should be responsible

for such oversight and, as applicable, review of such products or technologies; and

(B) whether there are applicable standards that should be considered to ensure the effectiveness of such products.

CHAPTER 5—POSTAPPROVAL STUDY REQUIREMENTS

SEC. 3041. CLARIFYING FDA POSTMARKET AUTHORITIES.

(a) DEFINITION OF ADVERSE DRUG EXPERIENCE.—Section 505–1(b)(1)(E) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355–1(b)(1)(E)) is amended by striking "of the drug" and inserting "of the drug, which may include reduced effectiveness under the conditions of use prescribed in the labeling of such drug, but which may not include reduced effectiveness that is in accordance with such labeling".

(b) SAFETY 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) by—

(A) striking "SAFETY INFORMATION" and inserting "SAFETY OR NEW EFFECTIVENESS INFORMATION"; and

(B) by striking "If the Secretary becomes" and all that follows through "in the labeling of

the drug" and inserting "If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug";

(2) in clause (i) of subparagraph (B), by inserting before the semicolon ", or new effectiveness information";

(3) in subparagraph (C) by striking "safety information" and inserting "safety or new effectiveness information"; and

(4) in subparagraph (E) by striking "safety information" and inserting "safety or new effectiveness information".

(c) GUIDANCE.—Not less than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance regarding the circumstances under which the Food and Drug Administration may require postmarket studies or clinical trials to assess the potential reduction in effectiveness of a drug and how such reduction in effectiveness could result in a change to the benefits of the drug and the risks to the patient. Such guidance shall also address how the Food and Drug Administration may apply this section and the amendments made

thereby with respect to circumstances under which the Food and Drug Administration may require postmarket studies or clinical trials and safety labeling changes related to the use of controlled substances for acute or chronic pain.

Subtitle B—Controlled Substance Provisions

CHAPTER 1—MORE FLEXIBILITY WITH RESPECT TO MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDERS

SEC. 3201. ALLOWING FOR MORE FLEXIBILITY WITH RESPECT TO MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDERS.

(a) CONFORMING APPLICABLE NUMBER.—Subclause (II) of section 303(g)(2)(B)(iii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(B)(iii)) is amended to read as follows:

"(II) The applicable number is—

"(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

"(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

"(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

"(dd) 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).".

(b) ELIMINATING ANY TIME LIMITATION FOR NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)) is amended—

(1) in subclause (I), by striking "or" at the end; and

(2) by amending subclause (II) to read as follows:

"(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or".

(c) IMPOSING A TIME LIMITATION FOR CLINICAL NURSE SPECIALISTS, CERTIFIED REGISTERED NURSE ANESTHETISTS, AND CERTIFIED NURSE MIDWIFES TO BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)), as amended by subsection (b), is further amended by adding at the end the following:

"(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.".

(d) DEFINITION OF QUALIFYING OTHER PRACTITIONER.—Section 303(g)(2)(G)(iv) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(iv)) is amended by striking "nurse practitioner or physician assistant" each place it appears and inserting "nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant".

(e) REPORT BY SECRETARY.—Not later than 2 years after the date of the enactment of this Act, the Secretary

of Health and Human Services, in consultation with the Drug Enforcement Administration, shall submit to Congress a report that assesses the care provided by qualifying practitioners (as defined in section 303(g)(2)(G)(iii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(iii))) who are treating, in the case of physicians, more than 100 patients, and in the case of qualifying practitioners who are not physicians, more than 30 patients. Such report shall include recommendations on future applicable patient number levels and limits. In preparing such report, the Secretary shall study, with respect to opioid use disorder treatment—

(1) the average frequency with which qualifying practitioners see their patients;

(2) the average frequency with which patients receive counseling, including the rates by which such counseling is provided by such a qualifying practitioner directly, or by referral;

(3) the frequency of toxicology testing, including the average frequency with which random toxicology testing is administered;

(4) the average monthly patient caseload for each type of qualifying practitioner;

(5) the treatment retention rates for patients;

(6) overdose and mortality rates; and

(7) any available information regarding the diversion of drugs by patients receiving such treatment from such a qualifying practitioner.

SEC. 3202. MEDICATION-ASSISTED TREATMENT FOR RECOVERY FROM SUBSTANCE USE DISORDER.

(a) WAIVERS FOR MAINTENANCE TREATMENT OR DETOXIFICATION.—Section 303(g)(2)(G)(ii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(ii)) is amended by adding at the end the following:

"(VIII) The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that—

"(aa) included not less than 8 hours of training on treating and managing opioid-dependent patients; and

"(bb) included, at a minimum—

"(AA) the training described in items (aa) through (gg) of subclause (IV); and

"(BB) training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.".

(b) TREATMENT FOR CHILDREN.—The Secretary of Health and Human Services shall consider ways to ensure that an adequate number of qualified practitioners, as defined in subparagraph (G)(ii) of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), who have a specialty in pediatrics or the treatment of children or adolescents, are granted a waiver under such section 303(g)(2) to treat children and adolescents with substance use disorders.

(c) TECHNICAL AMENDMENT.—Section 102(24) of the Controlled Substances Act (21 U.S.C. 802(24)) is amended by striking "Health, Education, and Welfare" and inserting "Health and Human Services".

SEC. 3203. GRANTS TO ENHANCE ACCESS TO SUBSTANCE USE DISORDER TREATMENT.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a grant program under which the Secretary may make grants to accredited schools of allopathic medicine or osteopathic medicine and teaching

hospitals located in the United States to support the development of curricula that meet the requirements under subclause (VIII) of section 303(g)(2)(G)(ii) of the Controlled Substances Act, as added by section 3202(a) of this Act.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, for grants under subsection (a), $4,000,000 for each of fiscal years 2019 through 2023.

SEC. 3204. DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO BE ADMINISTERED BY INJECTION OR IMPLANTATION.

(a) IN GENERAL.—The Controlled Substances Act is amended by inserting after section 309 (21 U.S.C. 829) the following:

"DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN ADMINISTERING PRACTITIONER

"SEC. 309A. (a) IN GENERAL.—Notwithstanding section 102(10), a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this title and the regulations issued by the Attorney General under this title, for the purpose of administering the controlled substance by the practitioner if—

"(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as ap-

plicable, at the location listed on the practitioner's certificate of registration issued under this title;

"(2) the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2) and—

"(A) the practitioner who issued the prescription is a qualifying practitioner authorized under, and acting within the scope of that section; and

"(B) the controlled substance is to be administered by injection or implantation;

"(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place;

"(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

"(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner; and

"(6) notwithstanding any exceptions under section 307, the prescribing practitioner, and the practi-

tioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

"(b) MODIFICATION OF NUMBER OF DAYS BEFORE WHICH CONTROLLED SUBSTANCE SHALL BE ADMINISTERED.—

"(1) INITIAL 2-YEAR PERIOD.—During the 2-year period beginning on the date of enactment of this section, the Attorney General, in coordination with the Secretary, may reduce the number of days described in subsection (a)(5) if the Attorney General determines that such reduction will—

"(A) reduce the risk of diversion; or

"(B) protect the public health.

"(2) MODIFICATIONS AFTER SUBMISSION OF REPORT.—After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5).

"(3) MINIMUM NUMBER OF DAYS.—Any modification under this subsection shall be for a period of not less than 7 days.".

(b) STUDY AND REPORT.—Not later than 2 years after the date of enactment of this section, the Comptroller General of the United States shall conduct a study and submit to Congress a report on access to and potential diversion of controlled substances administered by injection or implantation.

(c) TECHNICAL AND CONFORMING AMENDMENT.—The table of contents for the Comprehensive Drug Abuse Prevention and Control Act of 1970 is amended by inserting after the item relating to section 309 the following:

"Sec. 309A. Delivery of a controlled substance by a pharmacy to an administering practitioner.".

CHAPTER 2—EMPOWERING PHARMACISTS IN THE FIGHT AGAINST OPIOID ABUSE

SEC. 3211. SHORT TITLE.

This chapter may be cited as the "Empowering Pharmacists in the Fight Against Opioid Abuse Act".

SEC. 3212. 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, Commissioner of Food and Drugs, Director of the Centers for Disease Control and Prevention, and Assistant Secretary for Mental Health and Substance Use, shall develop and disseminate, as appropriate, materials for pharmacists, health care providers, and patients on—

(1) circumstances under which a pharmacist may, consistent with section 309 of the Controlled Substances Act (21 U.S.C. 829) 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 of doubtful, questionable, or suspicious origin; and

(2) other Federal requirements pertaining to declining to fill a prescription under such circumstances, including the partial fill of prescriptions for certain controlled substances.

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

(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 ability to decline to fill prescriptions in certain circumstances and a description of those circumstances (as described in the materials developed under subsection (a)(1)).

(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, including individuals with chronic pain.

CHAPTER 3—SAFE DISPOSAL OF UNUSED MEDICATION

SEC. 3221. SHORT TITLE.

This chapter may be cited as the "Safe Disposal of Unused Medication Act".

SEC. 3222. DISPOSAL OF CONTROLLED SUBSTANCES OF A HOSPICE PATIENT BY EMPLOYEES OF A QUALIFIED HOSPICE PROGRAM.

(a) IN GENERAL.—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 so long as such disposal occurs onsite in accordance with all applicable Federal, State, Tribal, and local law and—

"(i) the disposal occurs after the death of a person receiving hospice care;

"(ii) the controlled substance is expired; or

"(iii)(I) the employee is—

"(aa) the physician of the person receiving hospice care; and

"(bb) registered under section 303(f); and

"(II) the hospice patient no longer requires the controlled substance because the plan of care of the hospice patient has been modified.

"(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, physician assistant, 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 substances 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.".

(b) GUIDANCE.—The Attorney General may issue guidance to hospice programs (as defined in paragraph (5) of section 302(g) of the Controlled Substances Act (21 U.S.C. 822(g)), as added by subsection (a)) to assist the programs in satisfying the requirements under such paragraph (5).

(c) RULE OF CONSTRUCTION RELATING TO STATE AND LOCAL LAW.—Nothing in this section or the amendments made by this section shall be construed to prevent a State or local government from imposing additional controls or restrictions relating to the regulation of the disposal of controlled substances in hospice care or hospice programs.

SEC. 3223. GAO STUDY AND REPORT ON HOSPICE SAFE DRUG MANAGEMENT.

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the "Comptroller General") shall conduct a study on the requirements applicable to, and challenges of, hospice programs with regard to the management and disposal of controlled substances in the home of an individual.

(2) CONTENTS.—In conducting the study under paragraph (1), the Comptroller General shall include—

(A) an overview of any challenges encountered by selected hospice programs regarding the disposal of controlled substances, such as opioids, in a home setting, including any key changes in policies, procedures, or best practices for the disposal of controlled substances over time; and

(B) a description of Federal requirements, including requirements under the Medicare program, for hospice programs regarding the disposal of controlled substances in a home setting, and oversight of compliance with those requirements.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations, if any, for such legislation and administrative action as the Comptroller General determines appropriate.

CHAPTER 4—SPECIAL REGISTRATION FOR TELEMEDICINE CLARIFICATION

SEC. 3231. SHORT TITLE.

This chapter may be cited as the "Special Registration for Telemedicine Clarification Act of 2018".

SEC. 3232. REGULATIONS RELATING TO A SPECIAL REGISTRATION FOR TELEMEDICINE.

Section 311(h)(2) of the Controlled Substances Act (21 U.S.C. 831(h)(2)) is amended to read as follows:

"(2) REGULATIONS.—Not later than 1 year after the date of enactment of the SUPPORT for Patients and Communities Act, in consultation with the Sec-

retary, the Attorney General shall promulgate final regulations specifying—

"(A) the limited circumstances in which a special registration under this subsection may be issued; and

"(B) the procedure for obtaining a special registration under this subsection.".

CHAPTER 5—SYNTHETIC ABUSE AND LABELING OF TOXIC SUBSTANCES

SEC. 3241. CONTROLLED SUBSTANCE ANALOGUES.

Section 203 of the Controlled Substances Act (21 U.S.C. 813) is amended—

(1) by striking "A controlled" and inserting "(a) IN GENERAL.—A controlled"; and

(2) by adding at the end the following:

"(b) DETERMINATION.—In determining whether a controlled substance analogue was intended for human consumption under subsection (a), the following factors may be considered, along with any other relevant factors:

"(1) The marketing, advertising, and labeling of the substance.

"(2) The known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose.

"(3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold.

"(4) The diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance.

"(5) Whether the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.

"(6) Any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.

"(c) LIMITATION.—For purposes of this section, evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, shall not be sufficient to establish that the substance was not intended for human consumption.".

CHAPTER 6—ACCESS TO INCREASED DRUG DISPOSAL

SEC. 3251. SHORT TITLE.

This chapter may be cited as the "Access to Increased Drug Disposal Act of 2018".

SEC. 3252. DEFINITIONS.

In this chapter—

(1) the term "Attorney General" means the Attorney General, acting through the Assistant Attorney General for the Office of Justice Programs;

(2) the term "authorized collector" means a narcotic treatment program, a hospital or clinic with an on-site pharmacy, a retail pharmacy, or a reverse distributor, that is authorized as a collector under section 1317.40 of title 21, Code of Federal Regulations (or any successor regulation);

(3) the term "covered grant" means a grant awarded under section 3003; and

(4) the term "eligible collector" means a person who is eligible to be an authorized collector.

SEC. 3253. AUTHORITY TO MAKE GRANTS.

The Attorney General shall award grants to States to enable the States to increase the participation of eligible collectors as authorized collectors.

SEC. 3254. APPLICATION.

A State desiring a covered grant shall submit to the Attorney General an application that, at a minimum—

(1) identifies the single State agency that oversees pharmaceutical care and will be responsible for complying with the requirements of the grant;

(2) details a plan to increase participation rates of eligible collectors as authorized collectors; and

(3) describes how the State will select eligible collectors to be served under the grant.

SEC. 3255. USE OF GRANT FUNDS.

A State that receives a covered grant, and any subrecipient of the grant, may use the grant amounts only for the costs of installation, maintenance, training, purchasing, and disposal of controlled substances associated with the participation of eligible collectors as authorized collectors.

SEC. 3256. ELIGIBILITY FOR GRANT.

The Attorney General shall award a covered grant to 5 States, not less than 3 of which shall be States in the lowest quartile of States based on the participation rate of eligible collectors as authorized collectors, as determined by the Attorney General.

SEC. 3257. DURATION OF GRANTS.

The Attorney General shall determine the period of years for which a covered grant is made to a State.

SEC. 3258. ACCOUNTABILITY AND OVERSIGHT.

A State that receives a covered grant shall submit to the Attorney General a report, at such time and in such manner as the Attorney General may reasonably require, that—

(1) lists the ultimate recipients of the grant amounts;

(2) describes the activities undertaken by the State using the grant amounts; and

(3) contains performance measures relating to the effectiveness of the grant, including changes in the participation rate of eligible collectors as authorized collectors.

SEC. 3259. DURATION OF PROGRAM.

The Attorney General may award covered grants for each of the first 5 fiscal years beginning after the date of enactment of this Act.

SEC. 3260. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to the Attorney General such sums as may be necessary to carry out this chapter.

CHAPTER 7—USING DATA TO PREVENT OPIOID DIVERSION

SEC. 3271. SHORT TITLE.

This chapter may be cited as the "Using Data To Prevent Opioid Diversion Act of 2018".

SEC. 3272. PURPOSE.

(a) IN GENERAL.—The purpose of this chapter is to provide drug manufacturers and distributors with access to anonymized information through the Automated Reports

and Consolidated Orders System to help drug manufacturers and distributors identify, report, and stop suspicious orders of opioids and reduce diversion rates.

(b) RULE OF CONSTRUCTION.—Nothing in this chapter should be construed to absolve a drug manufacturer, drug distributor, or other Drug Enforcement Administration registrant from the responsibility of the manufacturer, distributor, or other registrant to—

(1) identify, stop, and report suspicious orders; or

(2) maintain effective controls against diversion in accordance with section 303 of the Controlled Substances Act (21 U.S.C. 823) or any successor law or associated regulation.

SEC. 3273. AMENDMENTS.

(a) RECORDS AND REPORTS OF REGISTRANTS.—Section 307 of the Controlled Substances Act (21 U.S.C. 827) is amended—

(1) by redesignating subsections (f), (g), and (h) as subsections (g), (h), and (i), respectively;

(2) by inserting after subsection (e) the following:

"(f)(1) The Attorney General shall, not less frequently than quarterly, make the following information available to manufacturer and distributor registrants through the Automated Reports and Consolidated Orders System, or

any subsequent automated system developed by the Drug Enforcement Administration to monitor selected controlled substances:

"(A) The total number of distributor registrants that distribute controlled substances to a pharmacy or practitioner registrant, aggregated by the name and address of each pharmacy and practitioner registrant.

"(B) The total quantity and type of opioids distributed, listed by Administration Controlled Substances Code Number, to each pharmacy and practitioner registrant described in subparagraph (A).

"(2) The information required to be made available under paragraph (1) shall be made available not later than the 30th day of the first month following the quarter to which the information relates.

"(3)(A) All registered manufacturers and distributors shall be responsible for reviewing the information made available by the Attorney General under this subsection.

"(B) In determining whether to initiate proceedings under this title against a registered manufacturer or distributor based on the failure of the registrant to maintain effective controls against diversion or otherwise comply with the requirements of this title or the regulations issued thereunder, the Attorney General may take into account that the

information made available under this subsection was available to the registrant."; and

(3) by inserting after subsection (i), as so redesignated, the following:

"(j) All of the reports required under this section shall be provided in an electronic format.".

(b) COOPERATIVE ARRANGEMENTS.—Section 503 of the Controlled Substances Act (21 U.S.C. 873) is amended by striking subsection (c) and inserting the following:

"(c)(1) The Attorney General shall, once every 6 months, prepare and make available to regulatory, licensing, attorneys general, and law enforcement agencies of States a standardized report containing descriptive and analytic information on the actual distribution patterns, as gathered through the Automated Reports and Consolidated Orders System, or any subsequent automated system, pursuant to section 307 and which includes detailed amounts, outliers, and trends of distributor and pharmacy registrants, in such States for the controlled substances contained in schedule II, which, in the discretion of the Attorney General, are determined to have the highest abuse.

"(2) If the Attorney General publishes the report described in paragraph (1) once every 6 months as required under paragraph (1), nothing in this subsection shall be construed to bring an action in any court to challenge the

sufficiency of the information or to compel the Attorney General to produce any documents or reports referred to in this subsection.".

(c) CIVIL AND CRIMINAL PENALTIES.—Section 402 of the Controlled Substances Act (21 U.S.C. 842) is amended—

(1) in subsection (a)—

(A) in paragraph (15), by striking "or" at the end;

(B) in paragraph (16), by striking the period at the end and inserting "; or"; and

(C) by inserting after paragraph (16) the following:

"(17) in the case of a registered manufacturer or distributor of opioids, to fail to review the most recent information, directly related to the customers of the manufacturer or distributor, made available by the Attorney General in accordance with section 307(f).";

and

(2) in subsection (c)—

(A) in paragraph (1), by striking subparagraph (B) and inserting the following:

"(B)(i) Except as provided in clause (ii), in the case of a violation of paragraph (5), (10), or (17) of subsection (a), the civil penalty shall not exceed $10,000.

"(ii) In the case of a violation described in clause (i) committed by a registered manufacturer or distributor of opioids and related to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the penalty shall not exceed $100,000."; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "or (D)" after "subparagraph (B)"; and

(ii) by adding at the end the following:

"(D) In the case of a violation described in subparagraph (A) that was a violation of paragraph (5), (10), or (17) of subsection (a) committed by a registered manufacturer or distributor of opioids that relates to the reporting of suspicious orders for opioids, failing to maintain effective controls against diversion of opioids, or failing to review the most recent information made available by the Attorney General in accordance with section 307(f), the criminal fine under title 18, United States Code, shall not exceed $500,000.".

SEC. 3274. REPORT.

Not later than 1 year after the date of enactment of this Act, the Attorney General shall submit to Congress a

report that provides information about how the Attorney General is using data in the Automation of Reports and Consolidated Orders System to identify and stop suspicious activity, including whether the Attorney General is looking at aggregate orders from individual pharmacies to multiple distributors that in total are suspicious, even if no individual order rises to the level of a suspicious order to a given distributor.

CHAPTER 8—OPIOID QUOTA REFORM

SEC. 3281. SHORT TITLE.

This chapter may be cited as the "Opioid Quota Reform Act".

SEC. 3282. STRENGTHENING CONSIDERATIONS FOR DEA OPIOID QUOTAS.

(a) IN GENERAL.—Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended—

(1) in subsection (a)—

(A) by inserting "(1)" after "(a)";

(B) in the second sentence, by striking "Production" and inserting "Except as provided in paragraph (2), production"; and

(C) by adding at the end the following:

"(2) The Attorney General may, if the Attorney General determines it will assist in avoiding the overproduction, shortages, or diversion of a controlled substance, estab-

lish an aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.";

(2) in subsection (b), in the first sentence, by striking "production" and inserting "manufacturing";

(3) in subsection (c), by striking "October" and inserting "December"; and

(4) by adding at the end the following:

"(i)(1)(A) In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a 'covered controlled substance'), the Attorney General shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

"(B) In estimating diversion under this paragraph, the Attorney General—

"(i) shall consider information the Attorney General, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health im-

pact related to the covered controlled substance in the United States; and

"(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

"(C) After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered.

"(2)(A) For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Attorney General, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

"(B) Not later than 1 year after the date of enactment of this subsection, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions,

and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

"(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

"(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

"(3) Not later than 1 year after the date of enactment of this subsection, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

"(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

"(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for col-

lection from approved drug collection receptacles, mail-back programs, and take-back events.".

(b) CONFORMING CHANGE.—The Law Revision Counsel is directed to amend the heading for subsection (b) of section 826 of title 21, United States Code, by striking "PRODUCTION" and inserting "MANUFACTURING".

CHAPTER 9—PREVENTING DRUG DIVERSION

SEC. 3291. SHORT TITLE.

This chapter may be cited as the "Preventing Drug Diversion Act of 2018".

SEC. 3292. IMPROVEMENTS TO PREVENT DRUG DIVERSION.

(a) DEFINITION.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

"(57) The term 'suspicious order' may include, but is not limited to—

"(A) an order of a controlled substance of unusual size;

"(B) an order of a controlled substance deviating substantially from a normal pattern; and

"(C) orders of controlled substances of unusual frequency.".

(b) SUSPICIOUS ORDERS.—Part C of the Controlled Substances Act (21 U.S.C. 821 et seq.) is amended by adding at the end the following:

"SEC. 312. SUSPICIOUS ORDERS.

"(a) REPORTING.—Each registrant shall—

"(1) design and operate a system to identify suspicious orders for the registrant;

"(2) ensure that the system designed and operated under paragraph (1) by the registrant complies with applicable Federal and State privacy laws; and

"(3) upon discovering a suspicious order or series of orders, notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

"(b) SUSPICIOUS ORDER DATABASE.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Attorney General shall establish a centralized database for collecting reports of suspicious orders.

"(2) SATISFACTION OF REPORTING REQUIREMENTS.—If a registrant reports a suspicious order to the centralized database established under paragraph (1), the registrant shall be considered to have com-

plied with the requirement under subsection (a)(3) to notify the Administrator of the Drug Enforcement Administration and the Special Agent in Charge of the Division Office of the Drug Enforcement Administration for the area in which the registrant is located or conducts business.

"(c) SHARING INFORMATION WITH THE STATES.—

"(1) IN GENERAL.—The Attorney General shall prepare and make available information regarding suspicious orders in a State, including information in the database established under subsection (b)(1), to the point of contact for purposes of administrative, civil, and criminal oversight relating to the diversion of controlled substances for the State, as designated by the Governor or chief executive officer of the State.

"(2) TIMING.—The Attorney General shall provide information in accordance with paragraph (1) within a reasonable period of time after obtaining the information.

"(3) COORDINATION.—In establishing the process for the provision of information under this subsection, the Attorney General shall coordinate with States to ensure that the Attorney General has access to information, as permitted under State law, possessed by

the States relating to prescriptions for controlled substances that will assist in enforcing Federal law.".

(c) REPORTS TO CONGRESS.—

(1) DEFINITION.—In this subsection, the term "suspicious order" has the meaning given that term in section 102 of the Controlled Substances Act, as amended by this chapter.

(2) ONE-TIME REPORT.—Not later than 1 year after the date of enactment of this Act, the Attorney General shall submit to Congress a report on the reporting of suspicious orders, which shall include—

(A) a description of the centralized database established under section 312 of the Controlled Substances Act, as added by this section, to collect reports of suspicious orders;

(B) a description of the system and reports established under section 312 of the Controlled Substances Act, as added by this section, to share information with States;

(C) information regarding how the Attorney General used reports of suspicious orders before the date of enactment of this Act and after the date of enactment of this Act, including how the Attorney General received the reports and what

actions were taken in response to the reports; and

(D) descriptions of the data analyses conducted on reports of suspicious orders to identify, analyze, and stop suspicious activity.

(3) ADDITIONAL REPORTS.—Not later than 1 year after the date of enactment of this Act, and annually thereafter until the date that is 5 years after the date of enactment of this Act, the Attorney General shall submit to Congress a report providing, for the previous year—

(A) the number of reports of suspicious orders;

(B) a summary of actions taken in response to reports, in the aggregate, of suspicious orders; and

(C) a description of the information shared with States based on reports of suspicious orders.

(4) ONE-TIME GAO REPORT.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States, in consultation with the Administrator of the Drug Enforcement Administration, shall submit to Congress a report on the reporting of suspicious orders, which shall include an evaluation of the utility of real-time reporting of

potential suspicious orders of opioids on a national level using computerized algorithms, including the extent to which such algorithms—

(A) would help ensure that potentially suspicious orders are more accurately captured, identified, and reported in real time to suppliers before orders are filled;

(B) may produce false positives of suspicious order reports that could result in market disruptions for legitimate orders of opioids; and

(C) would reduce the overall length of an investigation that prevents the diversion of suspicious orders of opioids.

TITLE IV—OFFSETS

SEC. 4001. PROMOTING VALUE IN MEDICAID MANAGED CARE.

Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)), as amended by sections 1013 and 1016, is further amended by adding at the end the following new paragraph:

"(9)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2020 (and before fiscal year 2024), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Sec-

retary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).

"(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—

"(i) has satisfied the requirement of section 438.8 of title 42, Code of Federal Regulations (or any successor regulation), by electing—

"(I) in the case of a State described in subparagraph (C), to apply a minimum medical loss ratio (as defined in subparagraph (D)(ii)) that is at least 85 percent but not greater than the minimum medical loss ratio (as so defined) that such State applied as of May 31, 2018; or

"(II) in the case of a State not described in subparagraph (C), to apply a minimum medical loss ratio that is equal to 85 percent; and

"(ii) recovered all or a portion of the expenditures as a result of the entity's failure to meet such ratio.

"(C) For purposes of subparagraph (B), a State described in this subparagraph is a State that as of May 31, 2018, applied a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in such subparagraph under the State plan under this title (or a waiver of the plan) that is equal to or greater than 85 percent.

"(D) For purposes of this paragraph:

"(i) The term 'managed care entity' means a medicaid managed care organization described in section 1932(a)(1)(B)(i).

"(ii) The term 'minimum medical loss ratio' means, with respect to a State, a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in subparagraph (B)

under the State plan under this title (or a waiver of the plan).

"(iii) The term 'other specified entity' means—

"(I) a prepaid inpatient health plan, as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation); and

"(II) a prepaid ambulatory health plan, as defined in such section (or any successor regulation).".

SEC. 4002. REQUIRING REPORTING BY GROUP HEALTH PLANS OF PRESCRIPTION DRUG COVERAGE INFORMATION FOR PURPOSES OF IDENTIFYING PRIMARY PAYER SITUATIONS UNDER THE MEDICARE PROGRAM.

Clause (i) of section 1862(b)(7)(A) of the Social Security Act (42 U.S.C. 1395y(b)(7)(A)) is amended to read as follows:

"(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been—

"(I) a primary plan to the program under this title; or

"(II) for calendar quarters beginning on or after January 1, 2020, a primary payer with respect to benefits relating to prescription drug coverage under part D; and".

SEC. 4003. ADDITIONAL RELIGIOUS EXEMPTION FROM HEALTH COVERAGE RESPONSIBILITY REQUIREMENT.

(a) IN GENERAL.—Section 5000A(d)(2)(A) of the Internal Revenue Code of 1986 is amended to read as follows:

"(A) RELIGIOUS CONSCIENCE EXEMPTIONS.—

"(i) IN GENERAL.—Such term shall not include any individual for any month if such individual has in effect an exemption under section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act which certifies that—

"(I) such individual is a member of a recognized religious sect or division thereof which is described in section 1402(g)(1), and is adherent of established tenets or teachings of such sect or division as described in such section; or

1 *"(II) such individual is a member*
2 *of a religious sect or division thereof*
3 *which is not described in section*
4 *1402(g)(1), who relies solely on a reli-*
5 *gious method of healing, and for whom*
6 *the acceptance of medical health serv-*
7 *ices would be inconsistent with the reli-*
8 *gious beliefs of the individual.*
9 *"(ii) SPECIAL RULES.—*
10 *"(I) MEDICAL HEALTH SERVICES*
11 *DEFINED.—For purposes of this sub-*
12 *paragraph, the term 'medical health*
13 *services' does not include routine den-*
14 *tal, vision and hearing services, mid-*
15 *wifery services, vaccinations, necessary*
16 *medical services provided to children,*
17 *services required by law or by a third*
18 *party, and such other services as the*
19 *Secretary of Health and Human Serv-*
20 *ices may provide in implementing sec-*
21 *tion 1311(d)(4)(H) of the Patient Pro-*
22 *tection and Affordable Care Act.*
23 *"(II) ATTESTATION REQUIRED.—*
24 *Clause (i)(II) shall apply to an indi-*
25 *vidual for months in a taxable year*

only if the information provided by the individual under section 1411(b)(5)(A) of such Act includes an attestation that the individual has not received medical health services during the preceding taxable year.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to taxable years beginning after December 31, 2018.

(c) CONSTRUCTION.—Nothing in the amendment made by subsection (a) shall preempt any State law requiring the provision of medical treatment for children, especially those who are seriously ill.

SEC. 4004. MODERNIZING THE REPORTING OF BIOLOGICAL AND BIOSIMILAR PRODUCTS.

Subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) is amended—

(1) in section 1111, as amended by section 3(1) of the Patient Right to Know Drug Prices Act—

(A) in the paragraph (3) inserted by such section 3(1), by striking "an application" and inserting "a biosimilar biological product application";

(B) in the paragraph (4) inserted by such section 3(1), by inserting "application" before "under section 351(k) of the Public Health Service Act";

(C) in the paragraph (5) inserted by such section 3(1), by striking "for licensure of a biological product under section 351(k) of the Public Health Service Act" and inserting "under section 351(k) of the Public Health Service Act for licensure of a biological product as biosimilar to, or interchangeable with, a reference product";

(D) in paragraph (7), as redesignated and amended by such section 3(1), by striking "or under section 351(a) of the Public Health Service Act" and inserting "or the owner, or exclusive licensee, of a patent included in a list provided under section 351(l)(3) of the Public Health Service Act"; and

(E) in the paragraph (12) added by such section 3(1), by striking "means a brand name drug for which a license is in effect under section 351(a)" and inserting "has the meaning given such term in section 351(i)"; and

(2) in section 1112, as amended by section 3(2) of the Patient Right to Know Drug Prices Act—

(A) in subsection (a)—

(i) in paragraph (1), by striking "for which a statement under section 351(l)(3)(B)(ii)(I) of the Public Health Service Act has been provided";

(ii) in paragraph (2)—

(I) in subparagraph (C)(i), by striking "brand name" and inserting "listed"; and

(II) by amending clause (ii) of subparagraph (C) to read as follows:

"(ii) any of the time periods referred to in section 351(k)(6) of the Public Health Service Act as such period applies to such biosimilar biological product application or to any other biosimilar biological product application based on the same reference product.";

(B) in subsection (b)—

(i) in the subsection heading, by inserting "OR BIOSIMILAR BIOLOGICAL PRODUCT APPLICANT" after "APPLICANT";

(ii) in paragraph (1)(B), by striking the first sentence and inserting the following: "A biosimilar biological product ap-

plicant that has submitted a biosimilar biological product application that references a reference product and another biosimilar biological product applicant that has submitted a biosimilar biological product application that references the same reference product shall each file the agreement in accordance with subsection (c).”; and

(iii) in paragraph (2)—

(I) by striking “2 generic drug applicants” and inserting “2 or more generic drug applicants”; and

(II) by striking “or an agreement between 2 biosimilar biological product applicants regarding the 1-year period referred to in section 351(k)(6)(A) of the Public Health Service Act as it applies to the biosimilar biological product applications with which the agreement is concerned” and inserting “, an agreement between 2 or more biosimilar biological product applicants regarding a time period referred to in section 351(k)(6) of the Public Health Service Act as it applies to the bio-

similar biological product, or an agreement between 2 or more biosimilar biological product applicants regarding the manufacture, marketing, or sale of a biosimilar biological product"; and

(C) in subsection (c)(2), by inserting "were entered into within 30 days of," after "condition for,".

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 measures 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) If determined appropriate by the Commission, recommendations for policies and actions by

Congress and the Centers for Medicare & Medicaid Services, such as on 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 nonprobability 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 meaning given such term in section 435.1010 of title 42, Code of Federal Regulations, or any successor regulation.

Subtitle C—CHIP Mental Health and Substance Use Disorder Parity

SEC. 5021. SHORT TITLE.

This subtitle may be cited as the "CHIP Mental Health and Substance Use Disorder 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 pregnant 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 "para-

graphs (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 Social 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 1 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 1 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.—Subject to subsection (d), beginning October 1, 2021, a State—

"(1) shall 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; and

"(2) in the case that such a provider is not able to conduct such a check despite a good faith effort by such provider—

"(A) shall require the provider to document such good faith effort, including the reasons why the provider was not able to conduct the check; and

"(B) may require the provider to submit, upon request, such documentation to the State.

"(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 pro-

gram 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 that has a contract to manage the pharmaceutical benefit with respect to individuals enrolled in the State plan (or under a 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 privacy 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 prescription drug monitoring

program described in subsection (b) before dispensing a controlled substance to such individual.

"(D) An accounting of any data or privacy breach of a qualified prescription drug monitoring program described in subsection (b), the number of covered individuals impacted by each such breach, and a description of the steps the State has taken to address each such breach, including, to the extent required by State or Federal law or otherwise determined appropriate by the State, alerting any such impacted individual and law enforcement of the breach.

"(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 prescrip-

tion drug monitoring programs to reduce the occurrence of abuse of controlled substances.

"(f) INCREASE TO FMAP AND FEDERAL MATCHING RATES FOR CERTAIN EXPENDITURES RELATING TO QUALIFIED PRESCRIPTION DRUG MONITORING PROGRAMS.—

"(1) IN GENERAL.—With respect to a State that meets the condition described in paragraph (2) and any quarter occurring during fiscal year 2019 or fiscal year 2020, the Federal medical assistance percentage or Federal matching rate that would otherwise apply to such State under section 1903(a) for such quarter, with respect to expenditures by the State for activities under the State plan (or a waiver of such plan) to design, develop, or implement a prescription drug monitoring program (and to make connections to such program) that satisfies the criteria described in paragraphs (1) and (2) of subsection (b), shall be equal to 100 percent.

"(2) CONDITION.—The condition described in this paragraph, with respect to a State, is that the State (in this paragraph 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 monitoring 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.

"(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 prescription drug monitoring 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).

1 *"(ii) EXCEPTIONS PROCESS.—Not later*
2 *than October 1, 2020, the Secretary, after*
3 *consultation with the National Association*
4 *of Medicaid Directors, national health care*
5 *provider associations, Medicaid beneficiary*
6 *advocates, and advocates for individuals*
7 *with rare diseases, shall determine, based on*
8 *such consultations, the types of health care*
9 *providers (if any) that should be exempted*
10 *from the definition of the term 'covered pro-*
11 *vider' for purposes of this section.".*
12 *(b) GUIDANCE.—Not later than October 1, 2019, the*
13 *Administrator of the Centers for Medicare & Medicaid Serv-*
14 *ices, in consultation with the Director of the Centers for*
15 *Disease Control and Prevention, shall issue guidance on*
16 *best practices on the uses of prescription drug monitoring*
17 *programs required of prescribers and on protecting the pri-*
18 *vacy of Medicaid beneficiary information maintained in*
19 *and accessed through prescription drug monitoring pro-*
20 *grams.*
21 *(c) DEVELOPMENT OF MODEL STATE PRACTICES.—*
22 *(1) IN GENERAL.—Not later than October 1,*
23 *2020, the Secretary of Health and Human Services*
24 *shall develop and publish model practices to assist*
25 *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 under a 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 contracts 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.

