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115TH CONGRESS
2D SESSION**H. R. 6**

IN THE SENATE OF THE UNITED STATES

JUNE 25, 2018

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Read the second time and placed on the calendar

AN ACT

To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Substance Use-Disorder Prevention that Promotes
6 Opioid Recovery and Treatment for Patients and Commu-
7 nities Act” or the “SUPPORT for Patients and Commu-
8 nities Act”.

9 (b) TABLE OF CONTENTS.—The table of contents for
10 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. Drug management program for at-risk beneficiaries.
- Sec. 1005. Medicaid drug review and utilization.
- Sec. 1006. Guidance to improve care for infants with neonatal abstinence syndrome and their mothers; GAO study on gaps in Medicaid coverage for pregnant and postpartum women with substance use disorder.
- Sec. 1007. Medicaid health homes for opioid-use-disorder Medicaid enrollees.

TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID
CRISIS

- Sec. 2001. Authority not to apply certain Medicare telehealth requirements in the case of certain treatment of a substance use disorder or co-occurring mental health disorder.
- Sec. 2002. Encouraging the use of non-opioid analgesics for the management of post-surgical pain.
- Sec. 2003. Requiring a review of current opioid prescriptions for chronic pain and screening for opioid use disorder to be included in the Welcome to Medicare initial preventive physical examination.
- Sec. 2004. Modification of payment for certain outpatient surgical services.
- Sec. 2005. Requiring e-prescribing for coverage of covered part D controlled substances.
- Sec. 2006. Requiring prescription drug plan sponsors under Medicare to establish drug management programs for at-risk beneficiaries.
- Sec. 2007. Medicare coverage of certain services furnished by opioid treatment programs.

TITLE III—OTHER HEALTH PROVISIONS TO ADDRESS THE
OPIOID CRISIS

- Sec. 3001. Clarifying FDA regulation of non-addictive pain and addiction therapies.
- Sec. 3002. Surveillance and Testing of Opioids to Prevent Fentanyl Deaths.
- Sec. 3003. Allowing for more flexibility with respect to medication-assisted treatment for opioid use disorders.
- Sec. 3004. High-quality, evidence-based opioid analgesic prescribing guidelines and report.
- Sec. 3005. Report on opioids prescribing practices for pregnant women.
- Sec. 3006. Guidelines for prescribing naloxone.
- Sec. 3007. Requiring a survey of substance use disorder treatment providers receiving Federal funding.

TITLE IV—OFFSETS

- Sec. 4001. Promoting value in Medicaid managed care.
- Sec. 4002. Extending period of application of Medicare secondary payer rules for individuals with end stage renal disease.

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

TITLE V—OTHER MEDICAID PROVISIONS

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

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

Subtitle B—Medicaid IMD Additional Info

Sec. 5011. Short title.

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

Subtitle C—CHIP Mental Health Parity

Sec. 5021. Short title.

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

Subtitle D—Medicaid Reentry

Sec. 5031. Short title.

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

Subtitle E—Medicaid Partnership

Sec. 5041. Short title.

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

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.

Subtitle B—Abuse Deterrent Access

Sec. 6011. Short title.

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

Subtitle C—Medicare Opioid Safety Education

Sec. 6021. Short title.

Sec. 6022. Provision of information regarding opioid use and pain management as part of Medicare & You handbook.

Subtitle D—Opioid Addiction Action Plan

- Sec. 6031. Short title.
 Sec. 6032. Action plan on recommendations for changes under Medicare and Medicaid to prevent opioids addictions and enhance access to medication-assisted treatment.

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

- Sec. 6041. Short