Subtitle F—IMD CARE Act

SEC. 5051. SHORT TITLE.

This title may be cited as the "Individuals in Medicaid Deserve Care that is Appropriate and Responsible in its Execution Act" or the "IMD CARE Act".

SEC. 5052. STATE OPTION TO PROVIDE MEDICAID COVERAGE FOR CERTAIN INDIVIDUALS WITH SUBSTANCE USE DISORDERS WHO ARE PATIENTS IN CERTAIN INSTITUTIONS FOR MENTAL DISEASES.

(a) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), as amended by preceding sections of this Act, is further amended—

(1) in section 1905(a), in the subdivision (B) that follows paragraph (30), by inserting "(except in the case of services provided under a State plan amendment described in section 1915(l))" before the period; and

(2) in section 1915, by adding at the end the following new subsection:

"(l) STATE PLAN AMENDMENT OPTION TO PROVIDE MEDICAL ASSISTANCE FOR CERTAIN INDIVIDUALS WHO ARE PATIENTS IN CERTAIN INSTITUTIONS FOR MENTAL DISEASES.—

"(1) IN GENERAL.—With respect to calendar quarters beginning during the period beginning October 1, 2019, and ending September 30, 2023, a State may elect, through a State plan amendment, to provide medical assistance for items and services furnished to an eligible individual who is a patient in an eligible institution for mental diseases in accordance with the requirements of this subsection.

"(2) PAYMENTS.—Subject to paragraphs (3) and (4), amounts expended under a State plan amendment under paragraph (1) for services described in such paragraph furnished, with respect to a 12-month period, to an eligible individual who is a patient in an eligible institution for mental diseases shall be treated as medical assistance for which payment is made under section 1903(a) but only to the extent that such services are furnished for not more than a period of 30 days (whether or not consecutive) during such 12-month period.

"(3) MAINTENANCE OF EFFORT.—

"(A) IN GENERAL.—As a condition for a State receiving payments under section 1903(a) for medical assistance provided in accordance with this subsection, the State shall (during the period in which it so furnished such medical as-

sistance through a State plan amendment under this subsection) maintain on an annual basis a level of funding expended by the State (and political subdivisions thereof) other than under this title from non-Federal funds for—

"(i) items and services furnished to eligible individuals who are patients in eligible institutions for mental diseases that is not less than the level of such funding for such items and services for the most recently ended fiscal year as of the date of enactment of this subsection or, if higher, for the most recently ended fiscal year as of the date the State submits a State plan amendment to the Secretary to provide such medical assistance in accordance with this subsection; and

"(ii) items and services (including services described in subparagraph (B)) furnished to eligible individuals in outpatient and community-based settings that is not less than the level of such funding for such items and services for the most recently ended fiscal year as of the date of enactment of this subsection or, if higher, for the most

recently ended fiscal year as of the date the State submits a State plan amendment to the Secretary to provide such medical assistance in accordance with this subsection.

"(B) SERVICES DESCRIBED.—For purposes of subparagraph (A)(ii), services described in this subparagraph are the following:

"(i) Outpatient and community-based substance use disorder treatment.

"(ii) Evidence-based recovery and support services.

"(iii) Clinically-directed therapeutic treatment to facilitate recovery skills, relapse prevention, and emotional coping strategies.

"(iv) Outpatient medication-assisted treatment, related therapies, and pharmacology.

"(v) Counseling and clinical monitoring.

"(vi) Outpatient withdrawal management and related treatment designed to alleviate acute emotional, behavioral, cognitive, or biomedical distress resulting from,

or occurring with, an individual's use of alcohol and other drugs.

"(vii) Routine monitoring of medication adherence.

"(viii) Other outpatient and community-based services for the treatment of substance use disorders, as designated by the Secretary.

"(C) STATE REPORTING REQUIREMENT.—

"(i) IN GENERAL.—Prior to approval of a State plan amendment under this subsection, as a condition for a State receiving payments under section 1903(a) for medical assistance provided in accordance with this subsection, the State shall report to the Secretary, in accordance with the process established by the Secretary under clause (ii), the information deemed necessary by the Secretary under such clause.

"(ii) PROCESS.—Not later than the date that is 8 months after the date of enactment of this subsection, the Secretary shall establish a process for States to report to the Secretary, at such time and in such manner as the Secretary deems appropriate,

such information as the Secretary deems necessary to verify a State's compliance with subparagraph (A).

"(4) ENSURING A CONTINUUM OF SERVICES.—

"(A) IN GENERAL.—As a condition for a State receiving payments under section 1903(a) for medical assistance provided in accordance with this subsection, the State shall carry out each of the requirements described in subparagraphs (B) through (D).

"(B) NOTIFICATION.—Prior to approval of a State plan amendment under this subsection, the State shall notify the Secretary of how the State will ensure that eligible individuals receive appropriate evidence-based clinical screening prior to being furnished with items and services in an eligible institution for mental diseases, including initial and periodic assessments to determine the appropriate level of care, length of stay, and setting for such care for each individual.

"(C) OUTPATIENT SERVICES; INPATIENT AND RESIDENTIAL SERVICES.—

"(i) OUTPATIENT SERVICES.—The State shall, at a minimum, provide medical assistance for services that could otherwise

be covered under the State plan, consistent with each of the following outpatient levels of care:

"(I) Early intervention for individuals who, for a known reason, are at risk of developing substance-related problems and for individuals for whom there is not yet sufficient information to document a diagnosable substance use disorder.

"(II) Outpatient services for less than 9 hours per week for adults, and for less than 6 hours per week for adolescents, for recovery or motivational enhancement therapies and strategies.

"(III) Intensive outpatient services for 9 hours or more per week for adults, and for 6 hours or more per week for adolescents, to treat multidimensional instability.

"(IV) Partial hospitalization services for 20 hours or more per week for adults and adolescents to treat multidimensional instability that does not require 24-hour care.

"(ii) INPATIENT AND RESIDENTIAL SERVICES.—The State shall provide medical assistance for services that could otherwise be covered under the State plan, consistent with at least 2 of the following inpatient and residential levels of care:

"(I) Clinically managed, low-intensity residential services that provide adults and adolescents with 24-hour living support and structure with trained personnel and at least 5 hours of clinical service per week per individual.

"(II) Clinically managed, population-specific, high-intensity residential services that provide adults with 24-hour care with trained counselors to stabilize multidimensional imminent danger along with less intense milieu and group treatment for those with cognitive or other impairments unable to use full active milieu or therapeutic community.

"(III) Clinically managed, medium-intensity residential services for

adolescents, and clinically managed, high-intensity residential services for adults, that provide 24-hour care with trained counselors to stabilize multi-dimensional imminent danger and preparation for outpatient treatment.

"(IV) Medically monitored, high-intensity inpatient services for adolescents, and medically monitored, intensive inpatient services withdrawal management for adults, that provide 24-hour nursing care, make physicians available for significant problems in Dimensions 1, 2, or 3, and provide counseling services 16 hours per day.

"(V) Medically managed, intensive inpatient services for adolescents and adults that provide 24-hour nursing care and daily physician care for severe, unstable problems in Dimensions 1, 2 or 3.

"(D) TRANSITION OF CARE.—In order to ensure an appropriate transition for an eligible individual from receiving care in an eligible institution for mental diseases to receiving care at

a lower level of clinical intensity within the continuum of care (including outpatient services), the State shall ensure that—

"(i) a placement in such eligible institution for mental diseases would allow for an eligible individual's successful transition to the community, considering such factors as proximity to an individual's support network (such as family members, employment, and counseling and other services near an individual's residence); and

"(ii) all eligible institutions for mental diseases that furnish items and services to individuals for which medical assistance is provided under the State plan—

"(I) are able to provide care at such lower level of clinical intensity; or

"(II) have an established relationship with another facility or provider that is able to provide care at such lower level of clinical intensity and accepts patients receiving medical assistance under this title under which the eligible institution for mental diseases may arrange for individuals to receive

such care from such other facility or provider.

"(5) APPLICATION TO MANAGED CARE.—Payments for, and limitations to, medical assistance furnished in accordance with this subsection shall be in addition to and shall not be construed to limit or supersede the ability of States to make monthly capitation payments to managed care organizations for individuals receiving treatment in institutions for mental diseases in accordance with section 438.6(e) of title 42, Code of Federal Regulations (or any successor regulation).

"(6) OTHER MEDICAL ASSISTANCE.—The provision of medical assistance for items and services furnished to an eligible individual who is a patient in an eligible institution for mental diseases in accordance with the requirements of this subsection shall not prohibit Federal financial participation for medical assistance for items or services that are provided to such eligible individual in or away from the eligible institution for mental disease during any period in which the eligible individual is receiving items or services in accordance with this subsection.

"(7) DEFINITIONS.—In this subsection:

"(A) DIMENSIONS 1, 2, OR 3.—The term 'Dimensions 1, 2, or 3' has the meaning given that term for purposes of the publication of the American Society of Addiction Medicine entitled 'The ASAM Criteria: Treatment Criteria for Addictive Substance-Related, and Co-Occurring Conditions, 2013'.

"(B) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who—

"(i) with respect to a State, is enrolled for medical assistance under the State plan or a waiver of such plan;

"(ii) is at least 21 years of age;

"(iii) has not attained 65 years of age; and

"(iv) has at least 1 substance use disorder.

"(C) ELIGIBLE INSTITUTION FOR MENTAL DISEASES.—The term 'eligible institution for mental diseases' means an institution for mental diseases that—

"(i) follows reliable, evidence-based practices; and

"(ii) offers at least 2 forms of medication-assisted treatment for substance use

disorders on site, including, in the case of medication-assisted treatment for opioid use disorder, at least 1 antagonist and 1 partial agonist.

"(D) INSTITUTION FOR MENTAL DISEASES.—The term 'institution for mental diseases' has the meaning given that term in section 1905(i).".

(b) RULE OF CONSTRUCTION.—Nothing in the amendments made by subsection (a) shall be construed as encouraging a State to place an individual in an inpatient or a residential care setting where a home or community-based care setting would be more appropriate for the individual, or as preventing a State from conducting or pursuing a demonstration project under section 1115 of the Social Security Act to improve access to, and the quality of, substance use disorder treatment for eligible populations.

Subtitle G—Medicaid Improvement Fund

SEC. 5061. MEDICAID IMPROVEMENT FUND.

Section 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w–1(b)(1)) is amended by striking "$0" and inserting "$31,000,000".

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 1 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—

(1) 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; and

(2) the effectiveness of abuse-deterrent opioid formulations in preventing opioid abuse or misuse; the impact of the use of abuse-deterrent opioid formulations on the use or abuse of other prescription or illicit opioids (including changes in deaths from such opioids); and other public health consequences of the use of abuse-deterrent opioid formulations, such as an increase in rates of human immunodeficiency virus.

(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. MEDICARE OPIOID SAFETY EDUCATION.

(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) references to educational resources regarding opioid use and pain management;

"(2) a description of categories of alternative, non-opioid pain management treatments covered under this title; and

"(3) a suggestion for the beneficiary to talk to a physician regarding opioid use and pain management.".

(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, 2020, 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 as described in subsection (b).

(b) ACTION PLAN COMPONENTS.—The action plan shall include a review by the Secretary of Medicare and Medicaid payment and coverage policies that may be viewed as potential obstacles to an effective response to the opioid crisis, and recommendations, as determined appropriate by the Secretary, on the following:

(1) A review of payment and coverage policies under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act, including a review of coverage and payment under such programs of all medication-assisted treatment approved by the Food and Drug Administration related to the treatment of opioid use disorder and other therapies that manage chronic and

acute pain and treat and minimize risk of opioid misuse and abuse, including in such review, payment under the Medicare prospective payment system for inpatient hospital 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)), to determine whether those payment policies resulted in incentives or disincentives that have contributed to the opioid crisis.

(2) Recommendations for payment and service delivery models to be tested as appropriate 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 use disorder and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse.

(3) Recommendations for data collection that could facilitate research and policy-making regarding prevention of opioid use disorder as well as data that would aid the Secretary in making coverage and payment decisions under the Medicare and Medicaid pro-

grams related to the access to appropriate opioid dependence treatments.

(4) A review of Medicare and Medicaid beneficiaries' access to the full range of medication-assisted treatment approved by the Food and Drug Administration for the treatment of opioid use disorder and other therapies that manage chronic and acute pain and treat and minimize risk of opioid misuse and abuse, including access of beneficiaries residing in rural or medically underserved communities.

(5) A review of payment and coverage policies under the Medicare program and the Medicaid program related 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, including barriers to patient access.

(c) STAKEHOLDER MEETINGS.—

(1) IN GENERAL.—Beginning not later than 3 months after the date of the enactment of this section, the Secretary shall convene a public stakeholder meeting to solicit public comment on the components of the action plan 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, 2020, the Secretary shall submit to Congress, and make public, a report that includes—

(1) a summary of the results of the Secretary's review and any recommendations 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), includ-

ing 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)), who may be a physician who meets the criterion in subclause (I); and

"(ii) may include other practitioners licensed under State law to furnish psy-

chiatric, 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 PRACTITIONER DEFINED.—For purposes of this section, the term 'eligible practitioner' means a physician or other health care practitioner, such as a nurse practitioner, that—

"(A) is enrolled under section 1866(j)(1);

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

"(C) 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.

"(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.

1 *"(B) PAYMENT AMOUNTS.—In carrying out*
2 *subparagraph (A), the Secretary may—*
3 *"(i) consider payments otherwise pay-*
4 *able under this title for opioid use disorder*
5 *treatment services and the needs of applica-*
6 *ble beneficiaries;*
7 *"(ii) pay a higher per applicable bene-*
8 *ficiary per month care management fee for*
9 *an applicable beneficiary who receives more*
10 *intensive treatment services from a partici-*
11 *pant and for whom those services are ap-*
12 *propriate based on clinical guidelines for*
13 *opioid use disorder care;*
14 *"(iii) pay a higher per applicable ben-*
15 *eficiary per month care management fee for*
16 *the month in which the applicable bene-*
17 *ficiary begins treatment with a participant*
18 *than in subsequent months, to reflect the*
19 *greater time and costs required for the plan-*
20 *ning and initiation of treatment, as com-*
21 *pared to maintenance of treatment; and*
22 *"(iv) take into account whether a par-*
23 *ticipant's opioid use disorder care team re-*
24 *fers applicable beneficiaries to other sup-*

pliers 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 furnished 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.

1 *"(III) Other criteria established*
2 *by the Secretary.*
3 *"(ii) REQUIRED CONSULTATION AND*
4 *CONSIDERATION.—In determining criteria*
5 *described in subparagraph (A), the Sec-*
6 *retary shall—*
7 *"(I) consult with stakeholders, in-*
8 *cluding clinicians in the primary care*
9 *community and in the field of addic-*
10 *tion medicine; and*
11 *"(II) consider existing clinical*
12 *guidelines for the treatment of opioid*
13 *use disorders.*
14 *"(C) NO DUPLICATE PAYMENT.—The Sec-*
15 *retary shall ensure that no duplicate payments*
16 *under this paragraph are made with respect to*
17 *an applicable beneficiary.*
18 *"(f) MULTIPAYER STRATEGY.—In carrying out the*
19 *Program, the Secretary shall encourage other payers to pro-*
20 *vide similar payments and to use similar criteria as ap-*
21 *plied under the Program under subsection (e)(2)(C). The*
22 *Secretary may enter into a memorandum of understanding*
23 *with other payers to align the methodology for payment*
24 *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 program. 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 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)), $5,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841.

"(2) CARE MANAGEMENT FEES AND INCENTIVES.—For the purposes of making payments under subsection (e), $10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 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, with respect to a period, a prescriber identified by the Secretary under subparagraph (D)(ii) of section 1860D–4(c)(4) of the Social Security Act (42 U.S.C. 1395w–104(c)(4)), as added by section 6065 of this Act, to be an outlier prescriber of opioids for such period.

(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, $75,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t), to 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.

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 Advantage 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 trans-

1 *mission shall comply with technical*
2 *standards adopted by the Secretary in*
3 *consultation with the National Council*
4 *for Prescription Drug Programs, other*
5 *standard setting organizations deter-*
6 *mined appropriate by the Secretary,*
7 *and stakeholders including PDP spon-*
8 *sors, Medicare Advantage organiza-*
9 *tions, health care professionals, and*
10 *health information technology software*
11 *vendors.*
12 *"(III) APPLICATION.—Notwith-*
13 *standing any other provision of law,*
14 *for purposes of this subparagraph, the*
15 *Secretary may require the use of such*
16 *standards adopted under subclause (II)*
17 *in lieu of any other applicable stand-*
18 *ards for an electronic transmission de-*
19 *scribed in clause (i) for a covered part*
20 *D drug for a part D eligible indi-*
21 *vidual.".*

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 2 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 or suspicious activities, as defined by the Secretary, of a provider of services (including a prescriber) or supplier re-

lated to 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 exclusion 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, in-

cluding 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 or suspicious activities of fraud, waste, or abuse of a provider of services (including a prescriber) or supplier, if such provider (including a prescriber) 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 or suspicious activities of fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program Integrity Manual 4.8. 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 not later than 2 years after the date of the 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 preclude or otherwise affect referrals to the Inspector General of the Department of Health and Human Services or other law enforcement entities.".

(b) CONTRACT REQUIREMENT TO COMMUNICATE PLAN CORRECTIVE ACTIONS AGAINST OPIOIDS 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 established under subparagraph (B), information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans related to inappropriate prescribing 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 'inappropriate prescribing' and a method for determining if a provider of services prescribes inappropriate prescribing; 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 ap-

plied 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. COMMIT TO OPIOID MEDICAL PRESCRIBER ACCOUNTABILITY AND SAFETY FOR SENIORS.

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) NOTIFICATION AND ADDITIONAL REQUIREMENTS WITH RESPECT TO OUTLIER PRESCRIBERS OF OPIOIDS.—

"(i) NOTIFICATION.—Not later than January 1, 2021, 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 as 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 thresh-

olds established under subclause (II), identify prescribers that are outlier opioids prescribers for a period of time specified by the Secretary.

"(II) ESTABLISHMENT OF THRESHOLDS.—For purposes of subclause (I) and subject to subclause (III), the Secretary shall, after consultation with stakeholders, establish thresholds, 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 following shall not be included in the analysis for identifying outlier prescribers of opioids under this clause:

"(aa) Claims for covered part D drugs for part D eligible individuals who are receiving hospice care under this title.

"(bb) Claims for covered part D drugs for part D eligible individuals who are receiving oncology services under this title.

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

"(iii) CONTENTS OF NOTIFICATION.—The Secretary shall include the following information in the notifications provided under clause (i):

"(I) Information on how such prescriber compares to other prescribers within the same specialty and geographic area.

"(II) Information on opioid prescribing guidelines, based on input from stakeholders, that may include the Centers for Disease Control and Prevention guidelines for prescribing opioids for chronic pain and guidelines developed by physician organizations.

"(III) Other information determined appropriate by the Secretary.

"(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 and changes in opioid prescribing utilization and trends.

"(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) ADDITIONAL REQUIREMENTS FOR PERSISTENT OUTLIER PRESCRIBERS.—In the case of a prescriber who the Secretary

determines is persistently identified under clause (ii) as an outlier prescriber of opioids, the following shall apply:

"(I) Such prescriber may be required to enroll in the program under this title under section 1866(j) if such prescriber is not otherwise required to enroll, but only after other appropriate remedies have been provided, such as the provision of education funded through section 6052 of the SUPPORT for Patients and Communities Act, for a period determined by the Secretary as sufficient to correct the prescribing patterns that lead to identification of such prescriber as a persistent outlier prescriber of opioids. The Secretary shall determine the length of the period for which such prescriber is required to maintain such enrollment, which shall be the minimum period necessary to correct such prescribing patterns.

"(II) Not less frequently than annually (and in a form and manner determined appropriate by the Sec-

retary), the Secretary, consistent with clause(iv)(I), shall communicate information on such prescribers to sponsors of a prescription drug plan and Medicare Advantage organizations offering an MA–PD plan.

"(vi) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make aggregate information under this subparagraph available on the internet website of the Centers for Medicare & Medicaid Services. Such information shall be in a form and manner determined appropriate by the Secretary and shall not identify any specific prescriber. In carrying out this clause, the Secretary shall consult with interested stakeholders.

"(vii) OPIOIDS DEFINED.—For purposes of this subparagraph, the term 'opioids' has such meaning as specified by the Secretary.

"(viii) OTHER ACTIVITIES.—Nothing in this subparagraph shall preclude the Secretary from conducting activities that provide prescribers with information as to how

they compare to other prescribers that are in addition to the activities under this subparagraph, including activities that were being conducted as of the date of the enactment of this subparagraph.".

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 recommendations 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 financial 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 sub-

paragraph, 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, Feder-

ally 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 Act on 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 Act on 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 appro-

priated, $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 cov-

erage 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)), as amended by section 6001, is further amended by adding at the end the following new clauses:

"(xxvi) 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)).

"(xxvii) Exploring ways to avoid unnecessary hospitalizations or emergency department 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 serv-

ices (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. DR. TODD GRAHAM 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 multidisciplinary, 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) 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 (E) 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 incorporating 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 approved 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 July 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 & Med-

icaid 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.

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 contract 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).

"(5) PRIORITIZATION OF MEASURE ENDORSEMENT.—The Secretary—

"(A) during the period beginning on the date of the enactment of this subsection and ending on December 31, 2023, shall prioritize the endorsement of measures relating to opioids and opioid use disorders by the entity with a con-

tract under subsection (a) of section 1890 in connection with endorsement of measures described in subsection (b)(2) of such section; and

"(B) on and after January 1, 2024, may prioritize the endorsement of such measures by such entity.".

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 a review of payment to ensure payment under the Medicare program under title XVIII of the Social Security Act accounts 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—Providing Reliable Options for Patients and Educational Resources

SEC. 6101. 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. 6102. REQUIRING MEDICARE ADVANTAGE PLANS AND PART D PRESCRIPTION DRUG PLANS TO INCLUDE INFORMATION ON RISKS ASSOCIATED WITH OPIOIDS AND COVERAGE OF NON-PHARMACOLOGICAL THERAPIES AND NONOPIOID MEDICATIONS OR DEVICES USED TO TREAT PAIN.

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 2-year period.".

SEC. 6103. 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. 6104. 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, 2020, 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 or 2019 about communication by hospital staff with an individual about such individual's pain.".

(b) RESTRICTION ON USE OF 2018 AND 2019 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 or 2019 about communication by hospital staff with an individual about the individual's pain.".

Subtitle L—Fighting the Opioid Epidemic With Sunshine

SEC. 6111. FIGHTING THE OPIOID EPIDEMIC WITH SUNSHINE.

(a) INCLUSION OF INFORMATION REGARDING PAYMENTS TO ADDITIONAL PRACTITIONERS.—

(1) IN GENERAL.—Section 1128G(e)(6) of the Social Security Act (42 U.S.C. 1320a–7h(e)(6)) is amended—

(A) in subparagraph (A), by adding at the end the following new clauses:

"(iii) A physician assistant, nurse practitioner, or clinical nurse specialist (as such terms are defined in section 1861(aa)(5)).

"(iv) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).

"(v) A certified nurse-midwife (as defined in section 1861(gg)(2))."; and

(B) in subparagraph (B), by inserting ", physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, or certified nurse-midwife" after "physician".

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to infor-

mation required to be submitted under section 1128G of the Social Security Act (42 U.S.C. 1320a–7h) on or after January 1, 2022.

(b) SUNSET OF EXCLUSION OF NATIONAL PROVIDER IDENTIFIER OF COVERED RECIPIENT IN INFORMATION MADE PUBLICLY AVAILABLE.—Section 1128G(c)(1)(C)(viii) of the Social Security Act (42 U.S.C. 1320a–7h(c)(1)(C)(viii)) is amended by striking "does not contain" and inserting "in the case of information made available under this subparagraph prior to January 1, 2022, does not contain".

(c) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to this section or the amendments made by this section.

TITLE VII—PUBLIC HEALTH PROVISIONS

Subtitle A—Awareness and Training

SEC. 7001. REPORT ON EFFECTS ON PUBLIC HEALTH OF SYNTHETIC DRUG USE.

(a) IN GENERAL.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services, in coordination with the Surgeon General of the Public Health Service, shall submit to the Committee on Energy and Commerce of the House of Rep-

resentatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the health effects of new psychoactive substances, including synthetic drugs, used by adolescents and young adults.

(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)).

SEC. 7002. FIRST RESPONDER TRAINING.

Section 546 of the Public Health Service Act (42 U.S.C. 290ee–1) is amended—

(1) in subsection (c)—

(A) in paragraph (2), by striking "and" at the end;

(B) in paragraph (3), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(4) train and provide resources for first responders and members of other key community sectors on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs to protect themselves from exposure to such drugs and respond appropriately when exposure occurs.";

(2) in subsection (d), by striking "and mechanisms for referral to appropriate treatment for an entity receiving a grant under this section" and inserting "mechanisms for referral to appropriate treatment, and safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs";

(3) in subsection (f)—

(A) in paragraph (3), by striking "and" at the end;

(B) in paragraph (4), by striking the period and inserting "; and"; and

(C) by adding at the end the following:

"(5) the number of first responders and members of other key community sectors trained on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.";

(4) by redesignating subsection (g) as subsection (h);

(5) by inserting after subsection (f) the following:

"(g) OTHER KEY COMMUNITY SECTORS.—In this section, the term 'other key community sectors' includes substance use disorder treatment providers, emergency medical services agencies, agencies and organizations working with prison and jail populations and offender reentry programs, health care providers, harm reduction groups, pharmacies,

community health centers, tribal health facilities, and mental health providers.''; and

(6) in subsection (h), as so redesignated, by striking ''$12,000,000 for each of fiscal years 2017 through 2021'' and inserting ''$36,000,000 for each of fiscal years 2019 through 2023''.

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

SEC. 7011. PILOT PROGRAM FOR PUBLIC HEALTH LABORATORIES TO DETECT FENTANYL AND OTHER SYNTHETIC OPIOIDS.

(a) GRANTS.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall award grants to, or enter into cooperative agreements with, Federal, State, and local agencies to improve coordination between public health laboratories and laboratories operated by law enforcement agencies, such as Customs and Border Protection and the Drug Enforcement Administration, to improve detection of synthetic opioids, including fentanyl and its analogues, as described in subsection (b).

(b) DETECTION ACTIVITIES.—The Secretary, in consultation with the Director of the National Institute of Standards and Technology, the Director of the Centers for

Disease Control and Prevention, the Attorney General of the United States, and the Administrator of the Drug Enforcement Administration, shall, for purposes of this section, develop or identify—

(1) best practices for safely handling and testing synthetic opioids, including fentanyl and its analogues, including with respect to reference materials, instrument calibration, and quality control protocols;

(2) reference materials and quality control standards related to synthetic opioids, including fentanyl and its analogues, to enhance—

(A) clinical diagnostics;

(B) postmortem data collection; and

(C) portable testing equipment utilized by law enforcement and public health officials; and

(3) procedures for the identification of new and emerging synthetic opioid formulations and procedures for reporting those findings to appropriate law enforcement agencies and Federal, State, and local public health laboratories and health departments, as appropriate.

(c) LABORATORIES.—The Secretary shall require recipients of grants or cooperative agreements under subsection (a) to—

(1) follow the best practices established under subsection (b) and have the appropriate capabilities to provide laboratory testing of controlled substances, such as synthetic fentanyl, and biospecimens for the purposes of aggregating and reporting public health information to Federal, State, and local public health officials, laboratories, and other entities the Secretary deems appropriate;

(2) work with law enforcement agencies and public health authorities, as practicable;

(3) provide early warning information to Federal, State, and local law enforcement agencies and public health authorities regarding trends or other data related to the supply of synthetic opioids, including fentanyl and its analogues;

(4) provide biosurveillance capabilities with respect to identifying trends in adverse health outcomes associated with non-fatal exposures; and

(5) provide diagnostic testing, as appropriate and practicable, for non-fatal exposures of emergency personnel, first responders, and other individuals.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $15,000,000 for each of fiscal years 2019 through 2023.

Subtitle C—Indexing Narcotics, Fentanyl, and Opioids

SEC. 7021. 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 6 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, on the Internet website of the Department of Health and Human Services, a public information dashboard that—

"(1) provides links to information on programs within the Department of Health and Human Services related to the reduction of opioid and other substance use disorders;

"(2) provides access, to the extent practicable and appropriate, to publicly available data, which may include data from agencies within the Department of Health and Human Services and—

"(A) other Federal agencies;

"(B) State, local, and Tribal governments;

"(C) nonprofit organizations;

"(D) law enforcement;

"(E) medical experts;

"(F) public health educators; and

"(G) research institutions regarding prevention, treatment, recovery, and other services for opioid and other substance use disorders;

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

"(4) identifies information on alternatives to controlled substances for pain management, such as approaches studied by the National Institutes of Health Pain Consortium, the National Center for Complimentary and Integrative Health, and other institutes and centers at the National Institutes of Health, as appropriate; and

"(5) identifies 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. 7022. INTERDEPARTMENTAL SUBSTANCE USE DISORDERS COORDINATING COMMITTEE.

(a) ESTABLISHMENT.—Not later than 3 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 coordination with the Director of National Drug Control Policy, establish a committee, to be known as the Interdepartmental Substance Use Disorders Coordinating Committee (in this section referred to as the "Committee"), to coordinate Federal activities related to substance use disorders.

(b) MEMBERSHIP.—

(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives:

(A) The Secretary, who shall serve 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 National Drug Control Policy.

(J) Representatives of other Federal agencies that support or conduct activities or programs related to substance use disorders, as determined appropriate by the Secretary.

(2) NON-FEDERAL MEMBERS.—The Committee shall include a minimum of 15 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 a substance use disorder;

(B) at least two such members shall be a director of a State substance abuse agency;

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

(D) 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 substance use disorders;

(E) at least one such member shall be a substance use disorder treatment professional who provides treatment services at a certified opioid treatment program;

(F) 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;

(G) 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;

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

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

(J) at least one such member shall be a public safety officer with extensive experience in interacting with adults with a substance use disorder; and

(K) at least one such member shall be an individual with experience providing services for homeless individuals 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 3 years and may be reappointed for one or more 3-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) identify areas for improved coordination of activities, if any, related to substance use disorders, including research, services, supports, and prevention activities across all relevant Federal agencies;

(2) identify and provide to the Secretary recommendations for improving Federal programs for

the prevention and treatment of, and recovery from, substance use disorders, including by expanding access to prevention, treatment, and recovery services;

(3) analyze substance use disorder prevention and treatment strategies in different regions of 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 substance use disorders and the process by which public feedback can be better integrated into such decisions; and

(6) make recommendations to ensure that substance use disorder research, services, supports, and prevention activities of the Department of Health and Human Services and other Federal agencies are not unnecessarily duplicative.

(f) ANNUAL REPORT.—Not later than 1 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 Internet website of the Department of Health and Human Services, which may include the public information dashboard established under section 1711 of the Public Health Service Act, as added by section 7021, a report summarizing the activities carried out by the Committee pursuant to subsection (e), including any findings resulting from such activities.

(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 6 years after the date on which the Committee is established under subsection (a).

SEC. 7023. NATIONAL MILESTONES TO MEASURE SUCCESS IN CURTAILING THE OPIOID CRISIS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), in coordination with the Administrator of the Drug Enforcement Administration and the Director of the Office of National Drug Control Policy, shall develop or identify existing national indicators (referred to in this section as the "national milestones") to measure success in curtailing the opioid crisis, with the goal of significantly reversing the incidence and prevalence of opioid misuse and abuse, and opioid-related morbidity and mortality in the United States within 5 years of such date of enactment.

(b) NATIONAL MILESTONES TO END THE OPIOID CRISIS.—The national milestones under subsection (a) shall include the following:

(1) Not fewer than 10 indicators or metrics to accurately and expediently measure progress in meeting the goal described in subsection (a), which shall, as appropriate, include, indicators or metrics related to—

(A) the number of fatal and non-fatal opioid overdoses;

(B) the number of emergency room visits related to opioid misuse and abuse;

(C) the number of individuals in sustained recovery from opioid use disorder;

(D) the number of infections associated with illicit drug use, such as HIV, viral hepatitis, and infective endocarditis, and available capacity for treating such infections;

(E) the number of providers prescribing medication-assisted treatment for opioid use disorders, including in primary care settings, community health centers, jails, and prisons;

(F) the number of individuals receiving treatment for opioid use disorder; and

(G) additional indicators or metrics, as appropriate, such as metrics pertaining to specific populations, including women and children, American Indians and Alaskan Natives, individuals living in rural and non-urban areas, and justice-involved populations, that would further clarify the progress made in addressing the opioid crisis.

(2) A reasonable goal, such as a percentage decrease or other specified metric, that signifies progress in meeting the goal described in subsection (a), and annual targets to help achieve that goal.

(c) CONSIDERATION OF OTHER SUBSTANCE USE DISORDERS.—In developing the national milestones under subsection (b), the Secretary shall, as appropriate, consider other substance use disorders in addition to opioid use disorder.

(d) EXTENSION OF PERIOD.—If the Secretary determines that the goal described in subsection (a) will not be achieved with respect to any indicator or metric established under subsection (b)(2) within 5 years of the date of enactment of this Act, the Secretary may extend the timeline for meeting such goal with respect to that indicator or metric. The Secretary shall include with any such extension a rationale for why additional time is needed and information on whether significant changes are needed in order to achieve such goal with respect to the indicator or metric.

(e) ANNUAL STATUS UPDATE.—Not later than one year after the date of enactment of this Act, the Secretary shall make available on the Internet website of the Department of Health and Human Services, and 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, an update on the progress, including expected progress in the subsequent year, in achieving the goals detailed in the national milestones. Each such update shall include the progress made in the

first year or since the previous report, as applicable, in meeting each indicator or metric in the national milestones.

SEC. 7024. STUDY ON PRESCRIBING LIMITS.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Attorney General of the United States, 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 on the impact of Federal and State laws and regulations that limit the length, quantity, or dosage of opioid prescriptions. Such report shall address—

(1) the impact of such limits on—

(A) the incidence and prevalence of overdose related to prescription opioids;

(B) the incidence and prevalence of overdose related to illicit opioids;

(C) the prevalence of opioid use disorders;

(D) medically appropriate use of, and access to, opioids, including any impact on travel expenses and pain management outcomes for patients, whether such limits are associated with significantly higher rates of negative health outcomes, including suicide, and whether the impact

of such limits differs based on the clinical indication for which opioids are prescribed;

(2) whether such limits lead to a significant increase in burden for prescribers of opioids or prescribers of treatments for opioid use disorder, including any impact on patient access to treatment, and whether any such burden is mitigated by any factors such as electronic prescribing or telemedicine; and

(3) the impact of such limits on diversion or misuse of any controlled substance in schedule II, III, or IV of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)).

Subtitle D—Ensuring Access to Quality Sober Living

SEC. 7031. NATIONAL RECOVERY HOUSING BEST PRACTICES.

Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following new section:

"SEC. 550. NATIONAL RECOVERY HOUSING BEST PRACTICES.

"(a) BEST PRACTICES FOR OPERATING RECOVERY HOUSING.—

"(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities specified in

paragraph (2), shall identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing.

"(2) CONSULTATION.—In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate—

"(A) relevant divisions of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Office of Inspector General, the Indian Health Service, and the Centers for Medicare & Medicaid Services;

"(B) the Secretary of Housing and Urban Development;

"(C) directors or commissioners, as applicable, of State health departments, tribal health departments, State Medicaid programs, and State insurance agencies;

"(D) representatives of health insurance issuers;

"(E) national accrediting entities and reputable providers of, and analysts of, recovery housing services, including Indian tribes, tribal organizations, and tribally designated housing

entities that provide recovery housing services, as applicable;

"(F) individuals with a history of substance use disorder; and

"(G) other stakeholders identified by the Secretary.

"(b) IDENTIFICATION OF FRAUDULENT RECOVERY HOUSING OPERATORS.—

"(1) IN GENERAL.—The Secretary, in consultation with the individuals and entities described in paragraph (2), shall identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.

"(2) CONSULTATION.—In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate, the individuals and entities specified in subsection (a)(2) and the Attorney General of the United States.

"(3) REQUIREMENTS.—

"(A) PRACTICES FOR IDENTIFICATION AND REPORTING.—In carrying out the activities described in paragraph (1), the Secretary shall consider how law enforcement, public and pri-

vate payers, and the public can best identify and report fraudulent recovery housing operators.

"(B) FACTORS TO BE CONSIDERED.—In carrying out the activities described in paragraph (1), the Secretary shall identify or develop indicators, which may include indicators related to—

"(i) unusual billing practices;

"(ii) average lengths of stays;

"(iii) excessive levels of drug testing (in terms of cost or frequency); and

"(iv) unusually high levels of recidivism.

"(c) DISSEMINATION.—The Secretary shall, as appropriate, disseminate the best practices identified or developed under subsection (a) and the common indicators identified or developed under subsection (b) to—

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

"(2) Indian tribes, tribal organizations, and tribally designated housing entities;

"(3) the Attorney General of the United States;

"(4) the Secretary of Labor;

"(5) the Secretary of Housing and Urban Development;

"(6) State and local law enforcement agencies;

"(7) health insurance issuers;

"(8) recovery housing entities; and

"(9) the public.

"(d) REQUIREMENTS.—In carrying out the activities described in subsections (a) and (b), the Secretary, in consultation with appropriate individuals and entities described in subsections (a)(2) and (b)(2), shall consider how recovery housing is able to support recovery and prevent relapse, recidivism, or overdose (including overdose death), including by improving access and adherence to treatment, including medication-assisted treatment.

"(e) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to provide the Secretary with the authority to require States to adhere to minimum standards in the State oversight of recovery housing.

"(f) 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 that promote sustained recovery from substance use disorders.

"(2) The terms 'Indian tribe' and 'tribal organization' have the meanings given those terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

"(3) The term 'tribally designated housing entity' has the meaning given that term in section 4 of the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4103).

"(g) 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. 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.".

SEC. 7042. PAIN RESEARCH.

Section 409J(b) of the Public Health Service Act (42 U.S.C. 284q(b)) is amended—

(1) in paragraph (5)—

(A) in subparagraph (A), by striking "and treatment of pain and diseases and disorders associated with pain" and inserting "treatment, and management of pain and diseases and disorders associated with pain, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration";

(B) in subparagraph (B), by striking "on the symptoms and causes of pain;" and inserting the following: "on—

"(i) the symptoms and causes of pain, including the identification of relevant biomarkers and screening models and the epidemiology of acute and chronic pain;

"(ii) the diagnosis, prevention, treatment, and management of acute and chronic pain, including with respect to non-phar-

macologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration; and

"(iii) risk factors for, and early warning signs of, substance use disorders in populations with acute and chronic pain; and"; and

(C) by striking subparagraphs (C) through (E) and inserting the following:

"(C) make recommendations to the Director of NIH—

"(i) to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

"(ii) on how best to disseminate information on pain care and epidemiological data related to acute and chronic pain; and

"(iii) on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.";

(2) by redesignating paragraph (6) as paragraph (7); and

(3) by inserting after paragraph (5) the following:

"(6) REPORT.—The Secretary shall ensure that recommendations and actions taken by the Director with respect to the topics discussed at the meetings described in paragraph (4) are included in appropriate reports to Congress.".

Subtitle F—Jessie's Law

SEC. 7051. 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 this section referred to as the "Secretary"), 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 paragraph (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, having access to information described in this section when prescribing or dispensing 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. 7052. COMMUNICATION WITH FAMILIES DURING EMERGENCIES.

(a) PROMOTING AWARENESS OF AUTHORIZED DISCLOSURES DURING EMERGENCIES.—The Secretary of Health and Human Services shall annually notify 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 7053 of this Act or section 11004 of the 21st Century Cures Act (42 U.S.C. 1320d–2 note).

SEC. 7053. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS FOR SUBSTANCE USE DISORDER PATIENT RECORDS.

(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary"), in consultation with appropriate experts, shall identify the following model programs and materials (or if no such programs or materials exist, recognize private or public entities to develop and disseminate such programs and materials):

(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) concerning the permitted uses and dis-

closures, consistent with the standards and regulations governing the privacy and security of substance use disorder patient records promulgated by the Secretary under section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) for the confidentiality of patient records.

(2) Model programs and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations described in paragraph (1).

(b) REQUIREMENTS.—The model programs and materials described in paragraphs (1) and (2) of subsection (a) shall address circumstances under which disclosure of substance use disorder patient records is needed to—

(1) facilitate communication between substance use disorder treatment providers and other health care providers to promote and provide the best possible integrated care;

(2) avoid inappropriate prescribing that can lead to dangerous drug interactions, overdose, or relapse; and

(3) notify and involve families and caregivers when individuals experience an overdose.

(c) PERIODIC UPDATES.—The Secretary shall—

(1) periodically review and update the model program and materials identified or developed under subsection (a); and

(2) disseminate such updated programs and materials to the individuals described in subsection (a)(1).

(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under this section, the Secretary shall solicit the input of relevant stakeholders.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section—

(1) $4,000,000 for fiscal year 2019;

(2) $2,000,000 for each of fiscal years 2020 and 2021; and

(3) $1,000,000 for each of fiscal years 2022 and 2023.

Subtitle G—Protecting Pregnant Women and Infants

SEC. 7061. REPORT ON ADDRESSING MATERNAL AND INFANT HEALTH IN THE OPIOID CRISIS.

(a) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services, in coordination with the Centers for Disease Control and Prevention, the National Institutes of

Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration, shall develop and 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—

(1) information on opioid, non-opioid, and non-pharmacologic pain management practices during pregnancy and after pregnancy;

(2) recommendations for increasing public awareness and education about substance use disorders, including opioid use disorders, during and after pregnancy, including available treatment resources in urban and rural areas;

(3) recommendations to prevent, identify, and reduce substance use disorders, including opioid use disorders, during pregnancy to improve care for pregnant women with substance use disorders and their infants; and

(4) an identification of areas in need of further research with respect to acute and chronic pain management during and after pregnancy.

(b) NO ADDITIONAL FUNDS.—No additional funds are authorized to be appropriated for purposes of carrying out subsection (a).

SEC. 7062. PROTECTING MOMS AND INFANTS.

(a) REPORT.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") 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, and make available to the public on the Internet website of the Department of Health and Human Services, a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to section 2 of the Protecting Our Infants Act of 2015 (Public Law 114–91). Such report shall include—

(A) an update on the implementation of the recommendations in the strategy, including information regarding the agencies involved in the implementation; and

(B) information on additional funding or authority the Secretary requires, if any, to implement the strategy, which may include authorities needed to coordinate implementation of

such strategy across the Department of Health and Human Services.

(2) PERIODIC UPDATES.—The Secretary shall periodically update the report under paragraph (1).

(b) RESIDENTIAL TREATMENT PROGRAMS FOR PREGNANT AND POSTPARTUM WOMEN.—Section 508(s) of the Public Health Service Act (42 U.S.C. 290bb–1(s)) is amended by striking "$16,900,000 for each of fiscal years 2017 through 2021" and inserting "$29,931,000 for each of fiscal years 2019 through 2023".

SEC. 7063. EARLY INTERVENTIONS FOR PREGNANT WOMEN AND INFANTS.

(a) DEVELOPMENT OF EDUCATIONAL MATERIALS BY CENTER FOR SUBSTANCE ABUSE PREVENTION.—Section 515(b) of the Public Health Service Act (42 U.S.C. 290bb–21(b)) is amended—

(1) in paragraph (13), by striking "and" at the end;

(2) in paragraph (14), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(15) in consultation with relevant stakeholders and in collaboration with the Director of the Centers for Disease Control and Prevention, develop educational materials for clinicians to use with pregnant

women for shared decision making regarding pain management and the prevention of substance use disorders during pregnancy.".

(b) GUIDELINES AND RECOMMENDATIONS BY CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507(b) of the Public Health Service Act (42 U.S.C. 290bb(b)) is amended—

(1) in paragraph (13), by striking "and" at the end;

(2) in paragraph (14), by striking the period at the end and inserting a semicolon; and

(3) by adding at the end the following:

"(15) in cooperation with the Secretary, implement and disseminate, as appropriate, the recommendations in the report entitled 'Protecting Our Infants Act: Final Strategy' issued by the Department of Health and Human Services in 2017; and".

(c) SUPPORT OF PARTNERSHIPS BY CENTER FOR SUBSTANCE ABUSE TREATMENT.—Section 507(b) of the Public Health Service Act (42 U.S.C. 290bb(b)), as amended by subsection (b), is further amended by adding at the end the following:

"(16) in cooperation with relevant stakeholders, and through public-private partnerships, encourage education about substance use disorders for pregnant

women and health care providers who treat pregnant women and babies.".

SEC. 7064. PRENATAL AND POSTNATAL HEALTH.

Section 317L of the Public Health Service Act (42 U.S.C. 247b–13) is amended—

(1) in subsection (a)—

(A) by amending paragraph (1) to read as follows:

"(1) to collect, analyze, and make available data on prenatal smoking and alcohol and other substance abuse and misuse, including—

"(A) data on—

"(i) the incidence, prevalence, and implications of such activities; and

"(ii) the incidence and prevalence of implications and outcomes, including neonatal abstinence syndrome and other maternal and child health outcomes associated with such activities; and

"(B) additional information or data, as appropriate, on family health history, medication exposures during pregnancy, demographic information, such as race, ethnicity, geographic location, and family history, and other relevant information, to inform such analysis;";

(B) in paragraph (2)—

(i) by striking "prevention of" and inserting "prevention and long-term outcomes associated with"; and

(ii) by striking "illegal drug use" and inserting "other substance abuse and misuse";

(C) in paragraph (3), by striking "and cessation programs; and" and inserting ", treatment, and cessation programs;";

(D) in paragraph (4), by striking "illegal drug use." and inserting "other substance abuse and misuse; and"; and

(E) by adding at the end the following:

"(5) to issue public reports on the analysis of data described in paragraph (1), including analysis of—

"(A) long-term outcomes of children affected by neonatal abstinence syndrome;

"(B) health outcomes associated with prenatal smoking, alcohol, and substance abuse and misuse; and

"(C) relevant studies, evaluations, or information the Secretary determines to be appropriate.";

(2) in subsection (b), by inserting "tribal entities," after "local governments,";

(3) by redesignating subsection (c) as subsection (d);

(4) by inserting after subsection (b) the following:

"(c) COORDINATING ACTIVITIES.—To carry out this section, the Secretary may—

"(1) provide technical and consultative assistance to entities receiving grants under subsection (b);

"(2) ensure a pathway for data sharing between States, tribal entities, and the Centers for Disease Control and Prevention;

"(3) ensure data collection under this section is consistent with applicable State, Federal, and Tribal privacy laws; and

"(4) coordinate with the National Coordinator for Health Information Technology, as appropriate, to assist States and Tribes in implementing systems that use standards recognized by such National Coordinator, as such recognized standards are available, in order to facilitate interoperability between such systems and health information technology systems, including certified health information technology."; and

(5) in subsection (d), as so redesignated, by striking "2001 through 2005" and inserting "2019 through 2023".

SEC. 7065. PLANS OF SAFE CARE.

(a) IN GENERAL.—Section 105(a) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106(a)) is amended by adding at the end the following:

"(7) GRANTS TO STATES TO IMPROVE AND COORDINATE THEIR RESPONSE TO ENSURE THE SAFETY, PERMANENCY, AND WELL-BEING OF INFANTS AFFECTED BY SUBSTANCE USE.—

"(A) PROGRAM AUTHORIZED.—The Secretary is authorized to make grants to States for the purpose of assisting child welfare agencies, social services agencies, substance use disorder treatment agencies, hospitals with labor and delivery units, medical staff, public health and mental health agencies, and maternal and child health agencies to facilitate collaboration in developing, updating, implementing, and monitoring plans of safe care described in section 106(b)(2)(B)(iii). Section 112(a)(2) shall not apply to the program authorized under this paragraph.

"(B) DISTRIBUTION OF FUNDS.—

"(i) RESERVATIONS.—Of the amounts made available to carry out subparagraph (A), the Secretary shall reserve—

"(I) no more than 3 percent for the purposes described in subparagraph (G); and

"(II) up to 3 percent for grants to Indian Tribes and tribal organizations to address the needs of infants born with, and identified as being affected by, substance abuse or withdrawal symptoms resulting from prenatal drug exposure or a fetal alcohol spectrum disorder and their families or caregivers, which to the extent practicable, shall be consistent with the uses of funds described under subparagraph (D).

"(ii) ALLOTMENTS TO STATES AND TERRITORIES.—The Secretary shall allot the amount made available to carry out subparagraph (A) that remains after application of clause (i) to each State that applies for such a grant, in an amount equal to the sum of—

"(I) $500,000; and

"(II) an amount that bears the same relationship to any funds made available to carry out subparagraph (A) and remaining after application of clause (i), as the number of live births in the State in the previous calendar year bears to the number of live births in all States in such year.

"(iii) RATABLE REDUCTION.—If the amount made available to carry out subparagraph (A) is insufficient to satisfy the requirements of clause (ii), the Secretary shall ratably reduce each allotment to a State.

"(C) APPLICATION.—A State desiring a grant under this paragraph shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include—

"(i) a description of—

"(I) the impact of substance use disorder in such State, including with respect to the substance or class of substances with the highest incidence of

abuse in the previous year in such State, including—

"(aa) the prevalence of substance use disorder in such State;

"(bb) the aggregate rate of births in the State of infants affected by substance abuse or withdrawal symptoms or a fetal alcohol spectrum disorder (as determined by hospitals, insurance claims, claims submitted to the State Medicaid program, or other records), if available and to the extent practicable; and

"(cc) the number of infants identified, for whom a plan of safe care was developed, and for whom a referral was made for appropriate services, as reported under section 106(d)(18);

"(II) the challenges the State faces in developing, implementing, and monitoring plans of safe care in accordance with section 106(b)(2)(B)(iii);

1 *"(III) the State's lead agency for*
2 *the grant program and how that agen-*
3 *cy will coordinate with relevant State*
4 *entities and programs, including the*
5 *child welfare agency, the substance use*
6 *disorder treatment agency, hospitals*
7 *with labor and delivery units, health*
8 *care providers, the public health and*
9 *mental health agencies, programs fund-*
10 *ed by the Substance Abuse and Mental*
11 *Health Services Administration that*
12 *provide substance use disorder treat-*
13 *ment for women, the State Medicaid*
14 *program, the State agency admin-*
15 *istering the block grant program under*
16 *title V of the Social Security Act (42*
17 *U.S.C. 701 et seq.), the State agency*
18 *administering the programs funded*
19 *under part C of the Individuals with*
20 *Disabilities Education Act (20 U.S.C.*
21 *1431 et seq.), the maternal, infant, and*
22 *early childhood home visiting program*
23 *under section 511 of the Social Secu-*
24 *rity Act (42 U.S.C. 711), the State ju-*
25 *dicial system, and other agencies, as*

determined by the Secretary, and Indian Tribes and tribal organizations, as appropriate, to implement the activities under this paragraph;

"(IV) how the State will monitor local development and implementation of plans of safe care, in accordance with section 106(b)(2)(B)(iii)(II), including how the State will monitor to ensure plans of safe care address differences between substance use disorder and medically supervised substance use, including for the treatment of a substance use disorder;

"(V) if applicable, how the State plans to utilize funding authorized under part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.) to assist in carrying out any plan of safe care, including such funding authorized under section 471(e) of such Act (as in effect on October 1, 2018) for mental health and substance abuse prevention and treatment services and in-home parent skill-based programs and

funding authorized under such section 472(j) (as in effect on October 1, 2018) for children with a parent in a licensed residential family-based treatment facility for substance abuse; and

"(VI) an assessment of the treatment and other services and programs available in the State to effectively carry out any plan of safe care developed, including identification of needed treatment, and other services and programs to ensure the well-being of young children and their families affected by substance use disorder, such as programs carried out under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.) and comprehensive early childhood development services and programs such as Head Start programs;

"(ii) a description of how the State plans to use funds for activities described in subparagraph (D) for the purposes of ensuring State compliance with requirements

under clauses (ii) and (iii) of section 106(b)(2)(B); and

"(iii) an assurance that the State will comply with requirements to refer a child identified as substance-exposed to early intervention services as required pursuant to a grant under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 et seq.).

"(D) USES OF FUNDS.—Funds awarded to a State under this paragraph may be used for the following activities, which may be carried out by the State directly, or through grants or subgrants, contracts, or cooperative agreements:

"(i) Improving State and local systems with respect to the development and implementation of plans of safe care, which—

"(I) shall include parent and caregiver engagement, as required under section 106(b)(2)(B)(iii)(I), regarding available treatment and service options, which may include resources available for pregnant, perinatal, and postnatal women; and

1 *"(II) may include activities such*
2 *as—*
3 *"(aa) developing policies,*
4 *procedures, or protocols for the*
5 *administration or development of*
6 *evidence-based and validated*
7 *screening tools for infants who*
8 *may be affected by substance use*
9 *withdrawal symptoms or a fetal*
10 *alcohol spectrum disorder and*
11 *pregnant, perinatal, and post-*
12 *natal women whose infants may*
13 *be affected by substance use with-*
14 *drawal symptoms or a fetal alco-*
15 *hol spectrum disorder;*
16 *"(bb) improving assessments*
17 *used to determine the needs of the*
18 *infant and family;*
19 *"(cc) improving ongoing case*
20 *management services;*
21 *"(dd) improving access to*
22 *treatment services, which may be*
23 *prior to the pregnant woman's de-*
24 *livery date; and*

"(ee) keeping families safely together when it is in the best interest of the child.

"(ii) Developing policies, procedures, or protocols in consultation and coordination with health professionals, public and private health facilities, and substance use disorder treatment agencies to ensure that—

"(I) appropriate notification to child protective services is made in a timely manner, as required under section 106(b)(2)(B)(ii);

"(II) a plan of safe care is in place, in accordance with section 106(b)(2)(B)(iii), before the infant is discharged from the birth or health care facility; and

"(III) such health and related agency professionals are trained on how to follow such protocols and are aware of the supports that may be provided under a plan of safe care.

"(iii) Training health professionals and health system leaders, child welfare workers, substance use disorder treatment

agencies, and other related professionals such as home visiting agency staff and law enforcement in relevant topics including—

"(I) State mandatory reporting laws established under section 106(b)(2)(B)(i) and the referral and process requirements for notification to child protective services when child abuse or neglect reporting is not mandated;

"(II) the co-occurrence of pregnancy and substance use disorder, and implications of prenatal exposure;

"(III) the clinical guidance about treating substance use disorder in pregnant and postpartum women;

"(IV) appropriate screening and interventions for infants affected by substance use disorder, withdrawal symptoms, or a fetal alcohol spectrum disorder and the requirements under section 106(b)(2)(B)(iii); and

"(V) appropriate multigenerational strategies to address

the mental health needs of the parent and child together.

"(iv) Establishing partnerships, agreements, or memoranda of understanding between the lead agency and other entities (including health professionals, health facilities, child welfare professionals, juvenile and family court judges, substance use and mental disorder treatment programs, early childhood education programs, maternal and child health and early intervention professionals (including home visiting providers), peer-to-peer recovery programs such as parent mentoring programs, and housing agencies) to facilitate the implementation of, and compliance with, section 106(b)(2) and clause (ii) of this subparagraph, in areas which may include—

"(I) developing a comprehensive, multi-disciplinary assessment and intervention process for infants, pregnant women, and their families who are affected by substance use disorder, withdrawal symptoms, or a fetal alcohol spectrum disorder, that includes

meaningful engagement with and takes into account the unique needs of each family and addresses differences between medically supervised substance use, including for the treatment of substance use disorder, and substance use disorder;

"(II) ensuring that treatment approaches for serving infants, pregnant women, and perinatal and postnatal women whose infants may be affected by substance use, withdrawal symptoms, or a fetal alcohol spectrum disorder, are designed to, where appropriate, keep infants with their mothers during both inpatient and outpatient treatment; and

"(III) increasing access to all evidence-based medication-assisted treatment approved by the Food and Drug Administration, behavioral therapy, and counseling services for the treatment of substance use disorders, as appropriate.

"(v) Developing and updating systems of technology for improved data collection and monitoring under section 106(b)(2)(B)(iii), including existing electronic medical records, to measure the outcomes achieved through the plans of safe care, including monitoring systems to meet the requirements of this Act and submission of performance measures.

"(E) REPORTING.—Each State that receives funds under this paragraph, for each year such funds are received, shall submit a report to the Secretary, disaggregated by geographic location, economic status, and major racial and ethnic groups, except that such disaggregation shall not be required if the results would reveal personally identifiable information on, with respect to infants identified under section 106(b)(2)(B)(ii)—

"(i) the number who experienced removal associated with parental substance use;

"(ii) the number who experienced removal and subsequently are reunified with parents, and the length of time between such removal and reunification;

"(iii) the number who are referred to community providers without a child protection case;

"(iv) the number who receive services while in the care of their birth parents;

"(v) the number who receive post-reunification services within 1 year after a reunification has occurred; and

"(vi) the number who experienced a return to out-of-home care within 1 year after reunification.

"(F) SECRETARY'S REPORT TO CONGRESS.—The Secretary shall submit an annual report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Education and the Workforce and the Committee on Appropriations of the House of Representatives that includes the information described in subparagraph (E) and recommendations or observations on the challenges, successes, and lessons derived from implementation of the grant program.

"(G) ASSISTING STATES' IMPLEMENTATION.—The Secretary shall use the amount re-

served under subparagraph (B)(i)(I) to provide written guidance and technical assistance to support States in complying with and implementing this paragraph, which shall include—

"(i) technical assistance, including programs of in-depth technical assistance, to additional States, territories, and Indian Tribes and tribal organizations in accordance with the substance-exposed infant initiative developed by the National Center on Substance Abuse and Child Welfare;

"(ii) guidance on the requirements of this Act with respect to infants born with and identified as being affected by substance use or withdrawal symptoms or fetal alcohol spectrum disorder, as described in clauses (ii) and (iii) of section 106(b)(2)(B), including by—

"(I) enhancing States' understanding of requirements and flexibilities under the law, including by clarifying key terms;

"(II) addressing state-identified challenges with developing, implementing, and monitoring plans of safe

care, including those reported under subparagraph (C)(i)(II);

"(III) disseminating best practices on implementation of plans of safe care, on such topics as differential response, collaboration and coordination, and identification and delivery of services for different populations, while recognizing needs of different populations and varying community approaches across States; and

"(IV) helping States improve the long-term safety and well-being of young children and their families;

"(iii) supporting State efforts to develop information technology systems to manage plans of safe care; and

"(iv) preparing the Secretary's report to Congress described in subparagraph (F).

"(H) SUNSET.—The authority under this paragraph shall sunset on September 30, 2023.".

(b) REPEAL.—The Abandoned Infants Assistance Act of 1988 (42 U.S.C. 5117aa et seq.) is repealed.

Subtitle H—Substance Use Disorder Treatment Workforce

SEC. 7071. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT WORKFORCE.

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 WORKFORCE

"SEC. 781. LOAN REPAYMENT PROGRAM FOR SUBSTANCE USE DISORDER TREATMENT WORKFORCE.

"(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 the requirements of service in substance use disorder treatment employment, 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), 1/6 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 employment.

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

"(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, 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) REQUIREMENTS OF SERVICE.—Any individual receiving payments under this program as required by an agreement under subsection (a) shall agree to an annual commitment to full-time employment, with no more than 1 year passing between any 2 years of covered employment, in substance use disorder treatment employment 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 people, 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 section; and

"(2) any Federally supported loan forgiveness program, including under section 338B, 338I, or 846 of this Act, or section 428J, 428L, 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 this section, 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 terms 'Indian tribe' and 'tribal organization' have the meanings given those terms in section 4 of the Indian Self-Determination and Education Assistance Act.

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

"(3) The term 'substance use disorder treatment employment' means full-time employment (including a fellowship)—

"(A) where the primary intent and function of the position is the direct treatment or recovery support of patients with or in recovery from a substance use disorder, including master's level social workers, psychologists, counselors, marriage and family therapists, psychiatric mental health practitioners, occupational therapists, psychology doctoral interns, and behavioral health paraprofessionals and physicians, physician assistants, and nurses, who are licensed or certified in accordance with applicable State and Federal laws; 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 behav-

ioral health center, recovery center, school, community-based organization, telehealth platform, migrant health center, health program or facility operated by an Indian 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 2023.".

SEC. 7072. CLARIFICATION REGARDING SERVICE IN SCHOOLS AND OTHER COMMUNITY-BASED SETTINGS.

Subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254 l et seq.) is amended by adding at the end the following:

"SEC. 338N. CLARIFICATION REGARDING SERVICE IN SCHOOLS AND OTHER COMMUNITY-BASED SETTINGS.

"(a) SCHOOLS AND COMMUNITY-BASED SETTINGS.—An entity to which a participant in the Scholarship Program or the Loan Repayment Program (referred to in this section as a 'participant') is assigned under section 333 may direct such participant to provide service as a behavioral or mental health professional at a school or other com-

munity-based setting located in a health professional shortage area.

"(b) OBLIGATED SERVICE.—

"(1) IN GENERAL.—Any service described in subsection (a) that a participant provides may count towards such participant's completion of any obligated service requirements under the Scholarship Program or the Loan Repayment Program, subject to any limitation imposed under paragraph (2).

"(2) LIMITATION.—The Secretary may impose a limitation on the number of hours of service described in subsection (a) that a participant may credit towards completing obligated service requirements, provided that the limitation allows a member to credit service described in subsection (a) for not less than 50 percent of the total hours required to complete such obligated service requirements.

"(c) RULE OF CONSTRUCTION.—The authorization under subsection (a) shall be notwithstanding any other provision of this subpart or subpart II.".

SEC. 7073. PROGRAMS FOR HEALTH CARE WORKFORCE.

(a) PROGRAM FOR EDUCATION AND TRAINING IN PAIN CARE.—Section 759 of the Public Health Service Act (42 U.S.C. 294i) is amended—

(1) in subsection (a), by striking "hospices, and other public and private entities" and inserting "hospices, tribal health programs (as defined in section 4 of the Indian Health Care Improvement Act), and other public and nonprofit private entities";

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include" and inserting "entity receiving an award under this section shall develop a comprehensive education and training plan that includes";

(B) in paragraph (1)—

(i) by inserting "preventing," after "diagnosing,"; and

(ii) by inserting "non-addictive medical products and non-pharmacologic treatments and" after "including";

(C) in paragraph (2)—

(i) by inserting "Federal, State, and local" after "applicable"; and

(ii) by striking "the degree to which" and all that follows through "effective pain care" and inserting "opioids";

(D) in paragraph (3), by inserting ", integrated, evidence-based pain management, and, as appropriate, non-pharmacotherapy" before the semicolon;

(E) in paragraph (4), by striking "; and" and inserting ";"; and

(F) by striking paragraph (5) and inserting the following:

"(5) recent findings, developments, and advancements in pain care research and the provision of pain care, which may include non-addictive medical products and non-pharmacologic treatments intended to treat pain; and

"(6) the dangers of opioid abuse and misuse, detection of early warning signs of opioid use disorders (which may include best practices related to screening for opioid use disorders, training on screening, brief intervention, and referral to treatment), and safe disposal options for prescription medications (including such options provided by law enforcement or other innovative deactivation mechanisms).";

(3) in subsection (d), by inserting "prevention," after "diagnosis,"; and

(4) in subsection (e), by striking "2010 through 2012" and inserting "2019 through 2023".

(b) MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING PROGRAM.—Section 756 of the Public Health Service Act (42 U.S.C. 294e–1) is amended—

(1) in subsection (a)—

(A) in paragraph (1), by inserting ", trauma," after "focus on child and adolescent mental health"; and

(B) in paragraphs (2) and (3), by inserting "trauma-informed care and" before "substance use disorder prevention and treatment services"; and

(2) in subsection (f), by striking "2018 through 2022" and inserting "2019 through 2023".

Subtitle I—Preventing Overdoses While in Emergency Rooms

SEC. 7081. PROGRAM TO SUPPORT COORDINATION AND CONTINUATION OF CARE FOR DRUG OVERDOSE PATIENTS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Sec-

retary") shall identify or facilitate the development of best practices for—

(1) emergency treatment of known or suspected drug overdose;

(2) the use of recovery coaches, as appropriate, to encourage individuals who experience a non-fatal overdose to seek treatment for substance use disorder and to support coordination and continuation of care;

(3) coordination and continuation of care and treatment, including, as appropriate, through referrals, of individuals after a drug overdose; and

(4) the provision or prescribing of overdose reversal medication, as appropriate.

(b) GRANT ESTABLISHMENT AND PARTICIPATION.—

(1) IN GENERAL.—The Secretary shall award grants on a competitive basis to eligible entities to support implementation of voluntary programs for care and treatment of individuals after a drug overdose, as appropriate, which may include implementation of the best practices described in subsection (a).

(2) ELIGIBLE ENTITY.—In this section, the term "eligible entity" means—

(A) a State substance abuse agency;

(B) an Indian Tribe or tribal organization; or

(C) an entity that offers treatment or other services for individuals in response to, or following, drug overdoses or a drug overdose, such as an emergency department, in consultation with a State substance abuse agency.

(3) APPLICATION.—An eligible entity desiring a grant under this section shall submit an application to the Secretary, at such time and in such manner as the Secretary may require, that includes—

(A) evidence that such eligible entity carries out, or is capable of contracting and coordinating with other community entities to carry out, the activities described in paragraph (4);

(B) evidence that such eligible entity will work with a recovery community organization to recruit, train, hire, mentor, and supervise recovery coaches and fulfill the requirements described in paragraph (4)(A); and

(C) such additional information as the Secretary may require.

(4) USE OF GRANT FUNDS.—An eligible entity awarded a grant under this section shall use such grant funds to—

(A) hire or utilize recovery coaches to help support recovery, including by—

1 *(i) connecting patients to a continuum*
2 *of care services, such as—*
3 *(I) treatment and recovery sup-*
4 *port programs;*
5 *(II) programs that provide non-*
6 *clinical recovery support services;*
7 *(III) peer support networks;*
8 *(IV) recovery community organi-*
9 *zations;*
10 *(V) health care providers, includ-*
11 *ing physicians and other providers of*
12 *behavioral health and primary care;*
13 *(VI) education and training pro-*
14 *viders;*
15 *(VII) employers;*
16 *(VIII) housing services; and*
17 *(IX) child welfare agencies;*
18 *(ii) providing education on overdose*
19 *prevention and overdose reversal to patients*
20 *and families, as appropriate;*
21 *(iii) providing follow-up services for*
22 *patients after an overdose to ensure contin-*
23 *ued recovery and connection to support*
24 *services;*

(iv) collecting and evaluating outcome data for patients receiving recovery coaching services; and

(v) providing other services the Secretary determines necessary to help ensure continued connection with recovery support services, including culturally appropriate services, as applicable;

(B) establish policies and procedures, pursuant to Federal and State law, that address the provision of overdose reversal medication, the administration of all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat substance use disorder, and subsequent continuation of, or referral to, evidence-based treatment for patients with a substance use disorder who have experienced a non-fatal drug overdose, in order to support long-term treatment, prevent relapse, and reduce recidivism and future overdose; and

(C) 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 and from treatment facilities.

(5) ADDITIONAL PERMISSIBLE USES.—In addition to the uses described in paragraph (4), a grant awarded under this section may be used, directly or through contractual arrangements, to provide—

(A) all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat substance use disorders or reverse overdose, pursuant to Federal and State law;

(B) withdrawal and detoxification services that include patient evaluation, stabilization, and preparation for treatment of substance use disorder, including treatment described in subparagraph (A), as appropriate; or

(C) mental health services provided by a certified professional who is licensed and qualified by education, training, or experience to assess the psychosocial background of patients, to contribute to the appropriate treatment plan for

patients with substance use disorder, and to monitor patient progress.

(6) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to eligible entities that meet any or all of the following criteria:

(A) The eligible entity 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))), 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))), or a hospital that receives disproportionate share hospital payments under section 1886(d)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)).

(B) The eligible entity is located in a State with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention, or under the jurisdiction of an Indian Tribe with an age-adjusted rate of drug overdose deaths that is above

the national overdose mortality rate, as determined through appropriate mechanisms as determined by the Secretary in consultation with Indian Tribes.

(C) The eligible entity demonstrates that recovery coaches will be placed in both health care settings and community settings.

(7) PERIOD OF GRANT.—A grant awarded to an eligible entity under this section shall be for a period of not more than 5 years.

(c) DEFINITIONS.—In this section:

(1) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms "Indian Tribe" and "tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(2) RECOVERY COACH.—the term "recovery coach" means an individual—

(A) with knowledge of, or experience with, recovery from a substance use disorder; and

(B) who has completed training from, and is determined to be in good standing by, a recovery services organization capable of conducting such training and making such determination.

(3) RECOVERY COMMUNITY ORGANIZATION.—The term "recovery community organization" has the meaning given such term in section 547(a) of the Public Health Service Act (42 U.S.C. 290ee–2(a)).

(d) 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 by the entity for non-fatal overdoses, including the number of non-fatal overdoses where overdose reversal medication was administered;

(B) the number of individuals administered medication-assisted treatment by the entity;

(C) the number of individuals referred by the entity to other treatment facilities after a non-fatal overdose, the types of such other facilities, and the number of such individuals admitted to such other facilities pursuant to such referrals; and

(D) the frequency and number of patients with reoccurrences, including readmissions for

non-fatal overdoses and evidence of relapse related to substance use disorder.

(2) REPORT BY SECRETARY.—Not later than 5 years after the date of enactment of this Act, the Secretary shall submit to Congress a report that includes an evaluation of the effectiveness of the grant program carried out under this section with respect to long term health outcomes of the population of individuals who have experienced a drug overdose, the percentage of patients treated or referred to treatment by grantees, and the frequency and number of patients who experienced relapse, were readmitted for treatment, or experienced another overdose.

(e) PRIVACY.—The requirements of this section, including with respect to data reporting and program oversight, shall be subject to all applicable Federal and State privacy laws.

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2019 through 2023.

Subtitle J—Alternatives to Opioids in the Emergency Department

SEC. 7091. EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS DEMONSTRATION PROGRAM.

(a) DEMONSTRATION PROGRAM GRANTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall carry out a demonstration program for purposes of awarding grants to hospitals and emergency departments, including freestanding emergency departments, to develop, implement, enhance, or study alternatives to opioids for pain management in such settings.

(2) ELIGIBILITY.—To be eligible to receive a grant under paragraph (1), 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.

(3) GEOGRAPHIC DISTRIBUTION.—In awarding grants under this section, the Secretary shall seek to ensure geographical distribution among grant recipients.

(4) USE OF FUNDS.—Grants under paragraph (1) shall be used to—

(A) target treatment approaches for painful conditions frequently treated in such settings;

(B) train providers and other hospital personnel on protocols or best practices related to the use and prescription of opioids and alter-

natives to opioids for pain management in the emergency department; and

(C) develop or continue strategies to provide alternatives to opioids, as appropriate.

(b) ADDITIONAL DEMONSTRATION PROGRAM.—The Secretary may carry out a demonstration program similar to the program under subsection (a) for other acute care settings.

(c) CONSULTATION.—The Secretary shall implement a process for recipients of grants under subsection (a) or (b) to share evidence-based and best practices and promote consultation with persons having robust knowledge, including emergency departments and physicians that have successfully implemented programs that use alternatives to opioids for pain management, as appropriate, such as approaches studied through the National Center for Complimentary and Integrative Health or other institutes and centers at the National Institutes of Health, as appropriate. The Secretary shall offer to each recipient of a grant under subsection (a) or (b) technical assistance as necessary.

(d) TECHNICAL ASSISTANCE.—The Secretary shall identify or facilitate the development of best practices on alternatives to opioids for pain management and provide technical assistance to hospitals and other acute care set-

tings on alternatives to opioids for pain management. The technical assistance provided shall be for the purpose of—

(1) utilizing information from recipients of a grant under subsection (a) or (b) that have successfully implemented alternatives to opioids programs;

(2) identifying or facilitating the development of best practices on the use of alternatives to opioids, which may include pain-management strategies that involve non-addictive medical products, non-pharmacologic treatments, and technologies or techniques to identify patients at risk for opioid use disorder;

(3) identifying or facilitating the development of best practices on the use of alternatives to opioids that target common painful conditions and include certain patient populations, such as geriatric patients, pregnant women, and children; and

(4) disseminating information on the use of alternatives to opioids to providers in acute care settings, which may include emergency departments, outpatient clinics, critical access hospitals, Federally qualified health centers, Indian Health Service health facilities, and tribal hospitals.

(e) 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 all applicable State and Federal privacy laws—

(1) a description of and specific information about the opioid alternative pain management programs, including the demographic characteristics of patients who were treated with an alternative pain management protocol, implemented in hospitals, emergency departments, and other acute care settings;

(2) data on the opioid alternative pain management strategies used, including the number of opioid prescriptions written—

(A) during a baseline period before the program began; or

(B) at various stages of the program; and

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

(4) any other information the Secretary determines appropriate.

(f) REPORT TO CONGRESS.—Not later than 1 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 (e), including data that allows for comparison of programs; and

(3) recommendations for broader implementation of pain management strategies that encourage the use of alternatives to opioids in hospitals, emergency departments, or other acute care settings.

(g) 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—Treatment, Education, and Community Help To Combat Addiction

SEC. 7101. ESTABLISHMENT OF REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.

Part D of title V of the Public Health Service Act, as amended by section 7031, is further amended by adding at the end the following new section:

"SEC. 551. REGIONAL CENTERS OF EXCELLENCE IN SUBSTANCE USE DISORDER EDUCATION.

"(a) IN GENERAL.—The Secretary, in consultation with appropriate agencies, shall award cooperative agree-

ments to eligible entities for the designation of such entities as Regional Centers of Excellence in Substance Use Disorder Education for purposes of improving health professional training resources with respect to substance use disorder prevention, treatment, and recovery.

"(b) ELIGIBILITY.—To be eligible to receive a cooperative agreement under subsection (a), an entity shall—

"(1) be an accredited entity that offers education to students in various health professions, which may include—

"(A) a teaching hospital;

"(B) a medical school;

"(C) a certified behavioral health clinic; or

"(D) any other health professions school, school of public health, or Cooperative Extension Program at institutions of higher education, as defined in section 101 of the Higher Education Act of 1965, engaged in the prevention, treatment, or recovery of substance use disorders;

"(2) demonstrate community engagement and partnerships with community stakeholders, including entities that train health professionals, mental health counselors, social workers, peer recovery specialists, substance use treatment programs, community health centers, physician offices, certified behavioral health

clinics, research institutions, and law enforcement; and

"(3) submit to the Secretary an application containing such information, at such time, and in such manner, as the Secretary may require.

"(c) ACTIVITIES.—An entity receiving an award under this section shall develop, evaluate, and distribute evidence-based resources regarding the prevention and treatment of, and recovery from, substance use disorders. Such resources may include information on—

"(1) the neurology and pathology of substance use disorders;

"(2) advancements in the treatment of substance use disorders;

"(3) techniques and best practices to support recovery from substance use disorders;

"(4) strategies for the prevention and treatment of, and recovery from substance use disorders across patient populations; and

"(5) other topic areas that are relevant to the objectives described in subsection (a).

"(d) GEOGRAPHIC DISTRIBUTION.—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 distribution.

"(e) EVALUATION.—The Secretary shall evaluate each project carried out by an entity receiving an award under this section and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

"(f) FUNDING.—There is authorized to be appropriated to carry out this section, $4,000,000 for each of fiscal years 2019 through 2023.".

SEC. 7102. YOUTH PREVENTION AND RECOVERY.

(a) SUBSTANCE ABUSE TREATMENT SERVICES FOR CHILDREN, ADOLESCENTS, AND YOUNG ADULTS.—Section 514 of the Public Health Service Act (42 U.S.C. 290bb–7) is amended—

*(1) in the section heading, by striking "**CHILDREN AND ADOLESCENTS**" and inserting "**CHILDREN, ADOLESCENTS, AND YOUNG ADULTS**";*

(2) in subsection (a)(2), by striking "children, including" and inserting "children, adolescents, and young adults, including"; and

(3) by striking "children and adolescents" each place it appears and inserting "children, adolescents, and young adults".

(b) RESOURCE CENTER.—The Secretary of Health and Human Services (referred to in this section as the "Secretary", except as otherwise provided), in consultation with

the Secretary of Education and other heads of agencies, including the Assistant Secretary for Mental Health and Substance Use and the Administrator of the Health Resources and Services Administration, as appropriate, shall establish a resource center to provide technical support to recipients of grants under subsection (c).

(c) YOUTH PREVENTION AND RECOVERY INITIATIVE.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Education, shall administer a program to provide support for communities to support the prevention of, treatment of, and recovery from, substance use disorders for children, adolescents, and young adults.

(2) DEFINITIONS.—In this subsection:

(A) ELIGIBLE ENTITY.—The term "eligible entity" means—

(i) a local educational agency that is seeking to establish or expand substance use prevention or recovery support services at one or more high schools;

(ii) a State educational agency;

(iii) an institution of higher education (or consortia of such institutions), which may include a recovery program at an institution of higher education;

(iv) a local board or one-stop operator;

(v) a nonprofit organization with appropriate expertise in providing services or programs for children, adolescents, or young adults, excluding a school;

(vi) a State, political subdivision of a State, Indian tribe, or tribal organization; or

(vii) a high school or dormitory serving high school students that receives funding from the Bureau of Indian Education.

(B) FOSTER CARE.—The term "foster care" has the meaning given such term in section 1355.20(a) of title 45, Code of Federal Regulations (or any successor regulations).

(C) HIGH SCHOOL.—The term "high school" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(D) HOMELESS YOUTH.—The term "homeless youth" has the meaning given the term "homeless children or youths" in section 725 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11434a).

(E) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(F) INSTITUTION OF HIGHER EDUCATION.—The term "institution of higher education" has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) and includes a "postsecondary vocational institution" as defined in section 102(c) of such Act (20 U.S.C. 1002(c)).

(G) LOCAL EDUCATIONAL AGENCY.—The term "local educational agency" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(H) LOCAL BOARD; ONE-STOP OPERATOR.—The terms "local board" and "one-stop operator" have the meanings given such terms in section 3 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3102).

(I) OUT-OF-SCHOOL YOUTH.—The term "out-of-school youth" has the meaning given such term in section 129(a)(1)(B) of the Workforce In-

novation and Opportunity Act (29 U.S.C. 3164(a)(1)(B)).

(J) RECOVERY PROGRAM.—The term "recovery program" means a program—

(i) to help children, adolescents, or young adults who are recovering from substance use disorders to initiate, stabilize, and maintain healthy and productive lives in the community; and

(ii) that includes peer-to-peer support delivered by individuals with lived experience in recovery, and communal activities to build recovery skills and supportive social networks.

(K) STATE EDUCATIONAL AGENCY.—The term "State educational agency" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act (20 U.S.C. 7801).

(3) BEST PRACTICES.—The Secretary, in consultation with the Secretary of Education, shall—

(A) identify or facilitate the development of evidence-based best practices for prevention of substance misuse and abuse by children, adolescents, and young adults, including for specific

populations such as youth in foster care, homeless youth, out-of-school youth, and youth who are at risk of or have experienced trafficking that address—

(i) primary prevention;

(ii) appropriate recovery support services;

(iii) appropriate use of medication-assisted treatment for such individuals, if applicable, and ways of overcoming barriers to the use of medication-assisted treatment in such population; and

(iv) efficient and effective communication, which may include the use of social media, to maximize outreach efforts;

(B) disseminate such best practices to State educational agencies, local educational agencies, schools and dormitories funded by the Bureau of Indian Education, institutions of higher education, recovery programs at institutions of higher education, local boards, one-stop operators, family and youth homeless providers, and nonprofit organizations, as appropriate;

(C) conduct a rigorous evaluation of each grant funded under this subsection, particularly

its impact on the indicators described in paragraph (7)(B); and

(D) provide technical assistance for grantees under this subsection.

(4) GRANTS AUTHORIZED.—The Secretary, in consultation with the Secretary of Education, shall award 3-year grants, on a competitive basis, to eligible entities to enable such entities, in coordination with Indian tribes, if applicable, and State agencies responsible for carrying out substance use disorder prevention and treatment programs, to carry out evidence-based programs for—

(A) prevention of substance misuse and abuse by children, adolescents, and young adults, which may include primary prevention;

(B) recovery support services for children, adolescents, and young adults, which may include counseling, job training, linkages to community-based services, family support groups, peer mentoring, and recovery coaching; or

(C) treatment or referrals for treatment of substance use disorders, which may include the use of medication-assisted treatment, as appropriate.

(5) SPECIAL CONSIDERATION.—In awarding grants under this subsection, the Secretary shall give special consideration to the unique needs of tribal, urban, suburban, and rural populations.

(6) APPLICATION.—To be eligible for a grant under this subsection, an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require. Such application shall include—

(A) a description of—

(i) the impact of substance use disorders in the population that will be served by the grant program;

(ii) how the eligible entity has solicited input from relevant stakeholders, which may include faculty, teachers, staff, families, students, and experts in substance use disorder prevention, treatment, and recovery in developing such application;

(iii) the goals of the proposed project, including the intended outcomes;

(iv) how the eligible entity plans to use grant funds for evidence-based activities, in accordance with this subsection to prevent, provide recovery support for, or treat sub-

stance use disorders amongst such individuals, or a combination of such activities; and

(v) how the eligible entity will collaborate with relevant partners, which may include State educational agencies, local educational agencies, institutions of higher education, juvenile justice agencies, prevention and recovery support providers, local service providers, including substance use disorder treatment programs, providers of mental health services, youth serving organizations, family and youth homeless providers, child welfare agencies, and primary care providers, in carrying out the grant program; and

(B) an assurance that the eligible entity will participate in the evaluation described in paragraph (3)(C).

(7) REPORTS TO THE SECRETARY.—Each eligible entity awarded a grant under this subsection shall submit to the Secretary a report at such time and in such manner as the Secretary may require. Such report shall include—

(A) a description of how the eligible entity used grant funds, in accordance with this subsection, including the number of children, adolescents, and young adults reached through programming; and

(B) a description, including relevant data, of how the grant program has made an impact on the intended outcomes described in paragraph (6)(A)(iii), including—

(i) indicators of student success, which, if the eligible entity is an educational institution, shall include student well-being and academic achievement;

(ii) substance use disorders amongst children, adolescents, and young adults, including the number of overdoses and deaths amongst children, adolescents, and young adults served by the grant during the grant period; and

(iii) other indicators, as the Secretary determines appropriate.

(8) REPORT TO CONGRESS.—The Secretary shall, not later than October 1, 2022, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and

Commerce and the Committee on Education and the Workforce of the House of Representatives a report summarizing the effectiveness of the grant program under this subsection, based on the information submitted in reports required under paragraph (7).

(9) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $10,000,000 to carry out this subsection for each of fiscal years 2019 through 2023.

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

SEC. 7111. INFORMATION 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)(C), by striking "; and" at the end and inserting a semicolon;

(2) by redesignating paragraph (6) as paragraph (7); and

(3) by inserting after paragraph (5) the following:

"(6) issue and periodically update information for entities applying for grants or cooperative agree-

ments from the Substance Abuse and Mental Health Services Administration in order to—

"(A) encourage the implementation and replication of evidence-based practices; and

"(B) provide technical assistance to applicants for funding, including with respect to justifications for such programs and activities; and".

Subtitle M—Comprehensive Opioid Recovery Centers

SEC. 7121. COMPREHENSIVE OPIOID RECOVERY CENTERS.

(a) IN GENERAL.—Part D of title V of the Public Health Service Act (42 U.S.C. 290dd et seq.), as amended by sections 7031 and 7101, is further amended by adding at the end the following new section:

"SEC. 552. COMPREHENSIVE OPIOID RECOVERY CENTERS.

"(a) IN GENERAL.—The Secretary shall award grants on a competitive basis to eligible entities to establish or operate a comprehensive opioid recovery center (referred to in this section as a 'Center'). A Center may be a single entity or an integrated delivery network.

"(b) GRANT PERIOD.—

"(1) IN GENERAL.—A grant awarded under subsection (a) shall be for a period of not less than 3 years and not more than 5 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 (j) such that not fewer than 10 grants may be awarded. Not more than one grant shall be made to entities in a single State for any one period.

"(d) APPLICATION.—

"(1) ELIGIBLE ENTITY.—An entity is eligible for a grant under this section if the entity offers treatment and other services for individuals with a substance use disorder.

"(2) SUBMISSION OF 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—

"(A) evidence that such entity carries out, or is capable of coordinating with other entities to carry out, the activities described in subsection (g); and

"(B) such other information as the Secretary may require.

"(e) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to eligible entities—

"(1) located in a State with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention; or

"(2) serving an Indian Tribe (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined through appropriate mechanisms determined by the Secretary in consultation with Indian Tribes.

"(f) PREFERENCE.—In awarding grants under subsection (a), the Secretary may give preference to eligible entities utilizing technology-enabled collaborative learning and capacity building models, including such models as defined in section 2 of the Expanding Capacity for Health Outcomes Act (Public Law 114–270; 130 Stat. 1395), to conduct the activities described in this section.

"(g) CENTER ACTIVITIES.—Each Center shall, at a minimum, carry out the following activities directly, through referral, or through contractual arrangements,

which may include carrying out such activities through technology-enabled collaborative learning and capacity building models described in subsection (f):

"(1) TREATMENT AND RECOVERY SERVICES.—Each Center shall—

"(A) Ensure that intake, evaluations, and periodic patient assessments meet the individualized clinical needs of patients, including by reviewing patient placement in treatment settings to support meaningful recovery.

"(B) Provide the full continuum of treatment services, including—

"(i) all drugs and devices approved or cleared under the Federal Food, Drug, and Cosmetic Act and all biological products licensed under section 351 of this Act to treat substance use disorders or reverse overdoses, pursuant to Federal and State law;

"(ii) medically supervised withdrawal management, that includes patient evaluation, stabilization, and readiness for and entry into treatment;

"(iii) counseling provided by a program counselor or other certified professional who is licensed and qualified by edu-

cation, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient, and to monitor patient progress;

"(iv) treatment, as appropriate, for patients with co-occurring substance use and mental disorders;

"(v) testing, as appropriate, for infections commonly associated with illicit drug use;

"(vi) residential rehabilitation, and outpatient and intensive outpatient programs;

"(vii) recovery housing;

"(viii) community-based and peer recovery support services;

"(ix) job training, job placement assistance, and continuing education assistance to support reintegration into the workforce; and

"(x) other best practices to provide the full continuum of treatment and services, as determined by the Secretary.

"(C) Ensure that all programs covered by the Center include medication-assisted treatment, as appropriate, and do not exclude individuals receiving medication-assisted treatment from any service.

"(D) Periodically conduct patient assessments to support sustained and clinically significant recovery, as defined by the Assistant Secretary for Mental Health and Substance Use.

"(E) Provide onsite access to medication, as appropriate, and toxicology services; for purposes of carrying out this section.

"(F) Operate a secure, confidential, and interoperable electronic health information system.

"(G) Offer family support services such as child care, family counseling, and parenting interventions to help stabilize families impacted by substance use disorder, as appropriate.

"(2) OUTREACH.—Each Center shall carry out outreach activities regarding the services offered through the Centers, which may include—

"(A) training and supervising outreach staff, as appropriate, to work with State and local health departments, health care providers,

the Indian Health Service, State and local educational agencies, schools funded by the Indian Bureau of Education, institutions of higher education, State and local workforce development boards, State and local community action agencies, public safety officials, first responders, Indian Tribes, child welfare agencies, as appropriate, and other community partners and the public, including patients, to identify and respond to community needs;

"(B) ensuring that the entities described in subparagraph (A) are aware of the services of the Center; and

"(C) disseminating and making publicly available, including through the internet, evidence-based resources that educate professionals and the public on opioid use disorder and other substance use disorders, including co-occurring substance use and mental disorders.

"(h) DATA REPORTING AND PROGRAM OVERSIGHT.—With respect to a grant awarded under subsection (a), 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 the population of individuals with a substance use disorder who received services from the Center, evaluated by an independent program evaluator through the use of outcomes measures, as determined by the Secretary;

"(3) the retention rate of program participants; and

"(4) any other information that the Secretary may require for the purpose of—ensuring that the Center is complying with all the requirements of the grant, including providing the full continuum of services described in subsection (g)(1)(B).

"(i) PRIVACY.—The provisions of this section, including with respect to data reporting and program oversight, shall be subject to all applicable Federal and State privacy laws.

"(j) 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 3 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 552(h) of the Public Health Service Act, as added by subsection (a).

(2) FINAL REPORT.—Not later than 2 years 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 the comprehensive services provided by the Centers established or operated pursuant to section 552 of the Public Health Service Act, as added by subsection (a), with respect to health outcomes of the population of individuals with substance use disorder who receive services from the Center, which shall include an evaluation of the effectiveness of services for treatment and recovery support and to reduce relapse, recidivism, and overdose; and

(B) recommendations, as appropriate, regarding ways to improve Federal programs related to substance use disorders, which may in-

clude dissemination of best practices for the treatment of substance use disorders to health care professionals.

Subtitle N—Trauma-Informed Care

SEC. 7131. CDC SURVEILLANCE AND DATA COLLECTION FOR CHILD, YOUTH, AND ADULT TRAUMA.

(a) DATA COLLECTION.—The Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director") may, in cooperation with the States, collect and report data on adverse childhood experiences through the Behavioral Risk Factor Surveillance System, the Youth Risk Behavior Surveillance System, and other relevant public health surveys or questionnaires.

(b) TIMING.—The collection of data under subsection (a) may occur biennially.

(c) DATA FROM RURAL AREAS.—The Director shall encourage each State that participates in collecting and reporting data under subsection (a) to collect and report data from rural areas within such State, in order to generate a statistically reliable representation of such areas.

(d) DATA FROM TRIBAL AREAS.—The Director may, in cooperation with Indian Tribes (as defined in section 4 of the Indian Self-Determination and Education Assistance Act) and pursuant to a written request from an Indian Tribe, provide technical assistance to such Indian

Tribe to collect and report data on adverse childhood experiences through the Behavioral Risk Factor Surveillance System, the Youth Risk Behavior Surveillance System, or another relevant public health survey or questionnaire.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $2,000,000 for each of fiscal years 2019 through 2023.

SEC. 7132. TASK FORCE TO DEVELOP BEST PRACTICES FOR TRAUMA-INFORMED IDENTIFICATION, REFERRAL, AND SUPPORT.

(a) ESTABLISHMENT.—There is established a task force, to be known as the Interagency Task Force on Trauma-Informed Care (in this section referred to as the "task force") that shall identify, evaluate, and make recommendations regarding—

(1) best practices with respect to children and youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma; and

(2) ways in which Federal agencies can better coordinate to improve the Federal response to families impacted by substance use disorders and other forms of trauma.

(b) MEMBERSHIP.—

1 *(1) COMPOSITION.—The task force shall be com-*
2 *posed of the heads of the following Federal depart-*
3 *ments and agencies, or their designees:*
4 *(A) The Centers for Medicare & Medicaid*
5 *Services.*
6 *(B) The Substance Abuse and Mental*
7 *Health Services Administration.*
8 *(C) The Agency for Healthcare Research*
9 *and Quality.*
10 *(D) The Centers for Disease Control and*
11 *Prevention.*
12 *(E) The Indian Health Service.*
13 *(F) The Department of Veterans Affairs.*
14 *(G) The National Institutes of Health.*
15 *(H) The Food and Drug Administration.*
16 *(I) The Health Resources and Services Ad-*
17 *ministration.*
18 *(J) The Department of Defense.*
19 *(K) The Office of Minority Health of the*
20 *Department of Health and Human Services.*
21 *(L) The Administration for Children and*
22 *Families.*
23 *(M) The Office of the Assistant Secretary*
24 *for Planning and Evaluation of the Department*
25 *of Health and Human Services.*

(N) The Office for Civil Rights of the Department of Health and Human Services.

(O) The Office of Juvenile Justice and Delinquency Prevention of the Department of Justice.

(P) The Office of Community Oriented Policing Services of the Department of Justice.

(Q) The Office on Violence Against Women of the Department of Justice.

(R) The National Center for Education Evaluation and Regional Assistance of the Department of Education.

(S) The National Center for Special Education Research of the Institute of Education Science.

(T) The Office of Elementary and Secondary Education of the Department of Education.

(U) The Office for Civil Rights of the Department of Education.

(V) The Office of Special Education and Rehabilitative Services of the Department of Education.

(W) The Bureau of Indian Affairs of the Department of the Interior.

(X) The Veterans Health Administration of the Department of Veterans Affairs.

(Y) The Office of Special Needs Assistance Programs of the Department of Housing and Urban Development.

(Z) The Office of Head Start of the Administration for Children and Families.

(AA) The Children's Bureau of the Administration for Children and Families.

(BB) The Bureau of Indian Education of the Department of the Interior.

(CC) Such other Federal agencies as the Secretaries determine to be appropriate.

(2) DATE OF APPOINTMENTS.—The heads of Federal departments and agencies shall appoint the corresponding members of the task force not later than 60 days after the date of enactment of this Act.

(3) CHAIRPERSON.—The task force shall be chaired by the Assistant Secretary for Mental Health and Substance Use, or the Assistant Secretary's designee.

(c) TASK FORCE DUTIES.—The task force shall—

(1) solicit input from stakeholders, including frontline service providers, educators, mental health professionals, researchers, experts in infant, child, and

youth trauma, child welfare professionals, and the public, in order to inform the activities under paragraph (2); and

(2) identify, evaluate, make recommendations, and update such recommendations not less than annually, to the general public, the Secretary of Education, the Secretary of Health and Human Services, the Secretary of Labor, the Secretary of the Interior, the Attorney General, and other relevant cabinet Secretaries, and Congress regarding—

(A) a set of evidence-based, evidence-informed, and promising best practices with respect to—

(i) prevention strategies for individuals at risk of experiencing or being exposed to trauma, including trauma as a result of exposure to substance use;

(ii) the identification of infants, children and youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma;

(iii) the expeditious referral to and implementation of trauma-informed practices and supports that prevent and mitigate the effects of trauma, which may include whole-

family and multi-generational approaches; and

(iv) community based or multi-generational practices that support children and their families;

(B) a national strategy on how the task force and member agencies will collaborate, prioritize options for, and implement a coordinated approach, which may include—

(i) data sharing;

(ii) providing support to infants, children, and youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma;

(iii) identifying options for coordinating 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 use or other trauma, including trauma related to substance use; and

(iv) other ways to improve coordination, planning, and communication within and across Federal agencies, offices, and programs, to better serve children and fami-

lies impacted by substance use disorders; and

(C) existing Federal authorities at the Department of Education, Department of Health and Human Services, Department of Justice, Department of Labor, Department of the Interior, and other relevant agencies, and specific Federal grant programs to disseminate best practices on, provide training in, or deliver services through, trauma-informed practices, and disseminate such information—

(i) in writing to relevant program offices at such agencies to encourage grant applicants in writing to use such funds, where appropriate, for trauma-informed practices; and

(ii) to the general public through the internet website of the task force.

(d) BEST PRACTICES.—In identifying, evaluating, and recommending the set of best practices under subsection (c), the task force shall—

(1) include guidelines for providing professional development and education for front-line services providers, including school personnel, early childhood education program providers, providers from child- or

youth-serving organizations, housing and homeless providers, primary and behavioral health care providers, child welfare and social services providers, juvenile and family court personnel, health care providers, individuals who are mandatory reporters of child abuse or neglect, trained nonclinical providers (including peer mentors and clergy), and first responders, in—

(A) understanding and identifying early signs and risk factors of trauma in infants, children, and youth, and their families as appropriate, including through screening processes and services;

(B) providing practices to prevent and mitigate the impact of trauma, including by fostering safe and stable environments and relationships; and

(C) developing and implementing policies, procedures, or systems that—

(i) are designed to quickly refer infants, children, youth, and their families as appropriate, who have experienced or are at risk of experiencing trauma to the appropriate trauma-informed screening and support and age-appropriate treatment, and to

ensure such infants, children, youth, and family members receive such support;

(ii) utilize and develop partnerships with early childhood education programs, local social services organizations, such as organizations serving youth, and clinical mental health or other health care providers with expertise in providing support services and age-appropriate trauma-informed and evidence-based treatment aimed at preventing or mitigating the effects of trauma;

(iii) educate children and youth to—

(I) understand and identify the signs, effects, or symptoms of trauma; and

(II) build the resilience and coping skills to mitigate the effects of experiencing trauma;

(iv) promote and support multigenerational practices that assist parents, foster parents, and kinship and other caregivers in accessing resources related to, and developing environments conducive to, the prevention and mitigation of trauma; and

(v) collect and utilize data from screenings, referrals, or the provision of services and supports to evaluate outcomes and improve processes for trauma-informed services and supports that are culturally sensitive, linguistically appropriate, and specific to age ranges and sex, as applicable;

(2) recommend best practices that are designed to avoid unwarranted custody loss or criminal penalties for parents or guardians in connection with infants, children, and youth who have experienced or are at risk of experiencing trauma; and

(3) recommend opportunities for local- and State-level partnerships 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 trauma, including related to substance use;

(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 trauma, including related to substance use;

(C) offer community-based prevention activities, including educating families and children on the effects of exposure to trauma, such as trauma related to substance use, 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 trauma, including related to substance use; and

(E) are designed to prevent separation and support reunification of families if in the best interest of the child.

(e) OPERATING PLAN.—Not later than 120 days after the date of enactment of this Act, the task force shall hold the first meeting. Not later than 2 years after such date of enactment, the task force shall submit to the Secretary of Education, Secretary of Health and Human Services, Secretary of Labor, Secretary of the Interior, the Attorney General, and Congress an operating plan for carrying out the activities of the task force described in subsection (c)(2). Such operating plan shall include—

(1) a list of specific activities that the task force plans to carry out for purposes of carrying out duties described in subsection (c)(2), which may include public engagement;

(2) a plan for carrying out the activities under subsection (c)(2);

(3) a list of members of the task force and other individuals who are not members of the task force that may be consulted to carry out such activities;

(4) an explanation of Federal agency involvement and coordination needed to carry out such activities, including any statutory or regulatory barriers to such coordination;

(5) a budget for carrying out such activities;

(6) a proposed timeline for implementing recommendations and efforts identified under subsection (c); and

(7) other information that the task force determines appropriate as related to its duties.

(f) FINAL REPORT.—Not later than 3 years after the date of the first meeting of the task force, the task force shall submit to the general public, Secretary of Education, Secretary of Health and Human Services, Secretary of Labor, Secretary of the Interior, the Attorney General, other relevant cabinet Secretaries, the Committee on Energy and

Commerce and the Committee on Education and the Workforce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, and Congress, a final report containing all of the findings and recommendations required under this section, and shall make such report available online in an accessible format.

(g) ADDITIONAL REPORTS.—In addition to the final report under subsection (f). the task force shall submit—

(1) a report to Congress identifying any recommendations identified under subsection (c) that require additional legislative authority to implement; and

(2) a report to the Governors describing the opportunities for local- and State-level partnerships, professional development, or best practices recommended under subsection (d)(3).

(h) DEFINITIONS.—In this section—

(1) the term "early childhood education program" has the meaning given such term in section 103 of the Higher Education Act of 1965 (20 U.S.C. 1003);

(2) The term "Governor" means the chief executive officer of a State; and

(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.

(i) SUNSET.—The task force shall sunset on the date that is 60 days after the submission of the final report under subsection (f), but not later than September 30, 2023.

SEC. 7133. NATIONAL CHILD TRAUMATIC STRESS INITIATIVE.

Section 582(j) of the Public Health Service Act (42 U.S.C. 290hh–1(j)) (relating to grants to address the problems of persons who experience violence-related stress) is amended by striking "$46,887,000 for each of fiscal years 2018 through 2022" and inserting "$63,887,000 for each of fiscal years 2019 through 2023".

SEC. 7134. GRANTS TO IMPROVE TRAUMA SUPPORT SERVICES AND MENTAL HEALTH CARE FOR CHILDREN AND YOUTH IN EDUCATIONAL SETTINGS.

(a) GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS AUTHORIZED.—The Secretary, in coordination with the Assistant Secretary for Mental Health and Substance Use, is authorized to award grants to, or enter into contracts or cooperative agreements with, State educational agencies, local educational agencies, Indian Tribes (as defined in section 4 of the Indian Self-Determination and

Education Assistance Act) or their tribal educational agencies, a school operated by the Bureau of Indian Education, a Regional Corporation, or a Native Hawaiian educational organization, for the purpose of increasing student access to evidence-based trauma support services and mental health care by developing innovative initiatives, activities, or programs to link local school systems with local trauma-informed support and mental health systems, including those under the Indian Health Service.

(b) DURATION.—With respect to a grant, contract, or cooperative agreement awarded or entered into under this section, the period during which payments under such grant, contract or agreement are made to the recipient may not exceed 4 years.

(c) USE OF FUNDS.—An entity that receives a grant, contract, or cooperative agreement under this section shall use amounts made available through such grant, contract, or cooperative agreement for evidence-based activities, which shall include any of the following:

(1) Collaborative efforts between school-based service systems and trauma-informed support and mental health service systems to provide, develop, or improve prevention, screening, referral, and treatment and support services to students, such as providing

trauma screenings to identify students in need of specialized support.

(2) To implement schoolwide positive behavioral interventions and supports, or other trauma-informed models of support.

(3) To provide professional development to teachers, teacher assistants, school leaders, specialized instructional support personnel, and mental health professionals that—

(A) fosters safe and stable learning environments that prevent and mitigate the effects of trauma, including through social and emotional learning;

(B) improves school capacity to identify, refer, and provide services to students in need of trauma support or behavioral health services; or

(C) reflects the best practices for trauma-informed identification, referral, and support developed by the Task Force under section 7132.

(4) Services at a full-service community school that focuses on trauma-informed supports, which may include a full-time site coordinator, or other activities consistent with section 4625 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7275).

(5) Engaging families and communities in efforts to increase awareness of child and youth trauma, which may include sharing best practices with law enforcement regarding trauma-informed care and working with mental health professionals to provide interventions, as well as longer term coordinated care within the community for children and youth who have experienced trauma and their families.

(6) To provide technical assistance to school systems and mental health agencies.

(7) To evaluate the effectiveness of the program carried out under this section in increasing student access to evidence-based trauma support services and mental health care.

(8) To establish partnerships with or provide subgrants to Head Start agencies (including Early Head Start agencies), public and private preschool programs, child care programs (including home-based providers), or other entities described in subsection (a), to include such entities described in this paragraph in the evidence-based trauma initiatives, activities, support services, and mental health systems established under this section in order to provide, develop, or improve prevention, screening, referral, and

treatment and support services to young children and their families.

(d) APPLICATIONS.—To be eligible to receive a grant, contract, or cooperative agreement under this section, an entity described in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include the following:

(1) A description of the innovative initiatives, activities, or programs to be funded under the grant, contract, or cooperative agreement, including how such program will increase access to evidence-based trauma support services and mental health care for students, and, as applicable, the families of such students.

(2) A description of how the program will provide linguistically appropriate and culturally competent services.

(3) A description of how the program will support students and the school in improving the school climate in order to support an environment conducive to learning.

(4) An assurance that—

(A) persons providing services under the grant, contract, or cooperative agreement are adequately trained to provide such services; and

(B) teachers, school leaders, administrators, specialized instructional support personnel, representatives of local Indian Tribes or tribal organizations as appropriate, other school personnel, and parents or guardians of students participating in services under this section will be engaged and involved in the design and implementation of the services.

(5) A description of how the applicant will support and integrate existing school-based services with the program in order to provide mental health services for students, as appropriate.

(6) A description of the entities in the community with which the applicant will partner or to which the applicant will provide subgrants in accordance with subsection (c)(8).

(e) INTERAGENCY AGREEMENTS.—

(1) LOCAL INTERAGENCY AGREEMENTS.—To ensure the provision of the services described in subsection (c), a recipient of a grant, contract, or cooperative agreement under this section, or their designee, shall establish a local interagency agreement among

local educational agencies, agencies responsible for early childhood education programs, Head Start agencies (including Early Head Start agencies), juvenile justice authorities, mental health agencies, child welfare agencies, and other relevant agencies, authorities, or entities in the community that will be involved in the provision of such services.

(2) CONTENTS.—In ensuring the provision of the services described in subsection (c), the local interagency agreement shall specify with respect to each agency, authority, or entity that is a party to such agreement—

(A) the financial responsibility for the services;

(B) the conditions and terms of responsibility for the services, including quality, accountability, and coordination of the services; and

(C) the conditions and terms of reimbursement among such agencies, authorities, or entities, including procedures for dispute resolution.

(f) EVALUATION.—The Secretary shall reserve not more than 3 percent of the funds made available under subsection (l) for each fiscal year to—

(1) conduct a rigorous, independent evaluation of the activities funded under this section; and

(2) disseminate and promote the utilization of evidence-based practices regarding trauma support services and mental health care.

(g) DISTRIBUTION OF AWARDS.—The Secretary shall ensure that grants, contracts, and cooperative agreements awarded or entered into under this section are equitably distributed among the geographical regions of the United States and among tribal, urban, suburban, and rural populations.

(h) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

(1) to prohibit an entity involved with a program carried out under this section from reporting a crime that is committed by a student to appropriate authorities; or

(2) to prevent Federal, State, and tribal law enforcement and judicial authorities from exercising their responsibilities with regard to the application of Federal, tribal, and State law to crimes committed by a student.

(i) SUPPLEMENT, NOT SUPPLANT.—Any services provided through programs carried out under this section shall supplement, and not supplant, existing mental health services, including any special education and related services

provided under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(j) CONSULTATION WITH INDIAN TRIBES.—In carrying out subsection (a), the Secretary shall, in a timely manner, meaningfully consult with Indian Tribes and their representatives to ensure notice of eligibility.

(k) DEFINITIONS.—In this section:

(1) ELEMENTARY SCHOOL.—The term "elementary school" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(2) EVIDENCE-BASED.—The term "evidence-based" has the meaning given such term in section 8101(21)(A)(i) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801(21)(A)(i)).

(3) NATIVE HAWAIIAN EDUCATIONAL ORGANIZATION.—The term "Native Hawaiian educational organization" has the meaning given such term in section 6207 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7517).

(4) LOCAL EDUCATIONAL AGENCY.—The term "local educational agency" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(5) REGIONAL CORPORATION.—The term "Regional Corporation" has the meaning given the term in section 3 of the Alaska Native Claims Settlement Act (43 U.S.C. 1602)).

(6) SCHOOL.—The term "school" means a public elementary school or public secondary school.

(7) SCHOOL LEADER.—The term "school leader" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(8) SECONDARY SCHOOL.—The term "secondary school" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(9) SECRETARY.—The term "Secretary" means the Secretary of Education.

(10) SPECIALIZED INSTRUCTIONAL SUPPORT PERSONNEL.—The term "specialized instructional support personnel" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(11) STATE EDUCATIONAL AGENCY.—The term "State educational agency" has the meaning given such term in section 8101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(l) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $50,000,000 for each of fiscal years 2019 through 2023.

SEC. 7135. 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, including trauma related to substance use 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, including trauma due to exposure to substance use;

(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, including due to exposure to substance use, 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 keep families safely together when it is in the best interest of the child.

(c) COORDINATION.—The Secretary of Health and Human Services shall coordinate with the task force to develop best practices for trauma-informed identification, referral, and support authorized under section 7132 in disseminating the information, resources, and technical assistance described under subsection (b).

(d) 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 O—Eliminating Opioid Related Infectious Diseases

SEC. 7141. 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, acting through the Director of the Centers for Disease Control and Prevention, may (directly or through grants to public and nonprofit private entities) provide for programs for the following:

"(1) To cooperate with States and Indian tribes in implementing or maintaining a national system to determine the incidence of infections commonly associated with illicit drug use, such as viral hepatitis, human immunodeficiency virus, and infective endo-

carditis, 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 described in paragraph (1) resulting from illicit 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 described in paragraph (1), including to improve coordination of treatment of substance use disorders and infectious diseases, with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, ob-

stetrician-gynecologists, and infectious disease clinicians, including 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) DEFINITION.—In this section, 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 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 P—Peer Support Communities of Recovery

SEC. 7151. BUILDING COMMUNITIES OF RECOVERY.

Section 547 of the Public Health Service Act (42 U.S.C. 290ee–2) is amended to read as follows:

"SEC. 547. BUILDING COMMUNITIES OF RECOVERY.

"(a) DEFINITION.—In this section, the term 'recovery community organization' means an independent nonprofit organization that—

"(1) mobilizes resources within and outside of the recovery community, which may include through

a peer support network, to increase the prevalence and quality of long-term recovery from substance use disorders; and

"(2) is wholly or principally governed by people in recovery for substance use disorders who reflect the community served.

"(b) GRANTS AUTHORIZED.—The Secretary shall award grants to recovery community organizations to enable such organizations to develop, expand, and enhance recovery services.

"(c) FEDERAL SHARE.—The Federal share of the costs of a program funded by a grant under this section may not exceed 85 percent.

"(d) USE OF FUNDS.—Grants awarded under subsection (b)—

"(1) shall be used to develop, expand, and enhance community and statewide recovery support services; and

"(2) may be used to—

"(A) build connections between recovery networks, including between recovery community organizations and peer support networks, and with other recovery support services, including—

"(i) behavioral health providers;

"(ii) primary care providers and physicians;

"(iii) educational and vocational schools;

"(iv) employers;

"(v) housing services;

"(vi) child welfare agencies; and

"(vii) other recovery support services that facilitate recovery from substance use disorders, including non-clinical community services;

"(B) reduce stigma associated with substance use disorders; and

"(C) conduct outreach on issues relating to substance use disorders and recovery, including—

"(i) identifying the signs of substance use disorder;

"(ii) the resources available to individuals with substance use disorder and to families of an individual with a substance use disorder, including programs that mentor and provide support services to children;

"(iii) the resources available to help support individuals in recovery; and

"(iv) related medical outcomes of substance use disorders, the potential of acquiring an infection commonly associated with illicit drug use, and neonatal abstinence syndrome among infants exposed to opioids during pregnancy.

"(e) SPECIAL CONSIDERATION.—In carrying out this section, the Secretary shall give special consideration to the unique needs of rural areas, including areas with an age-adjusted rate of drug overdose deaths that is above the national average and areas with a shortage of prevention and treatment services.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2019 through 2023.".

SEC. 7152. PEER SUPPORT TECHNICAL ASSISTANCE CENTER.

Title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by inserting after section 547 the following:

"SEC. 547A. PEER SUPPORT TECHNICAL ASSISTANCE CENTER.

"(a) ESTABLISHMENT.—The Secretary, acting through the Assistant Secretary, shall establish or operate a National Peer-Run Training and Technical Assistance Center

for Addiction Recovery Support (referred to in this section as the 'Center').

"(b) FUNCTIONS.—The Center established under subsection (a) shall provide technical assistance and support to recovery community organizations and peer support networks, including such assistance and support related to—

"(1) training on identifying—

"(A) signs of substance use disorder;

"(B) resources to assist individuals with a substance use disorder, or resources for families of an individual with a substance use disorder; and

"(C) best practices for the delivery of recovery support services;

"(2) the provision of translation services, interpretation, or other such services for clients with limited English speaking proficiency;

"(3) data collection to support research, including for translational research;

"(4) capacity building; and

"(5) evaluation and improvement, as necessary, of the effectiveness of such services provided by recovery community organizations.

"(c) BEST PRACTICES.—The Center established under subsection (a) shall periodically issue best practices for use

by recovery community organizations and peer support networks.

"(d) RECOVERY COMMUNITY ORGANIZATION.—In this section, the term 'recovery community organization' has the meaning given such term in section 547.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $1,000,000 for each of fiscal years 2019 through 2023.".

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

SEC. 7161. PREVENTING OVERDOSES OF CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Part J of title III of the Public Health Service Act (42 U.S.C. 280b et seq.) is amended by inserting after section 392 (42 U.S.C. 280b–1) the following:

"SEC. 392A. 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 and expand any evidence-based prevention activities described in paragraph (2);

"(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out such activity; and

"(C) award grants to States, localities, and Indian tribes for purposes of carrying out such activity.

"(2) EVIDENCE-BASED PREVENTION ACTIVITIES.—An evidence-based prevention activity described in this paragraph is any of the following activities:

"(A) Improving the efficiency and use of a new or currently operating prescription drug monitoring program, including by—

"(i) encouraging all authorized users (as specified by the State or other entity) to register with and use the program;

"(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;

"(iii) improving the ease of use of such program;

"(iv) providing for a mechanism for the program to notify authorized users of any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing or dispensing practices relating to such substances;

"(v) encouraging the analysis of prescription drug monitoring data for purposes of providing de-identified, aggregate reports based on such analysis to State public health agencies, State substance abuse agencies, State licensing boards, and other appropriate State agencies, as permitted under applicable Federal and State law and the policies of the prescription drug monitoring program and not containing any protected health information, to prevent inappropriate prescribing, drug diversion, or abuse and misuse of controlled substances, and to facilitate better coordination among agencies;

"(vi) enhancing interoperability between the program and any health information technology (including certified health

information technology), including by integrating program data into such technology;

"(vii) updating program capabilities to respond to technological innovation for purposes of appropriately addressing the occurrence and evolution of controlled substance overdoses;

"(viii) facilitating and encouraging data exchange between the program and the prescription drug monitoring programs of other States;

"(ix) enhancing data collection and quality, including improving patient matching and proactively monitoring data quality;

"(x) providing prescriber and dispenser practice tools, including prescriber practice insight reports for practitioners to review their prescribing patterns in comparison to such patterns of other practitioners in the specialty; and

"(xi) meeting the purpose of the program established under section 399O, as described in section 399O(a).

"(B) Promoting community or health system interventions.

"(C) Evaluating interventions to prevent controlled substance overdoses.

"(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.

"(3) ADDITIONAL GRANTS.—The Director may award grants to States, localities, and Indian Tribes—

"(A) to carry out innovative projects for grantees to rapidly respond to controlled substance misuse, abuse, and overdoses, including changes in patterns of controlled substance use; and

"(B) for any other evidence-based activity for preventing controlled substance misuse, abuse, and overdoses as the Director determines appropriate.

"(4) RESEARCH.—The Director, in coordination with the Assistant Secretary for Mental Health and Substance Use and the National Mental Health and

Substance Use Policy Laboratory established under section 501A, as appropriate and applicable, may conduct studies and evaluations to address substance use disorders, including preventing substance use disorders or other related topics the Director determines appropriate.

"(b) ENHANCED CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION, ANALYSIS, AND DISSEMINATION 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 data collection activities described in paragraph (2);

"(B) provide training and technical assistance to States, localities, and Indian tribes for purposes of carrying out such activity;

"(C) award grants to States, localities, and Indian tribes for purposes of carrying out 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

emergency departments as a result of the abuse of alcohol or other drugs).

"(2) CONTROLLED SUBSTANCE OVERDOSE DATA COLLECTION AND ANALYSIS ACTIVITIES.—A controlled substance overdose data collection, analysis, and dissemination activity described in this paragraph is any of the following activities:

"(A) Improving the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.

"(B) Enhancing the comprehensiveness of controlled substance overdose data by collecting information on such overdoses from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and emergency departments.

"(C) Modernizing the system for coding causes of death related to controlled substance overdoses to use an electronic-based system.

"(D) Using data to help identify risk factors associated with controlled substance overdoses.

"(E) Supporting entities involved in providing information on controlled substance overdoses, such as coroners, medical examiners,

and public health laboratories to improve accurate testing and standardized reporting of causes and contributing factors to controlled substances overdoses and analysis of various opioid analogues to controlled substance overdoses.

"(F) Working to enable and encourage the access, exchange, and use of information regarding controlled substance overdoses among data sources and entities.

"(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, section 399O of this Act, and section 102 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198), there is authorized to be appropriated $496,000,000 for each of fiscal years 2019 through 2023.".

(b) EDUCATION AND AWARENESS.—Section 102 of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198) is amended—

(1) by amending subsection (a) to read as follows:

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in coordination with the heads of other departments and agencies, shall advance education and awareness regarding the risks related to misuse and abuse of opioids, as appropriate, which may include developing or improving existing programs, conducting activities, and awarding grants that advance the education and awareness of—

"(1) the public, including patients and consumers—

"(A) generally; and

"(B) regarding such risks related to unused opioids and the dispensing options under section 309(f) of the Controlled Substances Act, as applicable; and

"(2) providers, which may include—

"(A) providing for continuing education on appropriate prescribing practices;

"(B) education related to applicable State or local prescriber limit laws, information on the use of non-addictive alternatives for pain management, and the use of overdose reversal drugs, as appropriate;

"(C) disseminating and improving the use of evidence-based opioid prescribing guidelines across relevant health care settings, as appropriate, and updating guidelines as necessary;

"(D) implementing strategies, such as best practices, to encourage and facilitate the use of prescriber guidelines, in accordance with State and local law;

"(E) disseminating information to providers about prescribing options for controlled substances, including such options under section 309(f) of the Controlled Substances Act, as applicable; and

"(F) disseminating information, as appropriate, on the National Pain Strategy developed by or in consultation with the Assistant Secretary for Health; and

"(3) other appropriate entities."; and

(2) in subsection (b)—

(A) by striking "opioid abuse" each place such term appears and inserting "opioid misuse and abuse"; and

(B) in paragraph (2), by striking "safe disposal of prescription medications and other" and inserting "non-addictive treatment options, safe disposal options for prescription medications, and other applicable".

SEC. 7162. 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, acting through the Director of the Centers for Disease Control and Prevention, in coordination with the heads of other departments and agencies as appropriate, shall support States or localities 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—

1 *"(i) enhancing functional components*
2 *to work toward—*
3 *"(I) universal use of PDMPs*
4 *among providers and their delegates, to*
5 *the extent that State laws allow;*
6 *"(II) more timely inclusion of*
7 *data within a PDMP;*
8 *"(III) active management of the*
9 *PDMP, in part by sending proactive*
10 *or unsolicited reports to providers to*
11 *inform prescribing; and*
12 *"(IV) ensuring the highest level of*
13 *ease in use of and access to PDMPs by*
14 *providers and their delegates, to the ex-*
15 *tent that State laws allow;*
16 *"(ii) in consultation with the Office of*
17 *the National Coordinator for Health Infor-*
18 *mation Technology, improving the intra-*
19 *state interoperability of PDMPs by—*
20 *"(I) making PDMPs more action-*
21 *able by integrating PDMPs within*
22 *electronic health records and health in-*
23 *formation technology infrastructure;*
24 *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) in consultation with the Office of the National Coordinator for Health Information Technology, 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) LEGISLATION.—As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it 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 or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

"(1) the reporting of dispensing in the State or locality 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 or locality 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;

"(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;

"(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and provided that such reports shall not include protected health information; and

"(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

"(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. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

"(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.

1 *"(i) PROGRESS REPORT.—Not later than 3 years after*
2 *the date of enactment of this section, the Secretary shall—*
3 *"(1) complete a study that—*
4 *"(A) determines the progress of grantees in*
5 *establishing and implementing PDMPs con-*
6 *sistent with this section;*
7 *"(B) provides an analysis of the extent to*
8 *which the operation of PDMPs has—*
9 *"(i) reduced inappropriate use, abuse,*
10 *diversion of, and overdose with, controlled*
11 *substances;*
12 *"(ii) established or strengthened initia-*
13 *tives to ensure linkages to substance use dis-*
14 *order treatment services; or*
15 *"(iii) affected patient access to appro-*
16 *priate care in States operating PDMPs;*
17 *"(C) determine the progress of grantees in*
18 *achieving interstate interoperability and intra-*
19 *state interoperability of PDMPs, including an*
20 *assessment of technical, legal, and financial bar-*
21 *riers to such progress and recommendations for*
22 *addressing these barriers;*
23 *"(D) determines the progress of grantees in*
24 *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 or locality 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 or localities 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 or localities 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 or locality may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

"(2) LIMITATION.—A State or locality 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 or locality 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, irrespective 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 respect 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 R—Review of Substance Use Disorder Treatment Providers Receiving Federal Funding

SEC. 7171. REVIEW OF SUBSTANCE USE DISORDER TREATMENT PROVIDERS RECEIVING FEDERAL FUNDING.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall conduct a review of entities that receive Federal funding for the provision of substance use disorder treatment services. The review shall include:

(1) The length of time the entity has provided substance use disorder treatment services and the geographic area served by the entity.

(2) A detailed analysis of the patient population served by the entity, including but not limited to the number of patients, types of diagnosed substance use disorders and the demographic information of such patients, including sex, race, ethnicity, and socioeconomic status.

(3) Detailed information on the types of substance use disorders for which the entity has the expe-

rience, capability, and capacity to provide such services.

(4) An analysis of how the entity handles patients requiring treatment for a substance use disorder that the organization is not able to treat.

(5) An analysis of what is needed in order to improve the entity's ability to meet the addiction treatment needs of the communities served by that entity.

(6) Based on the identified needs of the communities served, a description of unmet needs and inadequate services and how such needs and services could be better addressed to treat individuals with methamphetamine, cocaine, including crack cocaine, heroin, opioid, and other substance use disorders.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall develop and submit to Congress a plan to direct appropriate resources to entities that provide substance use disorder treatment services in order to address inadequacies in services or funding identified through the survey described in subsection (a).

Subtitle S—Other Health Provisions

SEC. 7181. STATE RESPONSE TO THE OPIOID ABUSE CRISIS.

(a) IN GENERAL.—Section 1003 of the 21st Century Cures Act (Public Law 114–255) is amended—

(1) in subsection (a)—

(A) by striking "the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c)" and inserting "subsection (h) to carry out the grant program described in subsection (b)"; and

(B) by inserting "and Indian Tribes" after "States";

(2) by striking subsection (b);

(3) by redesignating subsections (c) through (e) as subsections (b) through (d), respectively;

(4) by redesignating subsection (f) as subsection (j);

(5) in subsection (b), as so redesignated—

(A) in paragraph (1)—

(i) in the paragraph heading, by inserting "AND TRIBAL" after "STATE";

(ii) by striking "States for the purpose of addressing the opioid abuse crisis within such States" and inserting "States and Indian Tribes for the purpose of addressing

the opioid abuse crisis within such States and Indian Tribes";

(iii) by inserting "or Indian Tribes" after "preference to States"; and

(iv) by inserting before the period of the second sentence "or other Indian Tribes, as applicable"; and

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "to a State";

(ii) in subparagraph (A), by striking "Improving State" and inserting "Establishing or improving";

(iii) in subparagraph (C), by inserting "preventing diversion of controlled substances," after "treatment programs,"; and

(iv) in subparagraph (E), by striking "as the State determines appropriate, related to addressing the opioid abuse crisis within the State" and inserting "as the State or Indian Tribe determines appropriate, related to addressing the opioid abuse crisis within the State or Indian Tribe, including directing resources in ac-

cordance with local needs related to substance use disorders";

(6) in subsection (c), as so redesignated, by striking "subsection (c)" and inserting "subsection (b)";

(7) in subsection (d), as so redesignated—

(A) in the matter preceding paragraph (1), by striking "the authorization of appropriations under subsection (b)" and inserting "subsection (h)"; and

(B) in paragraph (1), by striking "subsection (c)" and inserting "subsection (b)"; and

(8) by inserting after subsection (d), as so redesignated, the following:

"(e) INDIAN TRIBES.—

"(1) DEFINITION.—For purposes of this section, the term 'Indian Tribe' has the meaning given the term 'Indian tribe' in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

"(2) APPROPRIATE MECHANISMS.—The Secretary, in consultation with Indian Tribes, shall identify and establish appropriate mechanisms for Tribes to demonstrate or report the information as required under subsections (b), (c), and (d).

"(f) REPORT TO CONGRESS.—Not later than 1 year after the date on which amounts are first awarded after the date of enactment of this subsection, pursuant to subsection (b), and annually thereafter, the Secretary 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 summarizing the information provided to the Secretary in reports made pursuant to subsection (c), including the purposes for which grant funds are awarded under this section and the activities of such grant recipients.

"(g) TECHNICAL ASSISTANCE.—The Secretary, including through the Tribal Training and Technical Assistance Center of the Substance Abuse and Mental Health Services Administration, shall provide State agencies and Indian Tribes, as applicable, with technical assistance concerning grant application and submission procedures under this section, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing the opioid crisis.

"(h) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the grant program under subsection (b), there is authorized to be appropriated $500,000,000 for each of fiscal years 2019 through 2021, to remain available until expended.

"(i) SET ASIDE.—Of the amounts made available for each fiscal year to award grants under subsection (b) for a fiscal year, 5 percent of such amount for such fiscal year shall be made available to Indian Tribes, and up to 15 percent of such amount for such fiscal year may be set aside for States with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of States according to the Director of the Centers for Disease Control and Prevention.".

(b) CONFORMING AMENDMENT.—Section 1004(c) of the 21st Century Cures Act (Public Law 114–255) is amended by striking ", the FDA Innovation Account, or the Account For the State Response to the Opioid Abuse Crisis" and inserting "or the FDA Innovation Account".

SEC. 7182. REPORT ON INVESTIGATIONS REGARDING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—Section 13003 of the 21st Century Cures Act (Public Law 114–255) is amended—

(1) in subsection (a)—

(A) by striking "with findings of any serious violation regarding" and inserting "concerning"; and

(B) by inserting "and the Committee on Education and the Workforce" after "Energy and Commerce"; and

(2) in subsection (b)(1)—

(A) by inserting "complaints received and number of" before "closed"; and

(B) by inserting before the period ", and, for each such investigation closed, which agency conducted the investigation, whether the health plan that is the subject of the investigation is fully insured or not fully insured and a summary of any coordination between the applicable State regulators and the Department of Labor, the Department of Health and Human Services, or the Department of the Treasury, and references to any guidance provided by the agencies addressing the category of violation committed".

(b) APPLICABILITY.—The amendments made by subsection (a) shall apply with respect to the second annual report required under such section 13003 and each such annual report thereafter.

SEC. 7183. CAREER ACT.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in consultation with the Secretary of Labor, shall

continue or establish a program to support individuals in substance use disorder treatment and recovery to live independently and participate in the workforce.

(b) GRANTS AUTHORIZED.—In carrying out the activities under this section, the Secretary shall, on a competitive basis, award grants for a period of not more than 5 years to entities to enable such entities to carry out evidence-based programs to help individuals in substance use disorder treatment and recovery to live independently and participate in the workforce. Such entities shall coordinate, as applicable, with Indian tribes or tribal organizations (as applicable), State boards and local boards (as defined in section 3 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3102), lead State agencies with responsibility for a workforce investment activity (as defined in such section 3), and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(c) PRIORITY.—

(1) IN GENERAL.—In awarding grants under this section, the Secretary shall give priority based on the State in which the entity is located. Priority shall be given among States according to a formula based on the rates described in paragraph (2) and weighted as described in paragraph (3).

(2) RATES.—The rates described in this paragraph are the following:

(A) The amount by which the rate of drug overdose deaths in the State, adjusted for age, is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention.

(B) The amount by which the rate of unemployment for the State, based on data provided by the Bureau of Labor Statistics for the preceding 5 calendar years for which there is available data, is above the national average.

(C) The amount by which rate of labor force participation in the State, based on data provided by the Bureau of Labor Statistics for the preceding 5 calendar years for which there is available data, is below the national average.

(3) WEIGHTING.—The rates described in paragraph (2) shall be weighted as follows:

(A) The rate described in paragraph (2)(A) shall be weighted 70 percent.

(B) The rate described in paragraph (2)(B) shall be weighted 15 percent.

(C) The rate described in paragraph (2)(C) shall be weighted 15 percent.

(d) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to entities located in areas within States with the greatest need, with such need based on the highest mortality rate related to substance use disorder.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means an entity that offers treatment or recovery services for individuals with substance use disorders, and partners with one or more local or State stakeholders, which may include local employers, community organizations, the local workforce development board, local and State governments, and Indian Tribes or tribal organizations, to support recovery, independent living, and participation in the workforce.

(2) INDIAN TRIBES; TRIBAL ORGANIZATION.—The terms "Indian Tribe" and "tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(3) STATE.—The term "State" includes only the several States and the District of Columbia.

(f) APPLICATIONS.—An eligible entity shall submit an application at such time and in such manner as the Secretary may require. In submitting an application, the entity shall demonstrate the ability to partner with local stakeholders, which may include local employers, community stakeholders, the local workforce development board, local and State governments, and Indian Tribes or tribal organizations, as applicable, to—

(1) identify gaps in the workforce due to the prevalence of substance use disorders;

(2) in coordination with statewide employment and training activities, including coordination and alignment of activities carried out by entities provided grant funds under section 8041, help individuals in recovery from a substance use disorder transition into the workforce, including by providing career services, training services as described in paragraph (2) of section 134(c) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3174(c)), and related services described in section 134(a)(3) of such Act (42 U.S.C. 3174(a)); and

(3) assist employers with informing their employees of the resources, such as resources related to substance use disorders that are available to their employees.

1 *(g) USE OF FUNDS.—An entity receiving a grant*
2 *under this section shall use the funds to conduct one or more*
3 *of the following activities:*
4 *(1) Hire case managers, care coordinators, pro-*
5 *viders of peer recovery support services, as described*
6 *in section 547(a) of the Public Health Service Act (42*
7 *U.S.C. 290ee–2(a)), or other professionals, as appro-*
8 *priate, to provide services that support treatment, re-*
9 *covery, and rehabilitation, and prevent relapse, re-*
10 *cidivism, and overdose, including by encouraging—*
11 *(A) the development and strengthening of*
12 *daily living skills; and*
13 *(B) the use of counseling, care coordination,*
14 *and other services, as appropriate, to support re-*
15 *covery from substance use disorders.*
16 *(2) Implement or utilize innovative technologies,*
17 *which may include the use of telemedicine.*
18 *(3) In coordination with the lead State agency*
19 *with responsibility for a workforce investment activ-*
20 *ity or local board described in subsection (b), pro-*
21 *vide—*
22 *(A) short-term prevocational training serv-*
23 *ices; and*

(B) training services that are directly linked to the employment opportunities in the local area or the planning region.

(h) SUPPORT FOR STATE STRATEGY.—An eligible entity shall include in its application under subsection (f) information describing how the services and activities proposed in such application are aligned with the State, outlying area, or Tribal strategy, as applicable, for addressing issues described in such application and how such entity will coordinate with existing systems to deliver services as described in such application.

(i) DATA REPORTING AND PROGRAM OVERSIGHT.—Each eligible entity awarded a grant under this section shall submit to the Secretary a report at such time and in such manner as the Secretary may require. Such report shall include a description of—

(1) the programs and activities funded by the grant;

(2) outcomes of the population of individuals with a substance use disorder the grantee served through activities described in subsection (g); and

(3) any other information that the Secretary may require for the purpose of ensuring that the grantee is complying with all of the requirements of the grant.

(j) REPORTS TO CONGRESS.—

(1) PRELIMINARY REPORT.—Not later than 2 years after the end of the first year of the grant period under this section, the Secretary shall submit to Congress a preliminary report that analyzes reports submitted under subsection (i).

(2) FINAL REPORT.—Not later than 2 years after submitting the preliminary report required under paragraph (1), the Secretary shall submit to Congress a final report that includes—

(A) a description of how the grant funding was used, including the number of individuals who received services under subsection (g)(3) and an evaluation of the effectiveness of the activities conducted by the grantee with respect to outcomes of the population of individuals with substance use disorder who receive services from the grantee; and

(B) recommendations related to best practices for health care professionals to support individuals in substance use disorder treatment or recovery to live independently and participate in the workforce.

(k) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $5,000,000 for each of fiscal

years 2019 through 2023 for purposes of carrying out this section.

TITLE VIII—MISCELLANEOUS

Subtitle A—Synthetics Trafficking and Overdose Prevention

SEC. 8001. SHORT TITLE.

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 required 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 ship-

ments 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 determination 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 1 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 detection 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 subtitle, 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 vio-

lations 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 1 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—Opioid Addiction Recovery Fraud Prevention

SEC. 8021. SHORT TITLE.

This subtitle may be cited as the "Opioid Addiction Recovery Fraud Prevention Act of 2018".

SEC. 8022. DEFINITIONS.

For purposes of this subtitle only, and not be construed or applied as to challenge or affect the characterization, definition, or treatment under any other statute, regulation, or rule:

(1) SUBSTANCE USE DISORDER TREATMENT PRODUCT.—The term "substance use disorder treatment product" means a product for use or marketed

for use in the treatment, cure, or prevention of a substance use disorder, including an opioid use disorder.

(2) SUBSTANCE USE DISORDER TREATMENT SERVICE.—The term "substance use disorder treatment service" means a service that purports to provide referrals to treatment, treatment, or recovery housing for people diagnosed with, having, or purporting to have a substance use disorder, including an opioid use disorder.

SEC. 8023. UNFAIR OR DECEPTIVE ACTS OR PRACTICES WITH RESPECT TO SUBSTANCE USE DISORDER TREATMENT SERVICE AND PRODUCTS.

(a) UNLAWFUL ACTIVITY.—It is unlawful to engage in an unfair or deceptive act or practice with respect to any substance use disorder treatment service or substance use disorder treatment product.

(b) ENFORCEMENT BY THE FEDERAL TRADE COMMISSION.—

(1) UNFAIR OR DECEPTIVE ACTS OR PRACTICES.—A violation of subsection (a) shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) regarding unfair or deceptive acts or practices.

(2) POWERS OF THE FEDERAL TRADE COMMISSION.—

(A) IN GENERAL.—The Federal Trade Commission shall enforce this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section.

(B) PRIVILEGES AND IMMUNITIES.—Any person who violates subsection (a) shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated and made part of this section.

(c) AUTHORITY PRESERVED.—Nothing in this subtitle shall be construed to limit the authority of the Federal Trade Commission or the Food and Drug Administration under any other provision of law.

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

SEC. 8041. ADDRESSING ECONOMIC AND WORKFORCE IMPACTS OF THE OPIOID CRISIS.

(a) DEFINITIONS.—Except as otherwise expressly provided, in this section:

(1) WIOA DEFINITIONS.—The terms "core program", "individual with a barrier to employment", "local area", "local board", "one-stop operator", "outlying area", "State", "State board", and "supportive services" have the meanings given the terms in section 3 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3102).

(2) EDUCATION PROVIDER.—The term "education provider" means—

(A) an institution of higher education, as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001); or

(B) a postsecondary vocational institution, as defined in section 102(c) of such Act (20 U.S.C. 1002(c)).

(3) ELIGIBLE ENTITY.—The term "eligible entity" means—

(A) a State workforce agency;

(B) an outlying area; or

(C) a Tribal entity.

(4) PARTICIPATING PARTNERSHIP.—The term "participating partnership" means a partnership—

(A) evidenced by a written contract or agreement; and

(B) including, as members of the partnership, a local board receiving a subgrant under subsection (d) and 1 or more of the following:

(i) The eligible entity.

(ii) A treatment provider.

(iii) An employer or industry organization.

(iv) An education provider.

(v) A legal service or law enforcement organization.

(vi) A faith-based or community-based organization.

(vii) Other State or local agencies, including counties or local governments.

(viii) Other organizations, as determined to be necessary by the local board.

(ix) Indian Tribes or tribal organizations.

(5) PROGRAM PARTICIPANT.—The term "program participant" means an individual who—

(A) is a member of a population of workers described in subsection (e)(2) that is served by a participating partnership through the pilot program under this section; and

(B) enrolls with the applicable participating partnership to receive any of the services described in subsection (e)(3).

(6) PROVIDER OF PEER RECOVERY SUPPORT SERVICES.—The term "provider of peer recovery support services" means a provider that delivers peer recovery support services through an organization described in section 547(a) of the Public Health Service Act (42 U.S.C. 290ee–2(a)).

(7) SECRETARY.—The term "Secretary" means the Secretary of Labor.

(8) STATE WORKFORCE AGENCY.—The term "State workforce agency" means the lead State agency with responsibility for the administration of a program under chapter 2 or 3 of subtitle B of title I of the Workforce Innovation and Opportunity Act (29 U.S.C. 3161 et seq., 3171 et seq.).

(9) SUBSTANCE USE DISORDER.—The term "substance use disorder" has the meaning given such term

by the Assistant Secretary for Mental Health and Substance Use.

(10) TREATMENT PROVIDER.—The term "treatment provider"—

(A) means a health care provider that—

(i) offers services for treating substance use disorders and is licensed in accordance with applicable State law to provide such services; and

(ii) accepts health insurance for such services, including coverage under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.); and

(B) may include—

(i) a nonprofit provider of peer recovery support services;

(ii) a community health care provider;

(iii) a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x));

(iv) an Indian health program (as defined in section 3 of the Indian Health Care Improvement Act (25 U.S.C. 1603)), including an Indian health program that serves

an urban center (as defined in such section); and

(v) a Native Hawaiian health center (as defined in section 12 of the Native Hawaiian Health Care Improvement Act (42 U.S.C. 11711)).

(11) TRIBAL ENTITY.—The term "Tribal entity" includes any Indian Tribe, tribal organization, Indian-controlled organization serving Indians, Native Hawaiian organization, or Alaska Native entity, as such terms are defined or used in section 166 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3221).

(b) PILOT PROGRAM AND GRANTS AUTHORIZED.—

(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Health and Human Services, shall carry out a pilot program to address economic and workforce impacts associated with a high rate of a substance use disorder. In carrying out the pilot program, the Secretary shall make grants, on a competitive basis, to eligible entities to enable such entities to make subgrants to local boards to address the economic and workforce impacts associated with a high rate of a substance use disorder.

(2) GRANT AMOUNTS.—The Secretary shall make each such grant in an amount that is not less than $500,000, and not more than $5,000,000, for a fiscal year.

(c) GRANT APPLICATIONS.—

(1) IN GENERAL.—An eligible entity applying for a grant under this section shall submit an application to the Secretary at such time and in such form and manner as the Secretary may reasonably require, including the information described in this subsection.

(2) SIGNIFICANT IMPACT ON COMMUNITY BY OPIOID AND SUBSTANCE USE DISORDER-RELATED PROBLEMS.—

(A) DEMONSTRATION.—An eligible entity shall include in the application—

(i) information that demonstrates significant impact on the community by problems related to opioid abuse or another substance use disorder, by—

(I) identifying the counties, communities, regions, or local areas that have been significantly impacted and will be served through the grant (each

referred to in this section as a "service area"); and

(II) demonstrating for each such service area, an increase equal to or greater than the national increase in such problems, between—

(aa) 1999; and

(bb) 2016 or the latest year for which data are available; and

(ii) a description of how the eligible entity will prioritize support for significantly impacted service areas described in clause (i)(I).

(B) INFORMATION.—To meet the requirements described in subparagraph (A)(i)(II), the eligible entity may use information including data on—

(i) the incidence or prevalence of opioid abuse and other substance use disorders;

(ii) the age-adjusted rate of drug overdose deaths, as determined by the Director of the Centers for Disease Control and Prevention;

(iii) the rate of non-fatal hospitalizations related to opioid abuse or other substance use disorders;

(iv) the number of arrests or convictions, or a relevant law enforcement statistic, that reasonably shows an increase in opioid abuse or another substance use disorder; or

(v) in the case of an eligible entity described in subsection (a)(3)(C), other alternative relevant data as determined appropriate by the Secretary.

(C) SUPPORT FOR STATE STRATEGY.—The eligible entity may include in the application information describing how the proposed services and activities are aligned with the State, outlying area, or Tribal strategy, as applicable, for addressing problems described in subparagraph (A) in specific service areas or across the State, outlying area, or Tribal land.

(3) ECONOMIC AND EMPLOYMENT CONDITIONS DEMONSTRATE ADDITIONAL FEDERAL SUPPORT NEEDED.—

(A) DEMONSTRATION.—An eligible entity shall include in the application information that

demonstrates that a high rate of a substance use disorder has caused, or is coincident to—

(i) an economic or employment downturn in the service area; or

(ii) persistent economically depressed conditions in such service area.

(B) INFORMATION.—To meet the requirements of subparagraph (A), an eligible entity may use information including—

(i) documentation of any layoff, announced future layoff, legacy industry decline, decrease in an employment or labor market participation rate, or economic impact, whether or not the result described in this clause is overtly related to a high rate of a substance use disorder;

(ii) documentation showing decreased economic activity related to, caused by, or contributing to a high rate of a substance use disorder, including a description of how the service area has been impacted, or will be impacted, by such a decrease;

(iii) information on economic indicators, labor market analyses, information

from public announcements, and demographic and industry data;

(iv) information on rapid response activities (as defined in section 3 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3102)) that have been or will be conducted, including demographic data gathered by employer or worker surveys or through other methods;

(v) data or documentation, beyond anecdotal evidence, showing that employers face challenges filling job vacancies due to a lack of skilled workers able to pass a drug test; or

(vi) any additional relevant data or information on the economy, workforce, or another aspect of the service area to support the application.

(d) SUBGRANT AUTHORIZATION AND APPLICATION PROCESS.—

(1) SUBGRANTS AUTHORIZED.—

(A) IN GENERAL.—An eligible entity receiving a grant under subsection (b)—

(i) may use not more than 5 percent of the grant funds for the administrative costs of carrying out the grant;

(ii) in the case of an eligible entity described in subparagraph (A) or (B) of subsection (a)(3), shall use the remaining grant funds to make subgrants to local entities in the service area to carry out the services and activities described in subsection (e); and

(iii) in the case of an eligible entity described in subsection (a)(3)(C), shall use the remaining grant funds to carry out the services and activities described in subsection (e).

(B) EQUITABLE DISTRIBUTION.—In making subgrants under this subsection, an eligible entity shall ensure, to the extent practicable, the equitable distribution of subgrants, based on—

(i) geography (such as urban and rural distribution); and

(ii) significantly impacted service areas as described in subsection (c)(2).

(C) TIMING OF SUBGRANT FUNDS DISTRIBUTION.—An eligible entity making subgrants

under this subsection shall disburse subgrant funds to a local board receiving a subgrant from the eligible entity by the later of—

(i) the date that is 90 days after the date on which the Secretary makes the funds available to the eligible entity; or

(ii) the date that is 15 days after the date that the eligible entity makes the subgrant under subparagraph (A)(ii).

(2) SUBGRANT APPLICATION.—

(A) IN GENERAL.—A local board desiring to receive a subgrant under this subsection from an eligible entity shall submit an application at such time and in such manner as the eligible entity may reasonably require, including the information described in this paragraph.

(B) CONTENTS.—Each application described in subparagraph (A) shall include—

(i) an analysis of the estimated performance of the local board in carrying out the proposed services and activities under the subgrant—

(I) based on—

(aa) primary indicators of performance described in section

116(c)(1)(A)(i) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3141(c)(1)(A)(i), to assess estimated effectiveness of the proposed services and activities, including the estimated number of individuals with a substance use disorder who may be served by the proposed services and activities;

(bb) the record of the local board in serving individuals with a barrier to employment; and

(cc) the ability of the local board to establish a participating partnership; and

(II) which may include or utilize—

(aa) data from the National Center for Health Statistics of the Centers for Disease Control and Prevention;

(bb) data from the Center for Behavioral Health Statistics and Quality of the Substance Abuse

and Mental Health Services Administration;

(cc) State vital statistics;

(dd) municipal police department records;

(ee) reports from local coroners; or

(ff) other relevant data; and

(ii) in the case of a local board proposing to serve a population described in subsection (e)(2)(B), a demonstration of the workforce shortage in the professional area to be addressed under the subgrant (which may include substance use disorder treatment and related services, non-addictive pain therapy and pain management services, mental health care treatment services, emergency response services, or mental health care), which shall include information that can demonstrate such a shortage, such as—

(I) the distance between—

(aa) communities affected by opioid abuse or another substance use disorder; and

(bb) facilities or professionals offering services in the professional area; or

(II) the maximum capacity of facilities or professionals to serve individuals in an affected community, or increases in arrests related to opioid or another substance use disorder, overdose deaths, or nonfatal overdose emergencies in the community.

(e) SUBGRANT SERVICES AND ACTIVITIES.—

(1) IN GENERAL.—Each local board that receives a subgrant under subsection (d) shall carry out the services and activities described in this subsection through a participating partnership.

(2) SELECTION OF POPULATION TO BE SERVED.—A participating partnership shall elect to provide services and activities under the subgrant to one or both of the following populations of workers:

(A) Workers, including dislocated workers, individuals with barriers to employment, new entrants in the workforce, or incumbent workers (employed or underemployed), each of whom—

(i) is directly or indirectly affected by a high rate of a substance use disorder; and

(ii) voluntarily confirms that the worker, or a friend or family member of the worker, has a history of opioid abuse or another substance use disorder.

(B) Workers, including dislocated workers, individuals with barriers to employment, new entrants in the workforce, or incumbent workers (employed or underemployed), who—

(i) seek to transition to professions that support individuals with a substance use disorder or at risk for developing such disorder, such as professions that provide—

(I) substance use disorder treatment and related services;

(II) services offered through providers of peer recovery support services;

(III) non-addictive pain therapy and pain management services;

(IV) emergency response services; or

(V) mental health care; and

(ii) need new or upgraded skills to better serve such a population of struggling or at-risk individuals.

(3) SERVICES AND ACTIVITIES.—Each participating partnership shall use funds available through a subgrant under this subsection to carry out 1 or more of the following:

(A) ENGAGING EMPLOYERS.—Engaging with employers to—

(i) learn about the skill and hiring requirements of employers;

(ii) learn about the support needed by employers to hire and retain program participants, and other individuals with a substance use disorder, and the support needed by such employers to obtain their commitment to testing creative solutions to employing program participants and such individuals;

(iii) connect employers and workers to on-the-job or customized training programs before or after layoff to help facilitate reemployment;

(iv) connect employers with an education provider to develop classroom instruction to complement on-the-job learning for program participants and such individuals;

(v) help employers develop the curriculum design of a work-based learning program for program participants and such individuals;

(vi) help employers employ program participants or such individuals engaging in a work-based learning program for a transitional period before hiring such a program participant or individual for full-time employment of not less than 30 hours a week; or

(vii) connect employers to program participants receiving concurrent outpatient treatment and job training services.

(B) SCREENING SERVICES.—Providing screening services, which may include—

(i) using an evidence-based screening method to screen each individual seeking participation in the pilot program to determine whether the individual has a substance use disorder;

(ii) conducting an assessment of each such individual to determine the services needed for such individual to obtain or re-

tain employment, including an assessment of strengths and general work readiness; or

(iii) accepting walk-ins or referrals from employers, labor organizations, or other entities recommending individuals to participate in such program.

(C) INDIVIDUAL TREATMENT AND EMPLOYMENT PLAN.—Developing an individual treatment and employment plan for each program participant—

(i) in coordination, as appropriate, with other programs serving the participant such as the core programs within the workforce development system under the Workforce Innovation and Opportunity Act (29 U.S.C. 3101 et seq.); and

(ii) which shall include providing a case manager to work with each participant to develop the plan, which may include—

(I) identifying employment and career goals;

(II) exploring career pathways that lead to in-demand industries and sectors, as determined by the State board and the head of the State work-

force agency or, as applicable, the Tribal entity;

(III) setting appropriate achievement objectives to attain the employment and career goals identified under subclause (I); or

(IV) developing the appropriate combination of services to enable the participant to achieve the employment and career goals identified under subclause (I).

(D) OUTPATIENT TREATMENT AND RECOVERY CARE.—In the case of a participating partnership serving program participants described in paragraph (2)(A) with a substance use disorder, providing individualized and group outpatient treatment and recovery services for such program participants that are offered during the day and evening, and on weekends. Such treatment and recovery services—

(i) shall be based on a model that utilizes combined behavioral interventions and other evidence-based or evidence-informed interventions; and

(ii) may include additional services such as—

(I) health, mental health, addiction, or other forms of outpatient treatment that may impact a substance use disorder and co-occurring conditions;

(II) drug testing for a current substance use disorder prior to enrollment in career or training services or prior to employment;

(III) linkages to community services, including services offered by partner organizations designed to support program participants; or

(IV) referrals to health care, including referrals to substance use disorder treatment and mental health services.

(E) SUPPORTIVE SERVICES.—Providing supportive services, which shall include services such as—

(i) coordinated wraparound services to provide maximum support for program participants to assist the program participants in maintaining employment and re-

covery for not less than 12 months, as appropriate;

(ii) assistance in establishing eligibility for assistance under Federal, State, Tribal, and local programs providing health services, mental health services, vocational services, housing services, transportation services, social services, or services through early childhood education programs (as defined in section 103 of the Higher Education Act of 1965 (20 U.S.C. 1003));

(iii) services offered through providers of peer recovery support services;

(iv) networking and mentorship opportunities; or

(v) any supportive services determined necessary by the local board.

(F) CAREER AND JOB TRAINING SERVICES.—Offering career services and training services, and related services, concurrently or sequentially with the services provided under subparagraphs (B) through (E). Such services shall include the following:

(i) Services provided to program participants who are in a pre-employment stage of the program, which may include—

(I) initial education and skills assessments;

(II) traditional classroom training funded through individual training accounts under chapter 3 of subtitle B of title I of the Workforce Innovation and Opportunity Act (29 U.S.C. 3171 et seq.);

(III) services to promote employability skills such as punctuality, personal maintenance skills, and professional conduct;

(IV) in-depth interviewing and evaluation to identify employment barriers and to develop individual employment plans;

(V) career planning that includes—

(aa) career pathways leading to in-demand, high-wage jobs; and

(bb) job coaching, job matching, and job placement services;

(VI) provision of payments and fees for employment and training-related applications, tests, and certifications; or

(VII) any other appropriate career service or training service described in section 134(c) of the Workforce Innovation and Opportunity Act (29 U.S.C. 3174(c)).

(ii) Services provided to program participants during their first 6 months of employment to ensure job retention, which may include—

(I) case management and support services, including a continuation of the services described in clause (i);

(II) a continuation of skills training, and career and technical education, described in clause (i) that is conducted in collaboration with the employers of such participants;

(III) mentorship services and job retention support for such participants; or

(IV) targeted training for managers and workers working with such participants (such as mentors), and human resource representatives in the business in which such participants are employed.

(iii) Services to assist program participants in maintaining employment for not less than 12 months, as appropriate.

(G) PROVEN AND PROMISING PRACTICES.—Leading efforts in the service area to identify and promote proven and promising strategies and initiatives for meeting the needs of employers and program participants.

(4) LIMITATIONS.—A participating partnership may not use—

(A) more than 10 percent of the funds received under a subgrant under subsection (d) for the administrative costs of the partnership;

(B) more than 10 percent of the funds received under such subgrant for the provision of treatment and recovery services, as described in paragraph (3)(D); and

(C) more than 10 percent of the funds received under such subgrant for the provision of

supportive services described in paragraph (3)(E) to program participants.

(f) PERFORMANCE ACCOUNTABILITY.—

(1) REPORTS.—The Secretary shall establish quarterly reporting requirements for recipients of grants and subgrants under this section that, to the extent practicable, are based on the performance accountability system under section 116 of the Workforce Innovation and Opportunity Act (29 U.S.C. 3141) and, in the case of a grant awarded to an eligible entity described in subsection (a)(3)(C), section 166(h) of such Act (29 U.S.C. 3221(h)), including the indicators described in subsection (c)(1)(A)(i) of such section 116 and the requirements for local area performance reports under subsection (d) of such section 116.

(2) EVALUATIONS.—

(A) AUTHORITY TO ENTER INTO AGREEMENTS.—The Secretary shall ensure that an independent evaluation is conducted on the pilot program carried out under this section to determine the impact of the program on employment of individuals with substance use disorders. The Secretary shall enter into an agreement with eli-

gible entities receiving grants under this section to pay for all or part of such evaluation.

(B) METHODOLOGIES TO BE USED.—The independent evaluation required under this paragraph shall use experimental designs using random assignment or, when random assignment is not feasible, other reliable, evidence-based research methodologies that allow for the strongest possible causal inferences.

(g) FUNDING.—

(1) COVERED FISCAL YEAR.—In this subsection, the term "covered fiscal year" means any of fiscal years 2019 through 2023.

(2) USING FUNDING FOR NATIONAL DISLOCATED WORKER GRANTS.—Subject to paragraph (4) and notwithstanding section 132(a)(2)(A) and subtitle D of the Workforce Innovation and Opportunity Act (29 U.S.C. 3172(a)(2)(A), 3221 et seq.), the Secretary may use, to carry out the pilot program under this section for a covered fiscal year—

(A) funds made available to carry out section 170 of such Act (29 U.S.C. 3225) for that fiscal year;

(B) funds made available to carry out section 170 of such Act that remain available for that fiscal year; and

(C) funds that remain available under section 172(f) of such Act (29 U.S.C. 3227(f)).

(3) AVAILABILITY OF FUNDS.—Funds appropriated under section 136(c) of such Act (29 U.S.C. 3181(c)) and made available to carry out section 170 of such Act for a fiscal year shall remain available for use under paragraph (2) for a subsequent fiscal year until expended.

(4) LIMITATION.—The Secretary may not use more than $100,000,000 of the funds described in paragraph (2) for any covered fiscal year under this section.

Subtitle D—Peer Support Counseling Program for Women Veterans

SEC. 8051. 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 2 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 E—Treating Barriers to Prosperity

SEC. 8061. SHORT TITLE.

This subtitle may be cited as the "Treating Barriers to Prosperity Act of 2018".

SEC. 8062. 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 F—Pilot Program to Help Individuals in Recovery From a Substance Use Disorder Become Stably Housed

SEC. 8071. PILOT PROGRAM TO HELP INDIVIDUALS IN RECOVERY FROM A SUBSTANCE USE DISORDER BECOME STABLY HOUSED.

(a) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated under this section such sums as may be necessary for each of fiscal years 2019 through 2023 for assistance to States to provide individuals in re-

covery from a substance use disorder stable, temporary housing for a period of not more than 2 years or until the individual secures permanent housing, whichever is earlier.

(b) ALLOCATION OF APPROPRIATED AMOUNTS.—

(1) IN GENERAL.—The amounts appropriated or otherwise made available to States under this section shall be allocated based on a funding formula established by the Secretary of Housing and Urban Development (referred to in this section as the "Secretary") not later than 60 days after the date of enactment of this Act.

(2) CRITERIA.—

(A) IN GENERAL.—The funding formula required under paragraph (1) shall ensure that any amounts appropriated or otherwise made available under this section are allocated to States with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, according to the Centers for Disease Control and Prevention.

(B) PRIORITY.—

(i) IN GENERAL.—Among such States, priority shall be given to States with the greatest need, as such need is determined by the Secretary based on the following factors,

and weighting such factors as described in clause (ii):

(I) The highest average rates of unemployment based on data provided by the Bureau of Labor Statistics for calendar years 2013 through 2017.

(II) The lowest average labor force participation rates based on data provided by the Bureau of Labor Statistics for calendar years 2013 through 2017.

(III) The highest age-adjusted rates of drug overdose deaths based on data from the Centers for Disease Control and Prevention.

(ii) WEIGHTING.—The factors described in clause (i) shall be weighted as follows:

(I) The rate described in clause (i)(I) shall be weighted at 15 percent.

(II) The rate described in clause (i)(II) shall be weighted at 15 percent.

(III) The rate described in clause (i)(III) shall be weighted at 70 percent.

(3) DISTRIBUTION.—Amounts appropriated or otherwise made available under this section shall be distributed according to the funding formula established by the Secretary under paragraph (1) not later than 30 days after the establishment of such formula.

(c) USE OF FUNDS.—

(1) IN GENERAL.—Any State that receives amounts pursuant to this section shall expend at least 30 percent of such funds within one year of the date funds become available to the grantee for obligation.

(2) PRIORITY.—Any State that receives amounts pursuant to this section shall distribute such amounts giving priority to entities with the greatest need and ability to deliver effective assistance in a timely manner.

(3) ADMINISTRATIVE COSTS.—Any State that receives amounts pursuant to this section may use up to 5 percent of any grant for administrative costs.

(d) RULES OF CONSTRUCTION.—

(1) IN GENERAL.—Except as otherwise provided by this section, amounts appropriated, or amounts otherwise made available to States under this section shall be treated as though such funds were community development block grant funds under title I of the

Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.).

(2) NO MATCH.—No matching funds shall be required in order for a State to receive any amounts under this section.

(e) AUTHORITY TO WAIVE OR SPECIFY ALTERNATIVE REQUIREMENTS.—

(1) IN GENERAL.—In administering any amounts appropriated or otherwise made available under this section, the Secretary may waive or specify alternative requirements to any provision under title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.) except for requirements related to fair housing, nondiscrimination, labor standards, the environment, and requirements that activities benefit persons of low- and moderate-income, upon a finding that such a waiver is necessary to expedite or facilitate the use of such funds.

(2) NOTICE OF INTENT.—The Secretary shall provide written notice of its intent to exercise the authority to specify alternative requirements under paragraph (1) to the Committee on Banking, Housing, and Urban Affairs of the Senate and the Committee on Financial Services of the House of Rep-

resentatives not later than 15 business days before such exercise of authority occurs.

(3) NOTICE TO THE PUBLIC.—The Secretary shall provide written notice of its intent to exercise the authority to specify alternative requirements under paragraph (1) to the public via notice, on the internet website of the Department of Housing and Urban Development, and by other appropriate means, not later than 15 business days before such exercise of authority occurs.

(f) TECHNICAL ASSISTANCE.—For the 2-year period following the date of enactment of this Act, the Secretary may use not more than 2 percent of the funds made available under this section for technical assistance to grantees.

(g) STATE.—For purposes of this section the term "State" includes any State as defined in section 102 of the Housing and Community Development Act of 1974 (42 U.S.C. 5302) and the District of Columbia.

Subtitle G—Human Services

SEC. 8081. SUPPORTING FAMILY-FOCUSED RESIDENTIAL TREATMENT.

(a) DEFINITIONS.—In this section:

(1) FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAM.—The term "family-focused residential treatment program" means a trauma-informed resi-

dential program primarily for substance use disorder treatment for pregnant and postpartum women and parents and guardians that allows children to reside with such women or their parents or guardians during treatment to the extent appropriate and applicable.

(2) MEDICAID PROGRAM.—The term "Medicaid program" means the program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(4) TITLE IV–E PROGRAM.—The term "title IV–E program" means the program for foster care, prevention, and permanency established under part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.).

(b) GUIDANCE ON FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAMS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary, in consultation with divisions of the Department of Health and Human Services administering substance use disorder or child welfare programs, shall develop and issue guidance to States identifying opportunities

to support family-focused residential treatment programs for the provision of substance use disorder treatment. Before issuing such guidance, the Secretary shall solicit input from representatives of States, health care providers with expertise in addiction medicine, obstetrics and gynecology, neonatology, child trauma, and child development, health plans, recipients of family-focused treatment services, and other relevant stakeholders.

(2) ADDITIONAL REQUIREMENTS.—The guidance required under paragraph (1) shall include descriptions of the following:

(A) Existing opportunities and flexibilities under the Medicaid program, including under waivers authorized under section 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n), for States to receive Federal Medicaid funding for the provision of substance use disorder treatment for pregnant and postpartum women and parents and guardians and, to the extent applicable, their children, in family-focused residential treatment programs.

(B) How States can employ and coordinate funding provided under the Medicaid program, the title IV-E program, and other programs ad-

ministered by the Secretary to support the provision of treatment and services provided by a family-focused residential treatment facility such as substance use disorder treatment and services, including medication-assisted treatment, family, group, and individual counseling, case management, parenting education and skills development, the provision, assessment, or coordination of care and services for children, including necessary assessments and appropriate interventions, non-emergency transportation for necessary care provided at or away from a program site, transitional services and supports for families leaving treatment, and other services.

(C) How States can employ and coordinate funding provided under the Medicaid program and the title IV–E program (including as amended by the Family First Prevention Services Act enacted under title VII of division E of Public Law 115–123, and particularly with respect to the authority under subsections (a)(2)(C) and (j) of section 472 and section 474(a)(1) of the Social Security Act (42 U.S.C. 672, 674(a)(1)) (as amended by section 50712 of Public Law 115–123) to provide foster care mainte-

nance payments for a child placed with a parent who is receiving treatment in a licensed residential family-based treatment facility for a substance use disorder) to support placing children with their parents in family-focused residential treatment programs.

SEC. 8082. IMPROVING RECOVERY AND REUNIFYING FAMILIES.

(a) FAMILY RECOVERY AND REUNIFICATION PROGRAM REPLICATION PROJECT.—Section 435 of the Social Security Act (42 U.S.C. 629e) is amended by adding at the end the following:

"(e) FAMILY RECOVERY AND REUNIFICATION PROGRAM REPLICATION PROJECT.—

"(1) PURPOSE.—The purpose of this subsection is to provide resources to the Secretary to support the conduct and evaluation of a family recovery and reunification program replication project (referred to in this subsection as the 'project') and to determine the extent to which such programs may be appropriate for use at different intervention points (such as when a child is at risk of entering foster care or when a child is living with a guardian while a parent is in treatment). The family recovery and reunification program conducted under the project shall use a re-

covery coach model that is designed to help reunify families and protect children by working with parents or guardians with a substance use disorder who have temporarily lost custody of their children.

"(2) PROGRAM COMPONENTS.—The family recovery and reunification program conducted under the project shall adhere closely to the elements and protocol determined to be most effective in other recovery coaching programs that have been rigorously evaluated and shown to increase family reunification and protect children and, consistent with such elements and protocol, shall provide such items and services as—

"(A) assessments to evaluate the needs of the parent or guardian;

"(B) assistance in receiving the appropriate benefits to aid the parent or guardian in recovery;

"(C) services to assist the parent or guardian in prioritizing issues identified in assessments, establishing goals for resolving such issues that are consistent with the goals of the treatment provider, child welfare agency, courts, and other agencies involved with the parent or guard-

ian or their children, and making a coordinated plan for achieving such goals;

"(D) home visiting services coordinated with the child welfare agency and treatment provider involved with the parent or guardian or their children;

"(E) case management services to remove barriers for the parent or guardian to participate and continue in treatment, as well as to re-engage a parent or guardian who is not participating or progressing in treatment;

"(F) access to services needed to monitor the parent's or guardian's compliance with program requirements;

"(G) frequent reporting between the treatment provider, child welfare agency, courts, and other agencies involved with the parent or guardian or their children to ensure appropriate information on the parent's or guardian's status is available to inform decision-making; and

"(H) assessments and recommendations provided by a recovery coach to the child welfare caseworker responsible for documenting the parent's or guardian's progress in treatment and recovery as well as the status of other areas identi-

fied in the treatment plan for the parent or guardian, including a recommendation regarding the expected safety of the child if the child is returned to the custody of the parent or guardian that can be used by the caseworker and a court to make permanency decisions regarding the child.

"(3) RESPONSIBILITIES OF THE SECRETARY.—

"(A) IN GENERAL.—The Secretary shall, through a grant or contract with 1 or more entities, conduct and evaluate the family recovery and reunification program under the project.

"(B) REQUIREMENTS.—In identifying 1 or more entities to conduct the evaluation of the family recovery and reunification program, the Secretary shall—

"(i) determine that the area or areas in which the program will be conducted have sufficient substance use disorder treatment providers and other resources (other than those provided with funds made available to carry out the project) to successfully conduct the program;

"(ii) determine that the area or areas in which the program will be conducted

have enough potential program participants, and will serve a sufficient number of parents or guardians and their children, so as to allow for the formation of a control group, evaluation results to be adequately powered, and preliminary results of the evaluation to be available within 4 years of the program's implementation;

"(iii) provide the entity or entities with technical assistance for the program design, including by working with 1 or more entities that are or have been involved in recovery coaching programs that have been rigorously evaluated and shown to increase family reunification and protect children so as to make sure the program conducted under the project adheres closely to the elements and protocol determined to be most effective in such other recovery coaching programs;

"(iv) assist the entity or entities in securing adequate coaching, treatment, child welfare, court, and other resources needed to successfully conduct the family recovery and

reunification program under the project; and

"(v) ensure the entity or entities will be able to monitor the impacts of the program in the area or areas in which it is conducted for at least 5 years after parents or guardians and their children are randomly assigned to participate in the program or to be part of the program's control group.

"(4) EVALUATION REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary, in consultation with the entity or entities conducting the family recovery and reunification program under the project, shall conduct an evaluation to determine whether the program has been implemented effectively and resulted in improvements for children and families. The evaluation shall have 3 components: a pilot phase, an impact study, and an implementation study.

"(B) PILOT PHASE.—The pilot phase component of the evaluation shall consist of the Secretary providing technical assistance to the entity or entities conducting the family recovery and

reunification program under the project to ensure—

"(i) the program's implementation adheres closely to the elements and protocol determined to be most effective in other recovery coaching programs that have been rigorously evaluated and shown to increase family reunification and protect children; and

"(ii) random assignment of parents or guardians and their children to be participants in the program or to be part of the program's control group is being carried out.

"(C) IMPACT STUDY.—The impact study component of the evaluation shall determine the impacts of the family recovery and reunification program conducted under the project on the parents and guardians and their children participating in the program. The impact study component shall—

"(i) be conducted using an experimental design that uses a random assignment research methodology;

"(ii) consistent with previous studies of other recovery coaching programs that have

been rigorously evaluated and shown to increase family reunification and protect children, measure outcomes for parents and guardians and their children over multiple time periods, including for a period of 5 years; and

"(iii) include measurements of family stability and parent, guardian, and child safety for program participants and the program control group that are consistent with measurements of such factors for participants and control groups from previous studies of other recovery coaching programs so as to allow results of the impact study to be compared with the results of such prior studies, including with respect to comparisons between program participants and the program control group regarding—

"(I) safe family reunification;

"(II) time to reunification;

"(III) permanency (such as through measures of reunification, adoption, or placement with guardians);

"(IV) safety (such as through measures of subsequent maltreatment);

"(V) parental or guardian treatment persistence and engagement;

"(VI) parental or guardian substance use;

"(VII) juvenile delinquency;

"(VIII) cost; and

"(IX) other measurements agreed upon by the Secretary and the entity or entities operating the family recovery and reunification program under the project.

"(D) IMPLEMENTATION STUDY.—The implementation study component of the evaluation shall be conducted concurrently with the conduct of the impact study component and shall include, in addition to such other information as the Secretary may determine, descriptions and analyses of—

"(i) the adherence of the family recovery and reunification program conducted under the project to other recovery coaching programs that have been rigorously evalu-

ated and shown to increase family reunification and protect children; and

"(ii) the difference in services received or proposed to be received by the program participants and the program control group.

"(E) REPORT.—The Secretary shall publish on an internet website maintained by the Secretary the following information:

"(i) A report on the pilot phase component of the evaluation.

"(ii) A report on the impact study component of the evaluation.

"(iii) A report on the implementation study component of the evaluation.

"(iv) A report that includes—

"(I) analyses of the extent to which the program has resulted in increased reunifications, increased permanency, case closures, net savings to the State or States involved (taking into account both costs borne by States and the Federal government), or other outcomes, or if the program did not produce such outcomes, an analysis of

why the replication of the program did not yield such results;

"(II) if, based on such analyses, the Secretary determines the program should be replicated, a replication plan; and

"(III) such recommendations for legislation and administrative action as the Secretary determines appropriate.

"(5) APPROPRIATION.—In addition to any amounts otherwise made available to carry out this subpart, out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated $15,000,000 for fiscal year 2019 to carry out the project, which shall remain available through fiscal year 2026.".

(b) CLARIFICATION OF PAYER OF LAST RESORT APPLICATION TO CHILD WELFARE PREVENTION AND FAMILY SERVICES.—Section 471(e)(10) of the Social Security Act (42 U.S.C. 671(e)(10)), as added by section 50711(a)(2) of division E of Public Law 115–123, is amended—

(1) in subparagraph (A), by inserting ", nor shall the provision of such services or programs be construed to permit the State to reduce medical or

other assistance available to a recipient of such services or programs" after "under this Act"; and

(2) by adding at the end the following:

"(C) PAYER OF LAST RESORT.—In carrying out its responsibilities to ensure access to services or programs under this subsection, the State agency shall not be considered to be a legally liable third party for purposes of satisfying a financial commitment for the cost of providing such services or programs with respect to any individual for whom such cost would have been paid for from another public or private source but for the enactment of this subsection (except that whenever considered necessary to prevent a delay in the receipt of appropriate early intervention services by a child or family in a timely fashion, funds provided under section 474(a)(6) may be used to pay the provider of services or programs pending reimbursement from the public or private source that has ultimate responsibility for the payment).".

(c) EFFECTIVE DATE.—The amendments made by subsection (b) shall take effect as if included in section 50711 of division E of Public Law 115–123.

SEC. 8083. BUILDING CAPACITY FOR FAMILY-FOCUSED RESIDENTIAL TREATMENT.

(a) DEFINITIONS.—In this section:

(1) ELIGIBLE ENTITY.—The term "eligible entity" means a State, county, local, or tribal health or child welfare agency, a private nonprofit organization, a research organization, a treatment service provider, an institution of higher education (as defined under section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001)), or another entity specified by the Secretary.

(2) FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAM.—The term "family-focused residential treatment program" means a trauma-informed residential program primarily for substance use disorder treatment for pregnant and postpartum women and parents and guardians that allows children to reside with such women or their parents or guardians during treatment to the extent appropriate and applicable.

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(b) SUPPORT FOR THE DEVELOPMENT OF EVIDENCE-BASED FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAMS.—

(1) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants to eligible entities for purposes of developing, enhancing, or evaluating family-focused residential treatment programs to increase the availability of such programs that meet the requirements for promising, supported, or well-supported practices specified in section 471(e)(4)(C) of the Social Security Act (42 U.S.C. 671(e)(4)(C))) (as added by the Family First Prevention Services Act enacted under title VII of division E of Public Law 115–123).

(2) EVALUATION REQUIREMENT.—The Secretary shall require any evaluation of a family-focused residential treatment program by an eligible entity that uses funds awarded under this section for all or part of the costs of the evaluation be designed to assist in the determination of whether the program may qualify as a promising, supported, or well-supported practice in accordance with the requirements of such section 471(e)(4)(C).

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Secretary to carry out this section, $20,000,000 for fiscal year 2019, which shall remain available through fiscal year 2023.

Subtitle H—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".

Subtitle I—Fighting Opioid Abuse in Transportation

SEC. 8101. SHORT TITLE.

This subtitle may be cited as the "Fighting Opioid Abuse in Transportation Act".

SEC. 8102. ALCOHOL AND CONTROLLED SUBSTANCE TESTING OF MECHANICAL EMPLOYEES.

(a) IN GENERAL.—Not later than 2 years after the date of enactment of this Act, the Secretary of Transportation shall publish a rule in the Federal Register revising the regulations promulgated under section 20140 of title 49,

United States Code, to cover all employees of railroad carriers who perform mechanical activities.

(b) DEFINITION OF MECHANICAL ACTIVITIES.—For the purposes of the rule under subsection (a), the Secretary shall define the term "mechanical activities" by regulation.

SEC. 8103. DEPARTMENT OF TRANSPORTATION PUBLIC DRUG AND ALCOHOL TESTING DATABASE.

(a) IN GENERAL.—Subject to subsection (c), the Secretary of Transportation shall—

(1) not later than March 31, 2019, establish and make publicly available on its website a database of the drug and alcohol testing data reported by employers for each mode of transportation; and

(2) update the database annually.

(b) CONTENTS.—The database under subsection (a) shall include, for each mode of transportation—

(1) the total number of drug and alcohol tests by type of substance tested;

(2) the drug and alcohol test results by type of substance tested;

(3) the reason for the drug or alcohol test, such as pre-employment, random, post-accident, reasonable suspicion or cause, return-to-duty, or follow-up, by type of substance tested; and

(4) the number of individuals who refused testing.

(c) COMMERCIALLY SENSITIVE DATA.—The Department of Transportation shall not release any commercially sensitive data or personally identifiable data furnished by an employer under this section unless the data is aggregated or otherwise in a form that does not identify the employer providing the data.

(d) SAVINGS CLAUSE.—Nothing in this section may be construed as limiting or otherwise affecting the requirements of the Secretary of Transportation to adhere to requirements applicable to confidential business information and sensitive security information, consistent with applicable law.

SEC. 8104. GAO REPORT ON DEPARTMENT OF TRANSPORTATION'S COLLECTION AND USE OF DRUG AND ALCOHOL TESTING DATA.

(a) IN GENERAL.—Not later than 2 years after the date the Department of Transportation public drug and alcohol testing database is established under section 8103, the Comptroller General of the United States shall—

(1) review the Department of Transportation Drug and Alcohol Testing Management Information System; and

(2) submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report on the review, including recommendations under subsection (c).

(b) CONTENTS.—The report under subsection (a) shall include—

(1) a description of the process the Department of Transportation uses to collect and record drug and alcohol testing data submitted by employers for each mode of transportation;

(2) an assessment of whether and, if so, how the Department of Transportation uses the data described in paragraph (1) in carrying out its responsibilities; and

(3) an assessment of the Department of Transportation public drug and alcohol testing database under section 8103.

(c) RECOMMENDATIONS.—The report under subsection (a) may include recommendations regarding—

(1) how the Department of Transportation can best use the data described in subsection (b)(1);

(2) any improvements that could be made to the process described in subsection (b)(1);

(3) whether and, if so, how the Department of Transportation public drug and alcohol testing database under section 8103 could be made more effective; and

(4) such other recommendations as the Comptroller General considers appropriate.

SEC. 8105. TRANSPORTATION WORKPLACE DRUG AND ALCOHOL TESTING PROGRAM; ADDITION OF FENTANYL AND OTHER SUBSTANCES.

(a) MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS.—

(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(A) determine whether a revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs to expand the opiate category on the list of authorized substance testing to include fentanyl is justified, based on the reliability and cost-effectiveness of available testing; and

(B) consider whether to include with the determination under subparagraph (A) a separate determination on whether a revision of the Mandatory Guidelines for Federal Workplace Drug

Testing Programs to expand the list of substances authorized for testing to include any other drugs or other substances listed in schedule I and II of section 202 of the Controlled Substances Act (21 U.S.C. 812) is justified based on the criteria described in subparagraph (A).

(2) REVISION OF GUIDELINES.—If an expansion of the substance list is determined to be justified under paragraph (1), the Secretary of Health and Human Services shall—

(A) notify the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives of the determination; and

(B) publish in the Federal Register, not later than 18 months after the date of the determination under that paragraph, a final notice of the revision of the Mandatory Guidelines for Federal Workplace Drug Testing Programs to expand the list of substances authorized to be tested to include the substance or substances determined to be justified for inclusion.

(3) REPORT.—If an expansion of the substance list is determined not to be justified under paragraph

(1), the Secretary of Health and Human Services shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report explaining, in detail, the reasons the expansion of the list of authorized substances is not justified.

(b) DEPARTMENT OF TRANSPORTATION DRUG-TESTING PANEL.—If an expansion is determined to be justified under subsection (a)(1), the Secretary of Transportation shall publish in the Federal Register, not later than 18 months after the date the final notice is published under subsection (a)(2), a final rule revising part 40 of title 49, Code of Federal Regulations, to include such substances in the Department of Transportation's drug-testing panel, consistent with the Mandatory Guidelines for Federal Workplace Drug Testing Programs as revised by the Secretary of Health and Human Services under subsection (a).

(c) SAVINGS PROVISION.—Nothing in this section may be construed as—

(1) delaying the publication of the notices described in sections 8106 and 8107 of this Act until the Secretary of Health and Human Services makes a determination or publishes a notice under this section; or

(2) limiting or otherwise affecting any authority of the Secretary of Health and Human Services or the Secretary of Transportation to expand the list of authorized substance testing to include an additional substance.

SEC. 8106. STATUS REPORTS ON HAIR TESTING GUIDELINES.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, and annually thereafter until the date that the Secretary of Health and Human Services publishes in the Federal Register a final notice of scientific and technical guidelines for hair testing in accordance with section 5402(b) of the Fixing America's Surface Transportation Act (Public Law 114-94; 129 Stat. 1312), the Secretary of Health and Human Services shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a report on—

(1) the status of the hair testing guidelines;

(2) an explanation for why the hair testing guidelines have not been issued; and

(3) an estimated date of completion of the hair testing guidelines.

(b) REQUIREMENT.—To the extent practicable and consistent with the objective of the hair testing described in

subsection (a) to detect illegal or unauthorized use of substances by the individual being tested, the final notice of scientific and technical guidelines under that subsection, as determined by the Secretary of Health and Human Services, shall eliminate the risk of positive test results, of the individual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.

SEC. 8107. MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING ORAL FLUID.

(a) DEADLINE.—Not later than December 31, 2018, the Secretary of Health and Human Services shall publish in the Federal Register a final notice of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid, based on the notice of proposed mandatory guidelines published in the Federal Register on May 15, 2015 (94 FR 28054).

(b) REQUIREMENT.—To the extent practicable and consistent with the objective of the testing described in subsection (a) to detect illegal or unauthorized use of substances by the individual being tested, the final notice of scientific and technical guidelines under that subsection, as determined by the Secretary of Health and Human Services, shall eliminate the risk of positive test results, of the indi-

vidual being tested, caused solely by the drug use of others and not caused by the drug use of the individual being tested.

(c) RULE OF CONSTRUCTION.—Nothing in this section may be construed as requiring the Secretary of Health and Human Services to reissue a notice of proposed mandatory guidelines to carry out subsection (a).

SEC. 8108. ELECTRONIC RECORDKEEPING.

(a) DEADLINE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall—

(1) ensure that each certified laboratory that requests approval for the use of completely paperless electronic Federal Drug Testing Custody and Control Forms from the National Laboratory Certification Program's Electronic Custody and Control Form systems receives approval for those completely paperless electronic forms instead of forms that include any combination of electronic traditional handwritten signatures executed on paper forms; and

(2) establish a deadline for a certified laboratory to request approval under paragraph (1).

(b) SAVINGS CLAUSE.—Nothing in this section may be construed as limiting or otherwise affecting any authority of the Secretary of Health and Human Services to grant

approval to a certified laboratory for use of completely paperless electronic Federal Drug Testing Custody and Control Forms, including to grant approval outside of the process under subsection (a).

(c) ELECTRONIC SIGNATURES.—Not later than 18 months after the date of the deadline under subsection (a)(2), the Secretary of Transportation shall issue a final rule revising part 40 of title 49, Code of Federal Regulations, to authorize, to the extent practicable, the use of electronic signatures or digital signatures executed to electronic forms instead of traditional handwritten signatures executed on paper forms.

SEC. 8109. STATUS REPORTS ON COMMERCIAL DRIVER'S LICENSE DRUG AND ALCOHOL CLEARINGHOUSE.

(a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, and annually thereafter until the compliance date, the Administrator of the Federal Motor Carrier Safety Administration shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Transportation and Infrastructure of the House of Representatives a status report on implementation of the final rule for the Commercial Driver's License Drug and Alcohol Clearinghouse (81 FR 87686), including—

(1) an updated schedule, including benchmarks, for implementing the final rule as soon as practicable, but not later than the compliance date; and

(2) a description of each action the Federal Motor Carrier Safety Administration is taking to implement the final rule before the compliance date.

(b) DEFINITION OF COMPLIANCE DATE.—In this section, the term "compliance date" means the earlier of—

(1) January 6, 2020; or

(2) the date that the national clearinghouse required under section 31306a of title 49, United States Code, is operational.

Subtitle J—Eliminating Kickbacks in Recovery

SEC. 8121. SHORT TITLE.

This subtitle may be cited as the "Eliminating Kickbacks in Recovery Act of 2018".

SEC. 8122. CRIMINAL PENALTIES.

(a) IN GENERAL.—Chapter 11 of title 18, United States Code, is amended by inserting after section 219 the following:

"§ 220. Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories

"(a) OFFENSE.—Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—

"(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

"(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

"(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

"(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

"(b) APPLICABILITY.—Subsection (a) shall not apply to—

"(1) a discount or other reduction in price obtained by a provider of services or other entity under a health care benefit program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity;

"(2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—

"(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

"(B) the number of tests or procedures performed; or

"(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

"(3) a discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap

discount program under section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

"(4) a payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of section 1001.952(d) of title 42, Code of Federal Regulations, as in effect on the date of enactment of this section;

"(5) a waiver or discount (as defined in section 1001.952(h)(5) of title 42, Code of Federal Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if—

"(A) the waiver or discount is not routinely provided; and

"(B) the waiver or discount is provided in good faith;

"(6) a remuneration described in section 1128B(b)(3)(I) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)(I));

"(7) a remuneration made pursuant to an alternative payment model (as defined in section 1833(z)(3)(C) of the Social Security Act) or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that

such arrangement is necessary for care coordination or value-based care; or

"(8) any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation.

"(c) REGULATIONS.—The Attorney General, in consultation with the Secretary of Health and Human Services, may promulgate regulations to clarify the exceptions described in subsection (b).

"(d) PREEMPTION.—

"(1) FEDERAL LAW.—This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a–7b).

"(2) STATE LAW.—Nothing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter.

"(e) DEFINITIONS.—In this section—

"(1) the terms 'applicable beneficiary' and 'applicable drug' have the meanings given those terms in section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

"(2) the term 'clinical treatment facility' means a medical setting , other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law;

"(3) the term 'health care benefit program' has the meaning given the term in section 24(b);

"(4) the term 'laboratory' has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a); and

"(5) the term 'recovery home' means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.".

(b) CLERICAL AMENDMENT.—The table of sections for chapter 11 of title 18, United States Code, is amended by inserting after the item related to section 219 the following:

"220. Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories.".

Subtitle K—Substance Abuse Prevention

SEC. 8201. SHORT TITLE.

This subtitle may be cited as the "Substance Abuse Prevention Act of 2018".

SEC. 8202. REAUTHORIZATION OF THE OFFICE OF NATIONAL DRUG CONTROL POLICY.

(a) OFFICE OF NATIONAL DRUG CONTROL POLICY REAUTHORIZATION ACT OF 1998.—

(1) IN GENERAL.—The Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1701 et seq.), as in effect on September 29, 2003, and as amended by the laws described in paragraph (2), is revived and restored.

(2) LAWS DESCRIBED.—The laws described in this paragraph are:

(A) The Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469; 120 Stat. 3502).

(B) The Presidential Appointment Efficiency and Streamlining Act of 2011 (Public Law 112–166; 126 Stat. 1283).

(b) REAUTHORIZATION.—

(1) IN GENERAL.—Section 714 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1711) is amended by striking "such sums as may be necessary for each of fiscal years 2006 through 2010" and inserting "$18,400,000 for each of fiscal years 2018 through 2023".

(2) REPEAL OF TERMINATION.—The Office of National Drug Control Policy Reauthorization Act of

1998 (21 U.S.C. 1701 et seq.) is amended by striking section 715 (21 U.S.C. 1712).

SEC. 8203. REAUTHORIZATION OF THE DRUG-FREE COMMUNITIES PROGRAM.

(a) REVIVAL OF NATIONAL NARCOTICS LEADERSHIP ACT OF 1988.—

(1) IN GENERAL.—Chapter 2 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.), except for subchapter II (21 U.S.C. 1541 et seq.), as in effect on September 29, 1997, and as amended by the laws described in paragraph (2), is revived and restored.

(2) LAWS DESCRIBED.—The laws described in this paragraph are:

(A) Public Law 107–82 (115 Stat. 814).

(B) The Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469: 120 Stat. 3502), as amended by paragraph (4).

(3) AMENDMENT TO TERMINATION PROVISION.—Section 1009 of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1056) is amended by inserting "and sections 1021 through 1035" after "section 1007".

(4) TECHNICAL CORRECTION.—

(A) IN GENERAL.—Title VIII of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469; 120 Stat. 3535) is amended by striking "Drug-Free Communities Act of 1997" each place it appears and inserting "National Narcotics Leadership Act of 1988".

(B) EFFECTIVE DATE.—The amendments made by subparagraph (A) shall take effect as though enacted as part of the Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469; 120 Stat. 3502).

(b) AMENDMENT TO NATIONAL NARCOTICS LEADERSHIP ACT OF 1988.—Chapter 2 of subtitle A of title I of the National Narcotics Leadership Act of 1988 (21 U.S.C. 1521 et seq.) is amended—

(1) in section 1022 (21 U.S.C. 1522), by striking "substance abuse" each place it appears and inserting "substance use and misuse";

(2) in section 1023 (21 U.S.C. 1523), by striking paragraph (9) and inserting the following:

"(9) SUBSTANCE USE AND MISUSE.—The term 'substance use and misuse' means—

"(A) the illegal use or misuse of drugs, including substances for which a listing is effect

under any of schedules I through V under section 202 of the Controlled Substances Act (21 U.S.C. 812);

"(B) the misuse of inhalants or over-the-counter drugs; or

"(C) the use of alcohol, tobacco, or other related product as such use is prohibited by State or local law.";

(3) in section 1024 (21 U.S.C. 1524), by striking subsections (a) and (b) and inserting the following:

"(a) IN GENERAL.—There is authorized to be appropriated to the Office of National Drug Control Policy to carry out this chapter $99,000,000 for each of fiscal years 2018 through 2023.

"(b) ADMINISTRATIVE COSTS.—Not more than 8 percent of the funds appropriated to carry out this chapter may be used by the Office of National Drug Control Policy to pay administrative costs associated with the responsibilities of the Office under this chapter.";

(4) in subchapter I (21 U.S.C. 1531 et seq.)—

(A) by striking "substance abuse" each place it appears and inserting "substance use and misuse"; and

(B) in section 1032(b)(1)(A) (21 U.S.C. 1532(b)(1)(A)), by striking clause (iii) and inserting the following:

"(iii) RENEWAL GRANTS.—Subject to clause (iv), the Administrator may award a renewal grant to a grant recipient under this subparagraph for each fiscal year of the 4-fiscal-year period following the first fiscal year for which the initial additional grant is awarded in an amount not to exceed the following:

"(I) For the first and second fiscal years of the 4-fiscal-year period, the amount of the non-Federal funds, including in-kind contributions, raised by the coalition for the applicable fiscal year is not less than 125 percent of the amount awarded.

"(II) For the third and fourth fiscal tears of the 4-fiscal-year period, the amount of the non-Federal funds, including in-kind contributions, raised by the coalition for the applicable fiscal year is not less than 150 percent of the amount awarded."; and

(5) by striking subchapter II (21 U.S.C. 1541 et seq.).

SEC. 8204. REAUTHORIZATION OF THE NATIONAL COMMUNITY ANTI-DRUG COALITION INSTITUTE.

Section 4 of Public Law 107–82 (21 U.S.C. 1521 note) is amended to read as follows:

"SEC. 4. AUTHORIZATION FOR NATIONAL COMMUNITY ANTIDRUG COALITION INSTITUTE.

"(a) IN GENERAL.—The Director shall, using amounts authorized to be appropriated by subsection (d), make a competitive grant to provide for the continuation of the National Community Anti-drug Coalition Institute.

"(b) ELIGIBLE ORGANIZATIONS.—An organization eligible for the grant under subsection (a) is any national nonprofit organization that represents, provides technical assistance and training to, and has special expertise and broad, national-level experience in community antidrug coalitions under this subchapter.

"(c) USE OF GRANT AMOUNT.—The organization that receives the grant under subsection (a) shall continue a National Community Anti-Drug Coalition Institute to—

"(1) provide education, training, and technical assistance for coalition leaders and community teams, with emphasis on the development of coalitions serving economically disadvantaged areas;

"(2) develop and disseminate evaluation tools, mechanisms, and measures to better assess and document coalition performance measures and outcomes; and

"(3) bridge the gap between research and practice by translating knowledge from research into practical information.

"(d) AUTHORIZATION OF APPROPRIATIONS.—The Director shall, using amounts authorized to be appropriated by section 1032 of the National Narcotics Leadership Act of 1988 (15 U.S.C. 1532), make a grant of $2 million under subsection (a), for each of the fiscal years 2018 through 2023.".

SEC. 8205. REAUTHORIZATION OF THE HIGH-INTENSITY DRUG TRAFFICKING AREA PROGRAM.

Section 707 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1706) is amended—

(1) in subsection (f), by striking "no Federal" and all that follows through "programs." and inserting the following: "not more than a total of 5 percent of Federal funds appropriated for the Program are expended for substance use disorder treatment programs and drug prevention programs.";

(2) in subsection (p)—

(A) in paragraph (4), by striking "and" at the end;

(B) in paragraph (5), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(6) $280,000,000 for each of fiscal years 2018 through 2023."; and

(3) in subsection (q)—

(A) by striking paragraph (2) and inserting the following:

"(2) REQUIRED USES.—The funds used under paragraph (1) shall be used to ensure the safety of neighborhoods and the protection of communities, including the prevention of the intimidation of witnesses of illegal drug distribution and related activities and the establishment of, or support for, programs that provide protection or assistance to witnesses in court proceedings."; and

(B) by adding at the end the following:

"(3) BEST PRACTICE MODELS.—The Director shall work with HIDTAs to develop and maintain best practice models to assist State, local, and Tribal governments in addressing witness safety, relocation, financial and housing assistance, or any other services related to witness protection or assistance in

cases of illegal drug distribution and related activities. The Director shall ensure dissemination of the best practice models to each HIDTA.".

SEC. 8206. REAUTHORIZATION OF DRUG COURT PROGRAM.

Section 1001(a)(25)(A) of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10261(a)(25)(A)) is amended by striking "Except as provided" and all that follows and inserting the following: "Except as provided in subparagraph (C), there is authorized to be appropriated to carry out part EE $75,000,000 for each of fiscal years 2018 through 2023.".

SEC. 8207. DRUG COURT TRAINING AND TECHNICAL ASSISTANCE.

Section 705 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1704) is amended by adding at the end the following:

"(e) DRUG COURT TRAINING AND TECHNICAL ASSISTANCE PROGRAM.—

"(1) GRANTS AUTHORIZED.—The Director may make a grant to a nonprofit organization for the purpose of providing training and technical assistance to drug courts.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out

this subsection $2,000,000 for each of fiscal years 2018 through 2023.".

SEC. 8208. DRUG OVERDOSE RESPONSE STRATEGY.

Section 707 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1706) is amended by adding at the end the following:

"(r) DRUG OVERDOSE RESPONSE STRATEGY IMPLEMENTATION.—The Director may use funds appropriated to carry out this section to implement a drug overdose response strategy in high intensity drug trafficking areas on a nationwide basis by—

"(1) coordinating multi-disciplinary efforts to prevent, reduce, and respond to drug overdoses, including the uniform reporting of fatal and non-fatal overdoses to public health and safety officials;

"(2) increasing data sharing among public safety and public health officials concerning drug-related abuse trends, including new psychoactive substances, and related crime; and

"(3) enabling collaborative deployment of prevention, intervention, and enforcement resources to address substance use addiction and narcotics trafficking.".

SEC. 8209. PROTECTING LAW ENFORCEMENT OFFICERS FROM ACCIDENTAL EXPOSURE.

Section 707 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1706), as amended by section 8208, is amended by adding at the end the following:

"(s) SUPPLEMENTAL GRANTS.—The Director is authorized to use not more than $10,000,000 of the amounts otherwise appropriated to carry out this section to provide supplemental competitive grants to high intensity drug trafficking areas that have experienced high seizures of fentanyl and new psychoactive substances for the purposes of—

"(1) purchasing portable equipment to test for fentanyl and other substances;

"(2) training law enforcement officers and other first responders on best practices for handling fentanyl and other substances; and

"(3) purchasing protective equipment, including overdose reversal drugs.".

SEC. 8210. COPS ANTI-METH PROGRAM.

Section 1701 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10381) is amended—

(1) by redesignating subsection (k) as subsection (l); and

(2) by inserting after subsection (j) the following:

"(k) COPS ANTI-METH PROGRAM.—The Attorney General shall use amounts otherwise appropriated to carry out this section for a fiscal year (beginning with fiscal year 2019) to make competitive grants, in amounts of not less than $1,000,000 for such fiscal year, to State law enforcement agencies with high seizures of precursor chemicals, finished methamphetamine, laboratories, and laboratory dump seizures for the purpose of locating or investigating illicit activities, such as precursor diversion, laboratories, or methamphetamine traffickers.".

SEC. 8211. COPS ANTI-HEROIN TASK FORCE PROGRAM.

Section 1701 of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10381) is amended—

(1) by redesignating subsection (l), as so redesignated by section 8210, as subsection (m); and

(2) by inserting after subsection (k), as added by section 8210, the following:

"(l) COPS ANTI-HEROIN TASK FORCE PROGRAM.—The Attorney General shall use amounts otherwise appropriated to carry out this section, or other amounts as appropriated, for a fiscal year (beginning with fiscal year 2019) to make competitive grants to State law enforcement agencies in States with high per capita rates of primary treatment ad-

missions, for the purpose of locating or investigating illicit activities, through Statewide collaboration, relating to the distribution of heroin, fentanyl, or carfentanil or relating to the unlawful distribution of prescription opioids.".

SEC. 8212. COMPREHENSIVE ADDICTION AND RECOVERY ACT EDUCATION AND AWARENESS.

Title VII of the Comprehensive Addiction and Recovery Act of 2016 (Public Law 114–198; 130 Stat. 735) is amended by adding at the end the following:

"SEC. 709. SERVICES FOR FAMILIES AND PATIENTS IN CRISIS.

"(a) IN GENERAL.—The Secretary of Health and Human Services may make grants to entities that focus on addiction and substance use disorders and specialize in family and patient services, advocacy for patients and families, and educational information.

"(b) ALLOWABLE USES.—A grant awarded under this section may be used for nonprofit national, State, or local organizations that engage in the following activities:

"(1) Expansion of resource center services with professional, clinical staff that provide, for families and individuals impacted by a substance use disorder, support, access to treatment resources, brief assessments, medication and overdose prevention education, compassionate listening services, recovery sup-

port or peer specialists, bereavement and grief support, and case management.

"(2) Continued development of health information technology systems that leverage new and upcoming technology and techniques for prevention, intervention, and filling resource gaps in communities that are underserved.

"(3) Enhancement and operation of treatment and recovery resources, easy-to-read scientific and evidence-based education on addiction and substance use disorders, and other informational tools for families and individuals impacted by a substance use disorder and community stakeholders, such as law enforcement agencies.

"(4) Provision of training and technical assistance to State and local governments, law enforcement agencies, health care systems, research institutions, and other stakeholders.

"(5) Expanding upon and implementing educational information using evidence-based information on substance use disorders.

"(6) Expansion of training of community stakeholders, law enforcement officers, and families across a broad-range of addiction, health, and related topics

on substance use disorders, local issues and community-specific issues related to the drug epidemic.

"(7) Program evaluation.".

SEC. 8213. REIMBURSEMENT OF SUBSTANCE USE DISORDER TREATMENT PROFESSIONALS.

Not later than January 1, 2020, the Comptroller General of the United States shall submit to Congress a report examining how substance use disorder services are reimbursed.

SEC. 8214. SOBRIETY TREATMENT AND RECOVERY TEAMS (START).

Title V of the Public Health Service Act (42 U.S.C. 290dd et seq.) is amended by adding at the end the following:

"SEC. 550. SOBRIETY TREATMENT AND RECOVERY TEAMS.

"(a) IN GENERAL.—The Secretary may make grants to States, units of local government, or tribal governments to establish or expand Sobriety Treatment And Recovery Team (referred to in this section as 'START') or other similar programs to determine the effectiveness of pairing social workers or mentors with families that are struggling with a substance use disorder and child abuse or neglect in order to help provide peer support, intensive treatment, and child welfare services to such families.

"(b) ALLOWABLE USES.—A grant awarded under this section may be used for one or more of the following activities:

"(1) Training eligible staff, including social workers, social services coordinators, child welfare specialists, substance use disorder treatment professionals, and mentors.

"(2) Expanding access to substance use disorder treatment services and drug testing.

"(3) Enhancing data sharing with law enforcement agencies, child welfare agencies, substance use disorder treatment providers, judges, and court personnel.

"(4) Program evaluation and technical assistance.

"(c) PROGRAM REQUIREMENTS.—A State, unit of local government, or tribal government receiving a grant under this section shall—

"(1) serve only families for which—

"(A) there is an open record with the child welfare agency; and

"(B) substance use disorder was a reason for the record or finding described in paragraph (1); and

"(2) coordinate any grants awarded under this section with any grant awarded under section 437(f) of the Social Security Act focused on improving outcomes for children affected by substance abuse.

"(d) TECHNICAL ASSISTANCE.—The Secretary may reserve not more than 5 percent of funds provided under this section to provide technical assistance on the establishment or expansion of programs funded under this section from the National Center on Substance Abuse and Child Welfare.".

SEC. 8215. PROVIDER EDUCATION.

Not later than 60 days after the date of enactment of this Act, the Attorney General, in consultation with the Secretary of Health and Human Services, shall complete the plan related to medical registration coordination required by Senate Report 114–239, which accompanied the Veterans Care Financial Protection Act of 2017 (Public Law 115–131; 132 Stat. 334).

SEC. 8216. DEFINITIONS.

Section 702 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1701) is amended—

(1) by striking paragraphs (5), (12), and (13);

(2) by redesignating paragraph (11) as paragraph (17);

(3) by redesignating paragraphs (9) and (10) as paragraphs (14) and (15), respectively;

(4) by redesignating paragraphs (6), (7), and (8) as paragraphs (10), (11), and (12), respectively;

(5) by redesignating paragraphs (1), (2), (3), and (4) as paragraphs (3), (4), (5), and (6), respectively;

(6) by inserting before paragraph (3), as so redesignated, the following:

"(1) AGENCY.—The term 'agency' has the meaning given the term 'executive agency' in section 102 of title 31, United States Code.

"(2) APPROPRIATE CONGRESSIONAL COMMITTEES.—

"(A) IN GENERAL.—The term 'appropriate congressional committees' means—

"(i) the Committee on the Judiciary, the Committee on Appropriations, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

"(ii) the Committee on Oversight and Government Reform, the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives.

"(B) SUBMISSION TO CONGRESS.—Any submission to Congress shall mean submission to the appropriate congressional committees.";

(7) by amending paragraph (3), as so redesignated, to read as follows:

"(3) DEMAND REDUCTION.—The term 'demand reduction' means any activity conducted by a National Drug Control Program Agency, other than an enforcement activity, that is intended to reduce or prevent the use of drugs or support, expand, or provide treatment and recovery efforts, including—

"(A) education about the dangers of illicit drug use;

"(B) services, programs, or strategies to prevent substance use disorder, including evidence-based education campaigns, community-based prevention programs, collection and disposal of unused prescription drugs, and services to at-risk populations to prevent or delay initial use of an illicit drug;

"(C) substance use disorder treatment;

"(D) support for long-term recovery from substance use disorders;

"(E) drug-free workplace programs;

"(F) drug testing, including the testing of employees;

"(G) interventions for illicit drug use and dependence;

"(H) expanding availability of access to health care services for the treatment of substance use disorders;

"(I) international drug control coordination and cooperation with respect to activities described in this paragraph;

"(J) pre- and post-arrest criminal justice interventions such as diversion programs, drug courts, and the provision of evidence-based treatment to individuals with substance use disorders who are arrested or under some form of criminal justice supervision, including medication assisted treatment;

"(K) other coordinated and joint initiatives among Federal, State, local, and Tribal agencies to promote comprehensive drug control strategies designed to reduce the demand for, and the availability of, illegal drugs;

"(L) international illicit drug use education, prevention, treatment, recovery, research,

rehabilitation activities, and interventions for illicit drug use and dependence; and

"(M) research related to illicit drug use and any of the activities described in this paragraph.";

(8) by inserting after paragraph (6), as so redesignated, the following:

"(7) EMERGING DRUG THREAT.—The term 'emerging drug threat' means the occurrence of a new and growing trend in the use of an illicit drug or class of drugs, including rapid expansion in the supply of or demand for such drug.

"(8) ILLICIT DRUG USE; ILLICIT DRUGS; ILLEGAL DRUGS.—The terms 'illicit drug use', 'illicit drugs', and 'illegal drugs' include the illegal or illicit use of prescription drugs.

"(9) LAW ENFORCEMENT.—The term 'law enforcement' or 'drug law enforcement' means all efforts by a Federal, State, local, or Tribal government agency to enforce the drug laws of the United States or any State, including investigation, arrest, prosecution, and incarceration or other punishments or penalties.";

(9) by amending paragraph (11), as so redesignated, to read as follows:

"(11) NATIONAL DRUG CONTROL PROGRAM AGENCY.—The term 'National Drug Control Program Agency' means any agency (or bureau, office, independent agency, board, division, commission, subdivision, unit, or other component thereof) that is responsible for implementing any aspect of the National Drug Control Strategy, including any agency that receives Federal funds to implement any aspect of the National Drug Control Strategy, but does not include any agency that receives funds for drug control activity solely under the National Intelligence Program or the Joint Military Intelligence Program.";

(10) in paragraph (12), as so redesignated—

(A) by inserting "or 'Strategy'" before "means"; and

(B) by inserting ", including any report, plan, or strategy required to be incorporated into or issued concurrently with such strategy" before the period at the end;

(11) by inserting after paragraph (12), as so redesignated, the following:

"(13) NONPROFIT ORGANIZATION.—The term 'nonprofit organization' means an organization that is described in section 501(c)(3) of the Internal Rev-

enue Code of 1986 and exempt from tax under section 501(a) of such Code.";

(12) in paragraph (14), as so redesignated, by striking "Unless the context clearly indicates otherwise, the" and inserting "The";

(13) by inserting after paragraph (15), as so redesignated, the following:

"(16) SUBSTANCE USE DISORDER TREATMENT.—The term 'substance use disorder treatment' means an evidence-based, professionally directed, deliberate, and planned regimen including evaluation, observation, medical monitoring, and rehabilitative services and interventions such as pharmacotherapy, behavioral therapy, and individual and group counseling, on an inpatient or outpatient basis, to help patients with substance use disorder reach recovery."; and

(14) in paragraph (17), as so redesignated—

(A) by redesignating subparagraphs (B), (C), (D), and (E), as subparagraphs (C), (D), (E), and (F), respectively;

(B) by inserting after subparagraph (A) the following:

"(B) domestic law enforcement;";

(C) in subparagraph (E), as so redesignated, by striking "and" at the end;

(D) in subparagraph (F), as so redesignated, by striking the period at the end and inserting a semicolon; and

(E) by adding at the end the following:

"(G) activities to prevent the diversion of drugs for their illicit use; and

"(H) research related to any of the activities described in this paragraph.".

SEC. 8217. AMENDMENTS TO ADMINISTRATION OF THE OFFICE.

(a) RESPONSIBILITIES OF OFFICE.—Section 703(a) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1702(a)) is amended—

(1) by striking paragraph (1) and inserting the following:

"(1) lead the national drug control effort, including coordinating with the National Drug Control Program Agencies;";

(2) in paragraph (2), by inserting before the semicolon the following: ", including the National Drug Control Strategy";

(3) in paragraph (3), by striking "and" at the end; and

(4) by striking paragraph (4) and all that follows through "the National Academy of Sciences." and inserting the following:

"(4) evaluate the effectiveness of national drug control policy efforts, including the National Drug Control Program Agencies' program, by developing and applying specific goals and performance measurements and monitoring the agencies' program-level spending;

"(5) identify and respond to emerging drug threats related to illicit drug use;

"(6) administer the Drug-Free Communities Program, the High-Intensity Drug Trafficking Areas Program, and other grant programs directly authorized to be administered by the Office in furtherance of the National Drug Control Strategy; and

"(7) facilitate broad-scale information sharing and data standardization among Federal, State, and local entities to support the national drug control efforts.".

(b) ETHICS GUIDELINES.—Section 703(d) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1702(d)) is amended by adding at the end the following:

"(4) ETHICS GUIDELINES.—The Director shall establish written guidelines setting forth the criteria to be used in determining whether a gift or donation should be declined under this subsection because the acceptance of the gift or donation would—

"(A) reflect unfavorably upon the ability of the Director or the Office, or any employee of the Office, to carry out responsibilities or official duties under this chapter in a fair and objective manner; or

"(B) compromise the integrity or the appearance of integrity of programs or services provided under this chapter or of any official involved in those programs or services.

"(5) REGISTRY OF GIFTS.—The Director shall maintain a list of—

"(A) the source and amount of each gift or donation accepted by the Office; and

"(B) the source and amount of each gift or donation accepted by a contractor to be used in its performance of a contract for the Office.

"(6) REPORT TO CONGRESS.—The Director shall include in the annual assessment under section 706(g) a copy of the registry maintained under paragraph (5).".

(c) APPOINTMENT OF DIRECTOR AND DEPUTY DIRECTOR.—Section 704(a) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703(a)) is amended—

(1) in paragraph (1), by striking subparagraphs (A), (B), and (C), and inserting the following:

"(A) DIRECTOR.—

"(i) IN GENERAL.—There shall be at the head of the Office a Director who shall hold the same rank and status as the head of an executive department listed in section 101 of title 5, United States Code.

"(ii) APPOINTMENT.—The Director shall be appointed by the President, by and with the advice and consent of the Senate, and shall serve at the pleasure of the President.

"(B) DEPUTY DIRECTOR.—There shall be a Deputy Director who shall report directly to the Director, and who shall be appointed by the President, and shall serve at the pleasure of the President.

"(C) COORDINATORS.—The following coordinators shall be appointed by the Director:

"(i) Performance Budget Coordinator, as described in section 704(c)(4).

"(ii) Interdiction Coordinator, as described in section 711.

"(iii) Emerging and Continuing Threats Coordinator, as described in section 709.

"(iv) State, Local, and Tribal Affairs Coordinator, to carry out the activities described in section 704(j).

"(v) Demand Reduction Coordinator, as described in subparagraph (D).

"(D) DEMAND REDUCTION COORDINATOR.—The Director shall designate or appoint a United States Demand Reduction Coordinator to be responsible for the activities described in section 702(3). The Director shall determine whether the coordinator position is a noncareer appointee in the Senior Executive Service or a career appointee in a position at level 15 of the General Schedule (or equivalent).";

(2) in paragraph (5), by striking "such official" and inserting "such officer or employee"; and

(3) by adding at the end the following:

"(6) PROHIBITION ON THE USE OF FUNDS FOR BALLOT INITIATIVES.—No funds authorized under this title may be obligated for the purpose of expressly advocating the passage or defeat of a State or local ballot initiative.".

(d) CONSULTATION.—Section 704(b) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703(b)) is amended—

(1) in paragraph (19), by striking "; and" and inserting a semicolon;

(2) in paragraph (20), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(21) in order to formulate the national drug control policies, goals, objectives, and priorities—

"(A) shall consult with and assist—

"(i) State and local governments;

"(ii) National Drug Control Program Agencies;

"(iii) each committee, working group, council, or other entity established under this chapter, as appropriate;

"(iv) the public;

"(v) appropriate congressional committees; and

"(vi) any other person in the discretion of the Director; and

"(B) may—

"(i) establish advisory councils;

"(ii) acquire data from agencies; and

"(iii) request data from any other entity.".

(e) NATIONAL DRUG CONTROL PROGRAM BUDGET.—Section 704(c) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703(c)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), by striking "paragraph (1)(C);" and inserting the following: "paragraph (1)(C) and include—

"(i) the funding level for each National Drug Control Program agency; and

"(ii) alternative funding structures that could improve progress on achieving the goals fo the National Drug Control Strategy; and";

(B) in subparagraph (B), strike "the President; and" and inserting "the President and Congress."; and

(C) by striking subparagraph (C);

(2) in paragraph (3)(E), by striking clause (ii) and inserting the following:

"(ii) CERTIFICATION.—The Director shall—

"(I) review each budget submission submitted under subparagraph (A);

"(II) based on the review under clause (i), make a determination as to whether the budget submission of a National Drug Control Program agency includes the funding levels and initiatives described in subparagraph (B); and

"(III) submit to the appropriate congressional committees—

"(aa) a written statement that either—

"(AA) certifies that the budget submission includes sufficient funding; or

"(BB) decertifies the budget submission as not including sufficient funding;

"(bb) a copy of the description made under subparagraph (B); and

"(cc) the budget recommendations made under subsection (b)(8)."; and

(3) by adding at the end the following:

"(5) PERFORMANCE-BUDGET COORDINATOR.—

"(A) DESIGNATION.—The Director shall designate or appoint a United States Performance-Budget Coordinator to—

"(i) ensure the Director has sufficient information necessary to analyze the performance of each National Drug Control Program Agency, the impact Federal funding has had on the goals in the Strategy, and the likely contributions to the goals of the Strategy based on funding levels of each National Drug Control Program Agency, to make an independent assessment of the budget request of each agency under this subsection;

"(ii) advise the Director on agency budgets, performance measures and targets, and additional data and research needed to

make informed policy decisions under this section and section 706; and

"(iii) other duties as may be determined by the Director with respect to measuring or assessing performance or agency budgets.

"(B) DETERMINATION OF POSITION.—The Director shall determine whether the coordinator position is a noncareer appointee in the Senior Executive Service or a career appointee in a position at level 15 of the General Schedule (or equivalent).

"(6) BUDGET ESTIMATE OR REQUEST SUBMISSION TO CONGRESS.—Whenever the Director submits any budget estimate or request to the President or the Office of Management and Budget, the Director shall concurrently transmit to the appropriate congressional committees a detailed statement of the budgetary needs of the Office to execute its mission based on the good-faith assessment of the Director.".

(f) POWERS AND RESPONSIBILITIES OF THE DIRECTOR.—Section 704 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703) is amended—

(1) in subsection (d)(8)—

(A) in subparagraph (D), by striking "and" at the end;

(B) in subparagraph (E)—

(i) in clause (i)—

(I) by striking "Congress, including to the Committees on Appropriations of the Senate and the House of Representatives, the authorizing committees for the Office," and inserting "the appropriate congressional committees"; and

(II) by striking "or agencies";

(ii) in clause (ii)—

(I) by striking "Congress" and inserting "the appropriate congressional committees"; and

(II) by adding "and" at the end; and

(iii) by adding at the end the following:

"(iii) funds may only be used for—

"(I) expansion of demand reduction activities;

"(II) interdiction of illicit drugs on the high seas, in United States ter-

ritorial waters, and at United States ports of entry by officers and employees of National Drug Control Program Agencies and domestic and foreign law enforcement officers;

"(III) accurate assessment and monitoring of international drug production and interdiction programs and policies;

"(IV) activities to facilitate and enhance the sharing of domestic and foreign intelligence information among National Drug Control Program Agencies related to the production and trafficking of drugs in the United States and foreign countries; and

"(V) research related to any of these activities.";

(2) in subsection (e)(2)(A), by striking "Notwithstanding any other provision of law" and inserting "Subject to the availability of appropriations"; and

(3) by adding at the end the following:

"(i) MODEL ACTS PROGRAM.—

"(1) IN GENERAL.—The Director shall provide for or shall enter into an agreement with a nonprofit organization to—

"(A) advise States on establishing laws and policies to address illicit drug use issues; and

"(B) revise such model State drug laws and draft supplementary model State laws to take into consideration changes in illicit drug use issues in the State involved.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $1,250,000 for each of fiscal years 2018 through 2023.

"(j) STATE, LOCAL, AND TRIBAL AFFAIRS COORDINATOR.—The Director shall designate or appoint a United States State, Local, and Tribal Affairs Coordinator to perform the duties of the Office outlined in this section and 706 and such other duties as may be determined by the Director with respect to coordination of drug control efforts between agencies and State, local, and Tribal governments. The Director shall determine whether the coordinator position is a noncareer appointee in the Senior Executive Service or a career appointee in a position at level 15 of the General Schedule (or equivalent).

"(k) HARM REDUCTION PROGRAMS .—When developing the national drug control policy, any policy of the Director, including policies relating to syringe exchange programs for intravenous drug users, shall be based on the best available medical and scientific evidence regarding the effectiveness of such policy in promoting individual health and preventing the spread of infectious disease and the impact of such policy on drug addiction and use. In making any policy relating to harm reduction programs, the Director shall consult with the National Institutes of Health and the National Academy of Sciences.".

(g) ACCOUNTING OF FUNDS EXPENDED.—Section 705 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1704(d)), as amended by section 8207 is further amended—

(1) by amending subsection (d) to read as follows:

"(d) ACCOUNTING OF FUNDS EXPENDED.—

"(1) IN GENERAL.—Not later than February 1 of each year, in accordance with guidance issued by the Director, the head of each National Drug Control Program Agency shall submit to the Director a detailed accounting of all funds expended by the agency for National Drug Control Program activities during the previous fiscal year and shall ensure such detailed ac-

counting is authenticated for the previous fiscal year by the Inspector General for such agency prior to the submission to the Director as frequently as determined by the Inspector General but not less frequently that every 3 years.

"(2) SUBMISSION TO CONGRESS.—The Director shall submit to Congress not later than April 1 of each year the information submitted to the Director under paragraph (1)."; and

(2) by adding at the end the following:

"(f) TRACKING SYSTEM FOR FEDERALLY FUNDED GRANT PROGRAMS.—

"(1) ESTABLISHMENT.—The Director, or the head of an agency designated by the Director, in coordination with the Secretary of Health and Human Services, shall track federally-funded grant programs to—

"(A) ensure the public has electronic access to information identifying:

"(i) all drug control grants and pertinent identifying information for each grant;

"(ii) any available performance metrics, evaluations, or other information indicating the effectiveness of such programs;

"(B) facilitate efforts to identify duplication, overlap, or gaps in funding to provide increased accountability of Federally-funded grants for substance use disorder treatment, prevention, and enforcement; and

"(C) identify barriers in the grant application process impediments that applicants currently have in the grant application process with applicable agencies.

"(2) NATIONAL DRUG CONTROL AGENCIES.—The head of each National Drug Control Program Agency shall provide to the Director a complete list of all drug control program grant programs and any other relevant information for inclusion in the system developed under paragraph (1) and annually update such list.

"(3) UPDATING EXISTING SYSTEMS.—The Director may meet the requirements of this subsection by utilizing, updating, or improving existing Federal information systems to ensure they meet the requirements of this subsection.

"(4) REPORT.—Not later than 3 years after the date of enactment of this subsection, the Comptroller General of the United States shall submit to Congress

a report examining implementation of this subsection.".

(h) TECHNICAL AND CONFORMING AMENDMENT.—Section 1105 of the Office of National Drug Control Policy Reauthorization Act of 2006 (21 U.S.C. 1701 note) is repealed.

SEC. 8218. EMERGING THREATS COMMITTEE, PLAN, AND MEDIA CAMPAIGN.

(a) IN GENERAL.—Section 709 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1708) is amended to read as follows:

"SEC. 709. EMERGING THREATS COMMITTEE, PLAN, AND MEDIA CAMPAIGN.

"(a) EMERGING THREATS COORDINATOR.—The Director shall designate or appoint a United States Emerging and Continuing Threats Coordinator to perform the duties of that position described in this section and such other duties as may be determined by the Director. The Director shall determine whether the coordinator position is a noncareer appointee in the Senior Executive Service or a career appointee in a position at level 15 of the General Schedule (or equivalent).

"(b) EMERGING THREATS COMMITTEE.—

"(1) IN GENERAL.—The Emerging Threats Committee shall—

"(A) monitor evolving and emerging drug threats in the United States;

"(B) identify and discuss evolving and emerging drug trends in the United States using the criteria required to be established under paragraph (6);

"(C) assist in the formulation of and oversee implementation of any plan described in subsection (d);

"(D) provide such other advice to the Coordinator and Director concerning strategy and policies for emerging drug threats and trends as the Committee determines to be appropriate; and

"(E) disseminate and facilitate the sharing with Federal, State, local, and Tribal officials and other entities as determined by the Director of pertinent information and data relating to—

"(i) recent trends in drug supply and demand;

"(ii) fatal and nonfatal overdoses;

"(iii) demand for and availability of evidence-based substance use disorder treatment, including the extent of the unmet treatment need, and treatment admission trends;

"(iv) recent trends in drug interdiction, supply, and demand from State, local, and Tribal law enforcement agencies; and

"(v) other subject matter as determined necessary by the Director.

"(2) CHAIRPERSON.—The Director shall designate one of the members of the Emerging Threats Committee to serve as Chairperson.

"(3) MEMBERS.—The Director shall appoint other members of the Committee, which shall include—

"(A) representatives from National Drug Control Program Agencies or other agencies;

"(B) representatives from State, local, and Tribal governments; and

"(C) representatives from other entities as designated by the Director.

"(4) MEETINGS.—The members of the Emerging Threats Committee shall meet, in person and not through any delegate or representative, not less frequently than once per calendar year, before June 1. At the call of the Director or the Chairperson, the Emerging Threats Committee may hold additional meetings as the members may choose.

"(5) CONTRACT, AGREEMENT, AND OTHER AUTHORITY.—The Director may award contracts, enter into interagency agreements, manage individual projects, and conduct other activities in support of the identification of emerging drug threats and in support of the development, implementation, and assessment of any Emerging Threat Response Plan.

"(6) CRITERIA TO IDENTIFY EMERGING DRUG THREATS.—Not later than 180 days after the date on which the Committee first meets, the Committee shall develop and recommend to the Director criteria to be used to identify an emerging drug threat or the termination of an emerging drug threat designation based on information gathered by the Committee, statistical data, and other evidence.

"(c) DESIGNATION.—

"(1) IN GENERAL.—The Director, in consultation with the Coordinator, the Committee, and the head of each National Drug Control Program Agency, may designate an emerging drug threat in the United States.

"(2) STANDARDS FOR DESIGNATION.—The Director, in consultation with the Coordinator, shall promulgate and make publicly available standards by which a designation under paragraph (1) and the ter-

mination of such designation may be made. In developing such standards, the Director shall consider the recommendations of the committee and other criteria the Director considers to be appropriate.

"(3) PUBLIC STATEMENT REQUIRED.—The Director shall publish a public written statement on the portal of the Office explaining the designation of an emerging drug threat or the termination of such designation and shall notify the appropriate congressional committees of the availability of such statement when a designation or termination of such designation has been made.

"(d) PLAN.—

"(1) PUBLIC AVAILABILITY OF PLAN.—Not later than 90 days after making a designation under subsection (c), the Director shall publish and make publicly available an Emerging Threat Response Plan and notify the President and the appropriate congressional committees of such plan's availability.

"(2) TIMING.—Concurrently with the annual submissions under section 706(g), the Director shall update the plan and report on implementation of the plan, until the Director issues the public statement required under subsection (c)(3) to terminate the emerging drug threat designation.

"(3) CONTENTS OF AN EMERGING THREAT RESPONSE PLAN.—The Director shall include in the plan required under this subsection—

"(A) a comprehensive strategic assessment of the emerging drug threat, including the current availability of, demand for, and effectiveness of evidence-based prevention, treatment, and enforcement programs and efforts to respond to the emerging drug threat;

"(B) comprehensive, research-based, short- and long-term, quantifiable goals for addressing the emerging drug threat, including for reducing the supply of the drug designated as the emerging drug threat and for expanding the availability and effectiveness of evidence-based substance use disorder treatment and prevention programs to reduce the demand for the emerging drug threat;

"(C) performance measures pertaining to the plan's goals, including quantifiable and measurable objectives and specific targets;

"(D) the level of funding needed to implement the plan, including whether funding is available to be reprogrammed or transferred to support implementation of the plan or whether

additional appropriations are necessary to implement the plan;

"(E) an implementation strategy for the media campaign under subsection (f), including goals as described under subparagraph (B) of this paragraph and performance measures, objectives, and targets, as described under subparagraph (C) of this paragraph; and

"(F) any other information necessary to inform the public of the status, progress, or response of an emerging drug threat.

"(4) IMPLEMENTATION.—

"(A) IN GENERAL.—Not later than 120 days after the date on which a designation is made under subsection (c), the Director, in consultation with the President, the appropriate congressional committees, and the head of each National Drug Control Program Agency, shall issue guidance on implementation of the plan described in this subsection to the National Drug Control Program Agencies and any other relevant agency determined to be necessary by the Director.

"(B) COORDINATOR'S RESPONSIBILITIES.—The Coordinator shall—

"(i) direct the implementation of the plan among the agencies identified in the plan, State, local, and Tribal governments, and other relevant entities;

"(ii) facilitate information-sharing between agencies identified in the plan, State, local, and Tribal governments, and other relevant entities; and

"(iii) monitor implementation of the plan by coordinating the development and implementation of collection and reporting systems to support performance measurement and adherence to the plan by agencies identified in plan, where appropriate.

"(C) REPORTING.—Not later than 180 days after the date on which a designation is made under subsection (c) and in accordance with subparagraph (A), the head of each agency identified in the plan shall submit to the Coordinator a report on implementation of the plan.

"(e) EVALUATION OF MEDIA CAMPAIGN.—Upon designation of an emerging drug threat, the Director shall evaluate whether a media campaign would be appropriate to address that threat.

"(f) NATIONAL ANTI-DRUG MEDIA CAMPAIGN.—

"(1) IN GENERAL.—The Director shall, to the extent feasible and appropriate, conduct a national anti-drug media campaign (referred to in this subtitle as the 'national media campaign') in accordance with this subsection for the purposes of—

"(A) preventing substance abuse among people in the United States;

"(B) educating the public about the dangers and negative consequences of substance use and abuse, including patient and family education about the characteristics and hazards of substance abuse and methods to safeguard against substance use, to include the safe disposal of prescription medications;

"(C) supporting evidence-based prevention programs targeting the attitudes, perception, and beliefs of persons concerning substance use and intentions to initiate or continue such use;

"(D) encouraging individuals affected by substance use disorders to seek treatment and providing such individuals with information on—

"(i) how to recognize addiction issues;

"(ii) what forms of evidence-based treatment options are available; and

"(iii) how to access such treatment;

"(E) combating the stigma of addiction and substance use disorders, including the stigma of treating such disorders with medication-assisted treatment therapies; and

"(F) informing the public about the dangers of any drug identified by the Director as an emerging drug threat as appropriate.

"(2) USE OF FUNDS.—

"(A) IN GENERAL.—Amounts made available to carry out this subsection for the national media campaign may only be used for the following:

"(i) The purchase of media time and space, including the strategic planning for, tracking, and accounting of, such purchases.

"(ii) Creative and talent costs, consistent with subparagraph (B)(i).

"(iii) Advertising production costs, which may include television, radio, internet, social media, and other commercial marketing venues.

"(iv) Testing and evaluation of advertising.

"(v) Evaluation of the effectiveness of the national media campaign.

"(vi) Costs of contracts to carry out activities authorized by this subsection.

"(vii) Partnerships with professional and civic groups, community-based organizations, including faith-based organizations, and government organizations related to the national media campaign.

"(viii) Entertainment industry outreach, interactive outreach, media projects and activities, public information, news media outreach, and corporate sponsorship and participation.

"(ix) Operational and management expenses.

"(B) SPECIFIC REQUIREMENTS.—

"(i) CREATIVE SERVICES.—In using amounts for creative and talent costs under subparagraph (A)(ii), the Director shall use creative services donated at no cost to the Government wherever feasible and may only procure creative services for advertising—

"(I) responding to high-priority or emergent campaign needs that cannot timely be obtained at no cost; or

"(II) intended to reach a minority, ethnic, or other special audience that cannot reasonably be obtained at no cost.

"(ii) TESTING AND EVALUATION OF ADVERTISING.—In using amounts for testing and evaluation of advertising under subparagraph (A)(iv), the Director shall test all advertisements prior to use in the national media campaign to ensure that the advertisements are effective with the target audience and meet industry-accepted standards. The Director may waive this requirement for advertisements using no more than 10 percent of the purchase of advertising time purchased under this subsection in a fiscal year and no more than 10 percent of the advertising space purchased under this subsection in a fiscal year, if the advertisements respond to emergent and time-sensitive campaign needs or the advertisements

will not be widely utilized in the national media campaign.

"(iii) CONSULTATION.—For the planning of the campaign under paragraph (1), the Director may consult with—

"(I) the head of any appropriate National Drug Control Program Agency;

"(II) experts on the designated drug;

"(III) State, local, and Tribal government officials and relevant agencies;

"(IV) communications professionals;

"(V) the public; and

"(VI) appropriate congressional committees.

"(iv) EVALUATION OF EFFECTIVENESS OF NATIONAL MEDIA CAMPAIGN.—In using amounts for the evaluation of the effectiveness of the national media campaign under subparagraph (A)(v), the Director shall—

"(I) designate an independent entity to evaluate by April 20 of each

year the effectiveness of the national media campaign based on data from—

"(aa) the Monitoring the Future Study published by the Department of Health and Human Services;

"(bb) the National Survey on Drug Use and Health; and

"(cc) other relevant studies or publications, as determined by the Director, including tracking and evaluation data collected according to marketing and advertising industry standards; and

"(II) ensure that the effectiveness of the national media campaign is evaluated in a manner that enables consideration of whether the national media campaign has contributed to changes in attitude or behaviors among the target audience with respect to substance use and such other measures of evaluation as the Director determines are appropriate.

"(3) ADVERTISING.—In carrying out this subsection, the Director shall ensure that sufficient funds are allocated to meet the stated goals of the national media campaign.

"(4) RESPONSIBILITIES AND FUNCTIONS UNDER THE PROGRAM.—

"(A) IN GENERAL.—The Director shall determine the overall purposes and strategy of the national media campaign.

"(B) DIRECTOR.—

"(i) IN GENERAL.—The Director shall approve—

"(I) the strategy of the national media campaign;

"(II) all advertising and promotional material used in the national media campaign; and

"(III) the plan for the purchase of advertising time and space for the national media campaign.

"(ii) IMPLEMENTATION.—The Director shall be responsible for implementing a focused national media campaign to meet the purposes set forth in paragraph (1) and shall ensure—

"(I) information disseminated through the campaign is accurate and scientifically valid; and

"(II) the campaign is designed using strategies demonstrated to be the most effective at achieving the goals and requirements of paragraph (1), which may include—

"(aa) a media campaign, as described in paragraph (2);

"(bb) local, regional, or population specific messaging;

"(cc) the development of websites to publicize and disseminate information;

"(dd) conducting outreach and providing educational resources for parents;

"(ee) collaborating with law enforcement agencies; and

"(ff) providing support for school-based public health education classes to improve teen knowledge about the effects of substance use.

"(5) PROHIBITIONS.—None of the amounts made available under paragraph (2) may be obligated or expended for any of the following:

"(A) To supplant current anti-drug community-based coalitions.

"(B) To supplant pro bono public service time donated by national and local broadcasting networks for other public service campaigns.

"(C) For partisan political purposes, or to express advocacy in support of or to defeat any clearly identified candidate, clearly identified ballot initiative, or clearly identified legislative or regulatory proposal.

"(D) To fund advertising that features any elected officials, persons seeking elected office, cabinet level officials, or other Federal officials employed pursuant to section 213 of Schedule C of title 5, Code of Federal Regulations.

"(E) To fund advertising that does not contain a primary message intended to reduce or prevent substance use.

"(F) To fund advertising containing a primary message intended to promote support for the national media campaign or private sector contributions to the national media campaign.

"(6) MATCHING REQUIREMENT.—

"(A) IN GENERAL.—Amounts made available under paragraph (2) for media time and space shall be matched by an equal amount of non-Federal funds for the national media campaign, or be matched with in-kind contributions of the same value.

"(B) NO-COST MATCH ADVERTISING DIRECT RELATIONSHIP REQUIREMENT.—The Director shall ensure that not less than 85 percent of no-cost match advertising directly relates to substance abuse prevention consistent with the specific purposes of the national media campaign.

"(C) NO-COST MATCH ADVERTISING NOT DIRECTLY RELATED.—The Director shall ensure that no-cost match advertising that does not directly relate to substance abuse prevention consistent with the purposes of the national media campaign includes a clear anti-drug message. Such message is not required to be the primary message of the match advertising.

"(7) FINANCIAL AND PERFORMANCE ACCOUNTABILITY.—The Director shall cause to be performed—

"(A) audits and reviews of costs of the national media campaign pursuant to section 4706 of title 41, United States Code; and

"(B) an audit to determine whether the costs of the national media campaign are allowable under chapter 43 of title 41, United States Code.

"(8) REPORT TO CONGRESS.—The Director shall submit on an annual basis a report to Congress that describes—

"(A) the strategy of the national media campaign and whether specific objectives of the national media campaign were accomplished;

"(B) steps taken to ensure that the national media campaign operates in an effective and efficient manner consistent with the overall strategy and focus of the national media campaign;

"(C) plans to purchase advertising time and space;

"(D) policies and practices implemented to ensure that Federal funds are used responsibly to purchase advertising time and space and eliminate the potential for waste, fraud, and abuse;

"(E) all contracts entered into with a corporation, partnership, or individual working on behalf of the national media campaign;

"(F) the results of any financial audit of the national media campaign;

"(G) a description of any evidence used to develop the national media campaign;

"(H) specific policies and steps implemented to ensure compliance with this section;

"(I) a detailed accounting of the amount of funds obligated during the previous fiscal year for carrying out the national media campaign, including each recipient of funds, the purpose of each expenditure, the amount of each expenditure, any available outcome information, and any other information necessary to provide a complete accounting of the funds expended; and

"(J) a review and evaluation of the effectiveness of the national media campaign strategy for the past year.

"(9) REQUIRED NOTICE FOR COMMUNICATION FROM THE OFFICE.—Any communication, including an advertisement, paid for or otherwise disseminated by the Office directly or through a contract awarded by the Office shall include a prominent notice inform-

ing the audience that the communication was paid for by the Office.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Office to carry out this section, $25,000,000 for each of fiscal years 2018 through 2023.".

(b) TECHNICAL AND CONFORMING AMENDMENT.—Subsection (a) of section 203 of the Office of National Drug Control Policy Reauthorization Act of 2006 (21 U.S.C. 1708a) is repealed.

SEC. 8219. DRUG INTERDICTION.

(a) REPEAL.—This first section 711 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1710) is repealed.

(b) AMENDMENTS.—Section 711 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1710), as added by Public Law 109–469 (120 Stat. 3507), is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "The United" and inserting "The Director shall designate or appoint an appointee in the Senior Executive Service or an appointee in a position at

level 15 of the General Schedule (or equivalent) as the United"; and

(ii) by striking "shall" and inserting "to";

(B) in paragraph (2)(B)—

(i) by striking "March 1" and inserting "September 1"; and

(ii) by striking "paragraph (3)" and inserting "paragraph (4)";

(C) in paragraph (3)—

(i) by striking "also, at his discretion,"; and

(ii) by striking "the Office of Supply Reduction for that purpose" and inserting "assist in carrying out such responsibilities"; and

(D) in paragraph (4)—

(i) in subparagraph (B), by striking "The United" and inserting "Before submission of the National Drug Control Strategy or annual assessment required under section 706, as applicable, the United";

(ii) by striking subparagraphs (C) and (E);

(iii) by redesignating subparagraph (D) as subparagraph (C);

(iv) in subparagraph (C), as so redesignated—

(I) in the matter preceding clause (i)—

(aa) by striking "March 1" and inserting "September 1";

(bb) by inserting "the Director, acting through" before "the United States";

(cc) by inserting a comma after "Coordinator";

(dd) by striking "a report on behalf of the Director"; and

(ee) by striking ", which shall include" and inserting "a report that";

(II) by redesignating clauses (i), (ii), and (iii) as subclauses (I), (II), and (III), and adjusting the margins accordingly;

(III) by inserting before subclause (I), as so redesignated, the following: "(i) includes—";

(IV) in clause (i), as so redesignated—

(aa) in subclause (I), as so redesignated, by inserting ", including information about how each National Drug Control Program agency conducting drug interdiction activities is engaging with relevant international partners" after "Plan";

(bb) in subclause (II), as so redesignated, by striking ", as well as" and inserting "and";

(cc) in subclause III, as so redesignated—

(AA) by striking ", as well as" and inserting "and"; and

(BB) by striking the period at the end and inserting "; and"; and

(V) by adding at the end the following:

"(ii) may include recommendations for changes to existing agency authorities or

laws governing interagency relationships.”; and

(v) by adding at the end the following: “(D) CLASSIFIED ANNEX.—Each report required to be submitted under subparagraph (C) shall be in unclassified form, but may include a classified annex.”;

(2) in subsection (b)—

(A) in paragraph (1)(B), by inserting “and how to strengthen international partnerships to better achieve the goals of that plan” after “that plan”;

(B) in paragraph (2)—

(i) in the paragraph heading, by striking “CHAIRMAN” and inserting “CHAIRPERSON”; and

(ii) by striking “chairman” and inserting “Chairperson”;

(C) in paragraph (3)—

(i) by striking “prior to March 1” and inserting “before June 1”;

(ii) by striking “either” each place it appears;

(iii) by striking “current chairman” and inserting “Chairperson”; and

(iv) by striking "they" and inserting "the members"; and

(D) in paragraph (4)—

(i) by striking "chairman" each place it appears and inserting "Chairperson";

(ii) in the first sentence, by striking "a report";

(iii) by inserting "a report" after "committees"; and

(iv) by striking the second sentence and inserting the following: "The report required under this paragraph shall be in unclassified form, but may include a classified annex."; and

(3) by adding at the end the following:

"(c) INTERNATIONAL COORDINATION.—The Director may facilitate international drug control coordination efforts.".

SEC. 8220. GAO AUDIT.

Not later than 4 years after the date of enactment of this Act, and every 4 years thereafter, the Comptroller General of the United States shall—

(1) conduct an audit relating to the programs and operations of—

(A) the Office; and

(B) certain programs within the Office, including—

(i) the High Intensity Drug Trafficking Areas Program;

(ii) the Drug-Free Communities Program; and

(iii) the campaign under section 709(f) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1708(f)); and

(2) submit to the Director and the appropriate congressional committees a report containing an evaluation of and recommendations on the—

(A) policies and activities of the programs and operations subject to the audit;

(B) economy, efficiency, and effectiveness in the administration of the reviewed programs and operations; and

(C) policy or management changes needed to prevent and detect fraud and abuse in such programs and operations.

SEC. 8221. NATIONAL DRUG CONTROL STRATEGY.

(a) IN GENERAL.—Section 706 of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1705) is amended to read as follows:

"SEC. 706. NATIONAL DRUG CONTROL STRATEGY.

"(a) IN GENERAL.—

"(1) STATEMENT OF DRUG POLICY PRIORITIES.—The Director shall release a statement of drug control policy priorities in the calendar year of a Presidential inauguration following the inauguration, but not later than April 1.

"(2) NATIONAL DRUG CONTROL STRATEGY SUBMITTED BY THE PRESIDENT.—Not later than the first Monday in February following the year in which the term of the President commences, and every 2 years thereafter, the President shall submit to Congress a National Drug Control Strategy.

"(b) DEVELOPMENT OF THE NATIONAL DRUG CONTROL STRATEGY.—

"(1) PROMULGATION.—The Director shall promulgate the National Drug Control Strategy, which shall set forth a comprehensive plan to reduce illicit drug use and the consequences of such illicit drug use in the United States by limiting the availability of and reducing the demand for illegal drugs and promoting prevention, early intervention, treatment, and recovery support for individuals with substance use disorders.

"(2) STATE AND LOCAL COMMITMENT.—The Director shall seek the support and commitment of

State, local, and Tribal officials in the formulation and implementation of the National Drug Control Strategy.

"(3) STRATEGY BASED ON EVIDENCE.—The Director shall ensure the National Drug Control Strategy is based on the best available evidence regarding the policies that are most effective in reducing the demand for and supply of illegal drugs.

"(4) PROCESS FOR DEVELOPMENT AND SUBMISSION OF NATIONAL DRUG CONTROL STRATEGY.—In developing and effectively implementing the National Drug Control Strategy, the Director—

"(A) shall consult with—

"(i) the heads of the National Drug Control Program Agencies;

"(ii) each Coordinator listed in section 704;

"(iii) the Interdiction Committee and the Emerging Threats Committee;

"(iv) the appropriate congressional committees and any other committee of jurisdiction;

"(v) State, local, and Tribal officials;

"(vi) private citizens and organizations, including community and faith-based

organizations, with experience and expertise in demand reduction;

"(vii) private citizens and organizations with experience and expertise in supply reduction; and

"(viii) appropriate representatives of foreign governments; and

"(B) in satisfying the requirements of subparagraph (A), shall ensure, to the maximum extent possible, that State, local, and Tribal officials and relevant private organizations commit to support and take steps to achieve the goals and objectives of the National Drug Control Strategy.

"(c) CONTENTS OF THE NATIONAL DRUG CONTROL STRATEGY.—

"(1) IN GENERAL.—The National Drug Control Strategy submitted under subsection (a)(2) shall include the following:

"(A) A mission statement detailing the major functions of the National Drug Control Program.

"(B) Comprehensive, research-based, long-range, quantifiable goals for reducing illicit drug

use, and the consequences of illicit drug use in the United States.

"(C) Annual quantifiable and measurable objectives and specific targets to accomplish long-term quantifiable goals that the Director determines may be achieved during each year beginning on the date on which the National Drug Control Strategy is submitted.

"(D) A 5-year projection for the National Drug Control Program and budget priorities.

"(E) A review of international, State, local, and private sector drug control activities to ensure that the United States pursues coordinated and effective drug control at all levels of government.

"(F) A description of how each goal established under subparagraph (B) will be achieved, including for each goal—

"(i) a list of each relevant National Drug Control Program Agency and each such agency's related programs, activities, and available assets and the role of each such program, activity, and asset in achieving such goal;

"(ii) a list of relevant stakeholders and each such stakeholder's role in achieving such goal;

"(iii) an estimate of Federal funding and other resources needed to achieve such goal;

"(iv) a list of each existing or new coordinating mechanism needed to achieve such goal; and

"(v) a description of the Office's role in facilitating the achievement of such goal.

"(G) For each year covered by the Strategy, a performance evaluation plan for each goal established under subparagraph (B) for each National Drug Control Program Agency, including—

"(i) specific performance measures for each National Drug Control Program Agency;

"(ii) annual and, to the extent practicable, quarterly objectives and targets for each performance measure; and

"(iii) an estimate of Federal funding and other resources needed to achieve each performance objective and target.

"(H) A list identifying existing data sources or a description of data collection needed to evaluate performance, including a description of how the Director will obtain such data.

"(I) A list of any anticipated challenges to achieving the National Drug Control Strategy goals and planned actions to address such challenges.

"(J) A description of how each goal established under subparagraph (B) was determined, including—

"(i) a description of each required consultation and a description of how such consultation was incorporated; and

"(ii) data, research, or other information used to inform the determination to establish the goal.

"(K) A description of the current prevalence of illicit drug use in the United States, including both the availability of illicit drugs and the prevalence of substance use disorders.

"(L) Such other statistical data and information as the Director considers appropriate to demonstrate and assess trends relating to illicit drug use, the effects and consequences of illicit

drug use (including the effects on children), supply reduction, demand reduction, drug-related law enforcement, and the implementation of the National Drug Control Strategy.

"(M) A systematic plan for increasing data collection to enable real time surveillance of drug control threats, developing analysis and monitoring capabilities, and identifying and addressing policy questions related to the National Drug Control Strategy and Program, which shall include—

"(i) a list of policy-relevant questions for which the Director and each National Drug Control Program Agency intends to develop evidence to support the National Drug Control Program and Strategy;

"(ii) a list of data the Director and each National Drug Control Program Agency intends to collect, use, or acquire to facilitate the use of evidence in drug control policymaking and monitoring;

"(iii) a list of methods and analytical approaches that may be used to develop evidence to support the National Drug Control Program and Strategy and related policy;

"(iv) a list of any challenges to developing evidence to support policymaking, including any barriers to accessing, collecting, or using relevant data;

"(v) a description of the steps the Director and the head of each National Drug Control Program Agency will take to effectuate the plan; and

"(vi) any other relevant information as determined by the Director.

"(N) A plan to expand treatment of substance use disorders, which shall—

"(i) identify unmet needs for treatment for substance use disorders and a strategy for closing the gap between available and needed treatment;

"(ii) describe the specific roles and responsibilities of the relevant National Drug Control Programs for implementing the plan;

"(iii) identify the specific resources required to enable the relevant National Drug Control Agencies to implement that strategy; and

"(iv) identify the resources, including private sources, required to eliminate the unmet need for evidence-based substance use disorder treatment.

"(2) CONSULTATION.—In developing the plan required under paragraph (1), the Director shall consult with the following:

"(A) The public.

"(B) Any evaluation or analysis units and personnel of the Office.

"(C) Office officials responsible for implementing privacy policy.

"(D) Office officials responsible for data governance.

"(E) The appropriate congressional committees.

"(F) Any other individual or entity as determined by the Director.

"(3) ADDITIONAL STRATEGIES.—

"(A) IN GENERAL.—The Director shall include in the National Drug Control Strategy the additional strategies described under this paragraph and shall comply with the following:

"(i) Provide a copy of the additional strategies to the appropriate congressional

committees and to the Committee on Armed Services and the Committee on Homeland Security of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs and the Committee on Armed Services of the Senate.

"(ii) Issue the additional strategies in consultation with the head of each relevant National Drug Control Program Agency, any relevant official of a State, local, or Tribal government, and the government of other relevant countries.

"(iii) Not change any existing agency authority or construe any strategy described under this paragraph to amend or modify any law governing interagency relationship but may include recommendations about changes to such authority or law.

"(iv) Present separately from the rest of any strategy described under this paragraph any information classified under criteria established by an Executive order, or whose public disclosure, as determined by the Director or the head of any relevant National Drug Control Program Agency,

would be detrimental to the law enforcement or national security activities of any Federal, State, local, or Tribal agency.

"(B) REQUIREMENT FOR SOUTHWEST BORDER COUNTERNARCOTICS STRATEGY.—

"(i) PURPOSES.—The Southwest Border Counternarcotics Strategy shall—

"(I) set forth the Government's strategy for preventing the illegal trafficking of drugs across the international border between the United States and Mexico, including through ports of entry and between ports of entry on that border;

"(II) state the specific roles and responsibilities of the relevant National Drug Control Program Agencies for implementing that strategy; and

"(III) identify the specific resources required to enable the relevant National Drug Control Program Agencies to implement that strategy.

"(ii) SPECIFIC CONTENT RELATED TO DRUG TUNNELS BETWEEN THE UNITED STATES AND MEXICO.—The Southwest Bor-

der Counternarcotics Strategy shall include—

"(I) a strategy to end the construction and use of tunnels and subterranean passages that cross the international border between the United States and Mexico for the purpose of illegal trafficking of drugs across such border; and

"(II) recommendations for criminal penalties for persons who construct or use such a tunnel or subterranean passage for such a purpose.

"(C) REQUIREMENT FOR NORTHERN BORDER COUNTERNARCOTICS STRATEGY.—

"(i) PURPOSES.—The Northern Border Counternarcotics Strategy shall—

"(I) set forth the strategy of the Federal Government for preventing the illegal trafficking of drugs across the international border between the United States and Canada, including through ports of entry and between ports of entry on the border;

"(II) state the specific roles and responsibilities of each relevant National Drug Control Program Agency for implementing the strategy;

"(III) identify the specific resources required to enable the relevant National Drug Control Program Agencies to implement the strategy;

"(IV) be designed to promote, and not hinder, legitimate trade and travel; and

"(V) reflect the unique nature of small communities along the international border between the United States and Canada, ongoing cooperation and coordination with Canadian law, enforcement authorities, and variations in the volumes of vehicles and pedestrians crossing through ports of entry along the international border between the United States and Canada.

"(ii) SPECIFIC CONTENT RELATED TO CROSS-BORDER INDIAN RESERVATIONS.—The Northern Border Counternarcotics Strategy shall include—

"(I) a strategy to end the illegal trafficking of drugs to or through Indian reservations on or near the international border between the United States and Canada; and

"(II) recommendations for additional assistance, if any, needed by Tribal law enforcement agencies relating to the strategy, including an evaluation of Federal technical and financial assistance, infrastructure capacity building, and interoperability deficiencies.

"(4) CLASSIFIED INFORMATION.—Any contents of the National Drug Control Strategy that involve information properly classified under criteria established by an Executive order shall be presented to Congress separately from the rest of the National Drug Control Strategy.

"(5) SELECTION OF DATA AND INFORMATION.—In selecting data and information for inclusion in the Strategy, the Director shall ensure—

"(A) the inclusion of data and information that will permit analysis of current trends against previously compiled data and informa-

tion where the Director believes such analysis enhances long-term assessment of the National Drug Control Strategy; and

"(B) the inclusion of data and information to permit a standardized and uniform assessment of the effectiveness of drug treatment programs in the United States.

"(d) SUBMISSION OF REVISED STRATEGY.—The President may submit to Congress a revised National Drug Control Strategy that meets the requirements of this section—

"(1) at any time, upon a determination of the President, in consultation with the Director, that the National Drug Control Strategy in effect is not sufficiently effective; or

"(2) if a new President or Director takes office.

"(e) FAILURE OF DIRECTOR TO SUBMIT NATIONAL DRUG CONTROL STRATEGY.—If the Director does not submit a National Drug Control Strategy to Congress in accordance with subsection (a)(2), not later than five days after the first Monday in February following the year in which the term of the President commences, the Director shall send a notification to the appropriate congressional committees—

"(1) explaining why the Strategy was not submitted; and

"(2) specifying the date by which the Strategy will be submitted.

"(f) DRUG CONTROL DATA DASHBOARD.—

"(1) IN GENERAL.—The Director shall collect and disseminate, as appropriate, such information as the Director determines is appropriate, but not less than the information described in this subsection. The data shall be publicly available in a machine-readable format on the online portal of the Office, and to the extent practicable on the Drug Control Data Dashboard.

"(2) ESTABLISHMENT.—The Director shall publish to the online portal of the office in a machine-readable, sortable, and searchable format, or to the extent practicable, establish and maintain a data dashboard on the online portal of the Office to be known as the 'Drug Control Data Dashboard'. To the extent practicable, when establishing the Drug Control Dashboard, the Director shall ensure the user interface of the dashboard is constructed with modern design standards. To the extent practicable, the data made available on the dashboard shall be publicly available in a machine-readable format and searchable by year, agency, drug, and location.

"(3) DATA.—The data included in the Drug Control Data Dashboard shall be updated quarterly to the extent practicable, but not less frequently than annually and shall include, at a minimum, the following:

"(A) For each substance identified by the Director as having a significant impact on the prevalence of illicit drug use—

"(i) data sufficient to show the quantities of such substance available in the United States, including—

"(I) the total amount seized and disrupted in the calendar year and each of the previous 3 calendar years, including to the extent practicable the amount seized by State, local, and Tribal governments;

"(II) the known and estimated flows into the United States from all sources in the calendar year and each of the previous 3 calendar years;

"(III) the total amount of known flows that could not be interdicted or disrupted in the calendar year and each of the previous 3 calendar years;

"(IV) the known and estimated levels of domestic production in the calendar year and each of the previous three calendar years, including the levels of domestic production if the drug is a prescription drug, as determined under the Federal Food, Drug, and Cosmetic Act, for which a listing is in effect under section 202 of the Controlled Substances Act (21 U.S.C. 812);

"(V) the average street price for the calendar year and the highest known street price during the preceding 10-year period; and

"(VI) to the extent practicable, related prosecutions by State, local, and Tribal governments;

"(ii) data sufficient to show the frequency of use of such substance, including—

"(I) use of such substance in the workplace and productivity lost by such use;

"(II) use of such substance by arrestees, probationers, and parolees;

"(III) crime and criminal activity related to such substance;

"(IV) to the extent practicable, related prosecutions by State, local, and Tribal governments;

"(B) For the calendar year and each of the previous three years data sufficient to show, disaggregated by State and, to the extent feasible, by region within a State, county, or city, the following:

"(i) The number of fatal and non-fatal overdoses caused by each drug identified under subparagraph (A)(i).

"(ii) The prevalence of substance use disorders.

"(iii) The number of individuals who have received substance use disorder treatment, including medication assisted treatment, for a substance use disorder, including treatment provided through publicly-financed health care programs.

"(iv) The extent of the unmet need for substance use disorder treatment, including the unmet need for medication-assisted treatment.

"(C) Data sufficient to show the extent of prescription drug diversion, trafficking, and misuse in the calendar year and each of the previous 3 calendar years.

"(D) Any quantifiable measures the Director determines to be appropriate to detail progress toward the achievement of the goals of the National Drug Control Strategy.

"(g) DEVELOPMENT OF AN ANNUAL NATIONAL DRUG CONTROL ASSESSMENT.—

"(1) TIMING.—Not later than the first Monday in February of each year, the Director shall submit to the President, Congress, and the appropriate congressional committees, a report assessing the progress of each National Drug Control Program Agency toward achieving each goal, objective, and target contained in the National Drug Control Strategy applicable to the prior fiscal year.

"(2) PROCESS FOR DEVELOPMENT OF THE ANNUAL ASSESSMENT.—Not later than November 1 of each year, the head of each National Drug Control Program Agency shall submit, in accordance with guidance issued by the Director, to the Director an evaluation of progress by the agency with respect to the National Drug Control Strategy goals using the

performance measures for the agency developed under this title, including progress with respect to—

"(A) success in achieving the goals of the National Drug Control Strategy;

"(B) success in reducing domestic and foreign sources of illegal drugs;

"(C) success in expanding access to and increasing the effectiveness of substance use disorder treatment;

"(D) success in protecting the borders of the United States (and in particular the Southwestern border of the United States) from penetration by illegal narcotics;

"(E) success in reducing crime associated with drug use in the United States;

"(F) success in reducing the negative health and social consequences of drug use in the United States;

"(G) implementation of evidence-based substance use disorder treatment and prevention programs in the United States and improvements in the adequacy and effectiveness of such programs; and

"(H) success in increasing the prevention of illicit drug use.

"(3) CONTENTS OF THE ANNUAL ASSESSMENT.—The Director shall include in the annual assessment required under paragraph (1)—

"(A) a summary of each evaluation received by the Director under paragraph (2);

"(B) a summary of the progress of each National Drug Control Program Agency toward the National Drug Control Strategy goals of the agency using the performance measures for the agency developed under this chapter;

"(C) an assessment of the effectiveness of each National Drug Control Program Agency and program in achieving the National Drug Control Strategy for the previous year, including a specific evaluation of whether the applicable goals, measures, objectives, and targets for the previous year were met; and

"(D) the assessments required under this subsection shall be based on the Performance Measurement System.".

(b) TECHNICAL AND CONFORMING AMENDMENTS.—

(1) Section 704(b) of the Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1703(b)) is amended—

(A) by striking paragraphs (13) and (17); and

(B) in paragraph (14)(A), by striking "paragraph (13)" and inserting "section 706(g)(2)".

(2) The Office of National Drug Control Policy Reauthorization Act of 2006 (Public Law 109–469; 120 Stat. 3502) is amended by striking sections 1110 and 1110A.

SEC. 8222. TECHNICAL AND CONFORMING AMENDMENTS TO THE OFFICE OF NATIONAL DRUG CONTROL POLICY REAUTHORIZATION ACT OF 1998.

The Office of National Drug Control Policy Reauthorization Act of 1998 (21 U.S.C. 1701 et seq.) is amended—

(1) by striking section 703(b) (21 U.S.C. 1702(b));

(2) in section 704 (21 U.S.C. 1703)—

(A) in subsection (c)—

(i) in paragraph (3)(C)—

(I) in the matter before clause (i), by inserting "requests a level of funding that will not enable achievement of the goals of the National Drug Control Strategy, including" after "request that";

(II) in clause (iii)—

(aa) by striking "drug treatment" and inserting "substance use disorder prevention and treatment"; and

(bb) by striking the semicolon at the end and inserting "; and";

(III) by striking clauses (iv), (vi), and (vii);

(IV) by redesignating clause (v) as clause (iv); and

(V) in clause (iv), as so redesignated, by striking the semicolon and inserting a period;

(ii) in paragraph (4)(A), by striking "$1,000,000" and inserting "$5,000,000 or 10 percent of a specific program or account"; and

(B) in subsection (f)—

(i) by striking the first paragraph (5); and

(ii) by striking the second paragraph (4); and

(3) by striking section 708 (21 U.S.C. 1707).

Subtitle L—Budgetary Effects

SEC. 8231. BUDGETARY EFFECT.

(a) IN GENERAL.—The budgetary effects of this Act shall not be entered on either PAYGO scorecard maintained pursuant to section 4(d) of the Statutory Pay-As-You-Go Act of 2010 (2 U.S.C. 933(d)).

(b) SENATE PAYGO SCORECARDS.—The budgetary effects of this Act shall not be entered on any PAYGO scorecard maintained for purposes of section 4106 of H. Con. Res. 71 (115th Congress).

Attest:

Clerk.

115th CONGRESS
2d Session

H.R. 6

HOUSE AMENDMENT TO SENATE AMENDMENT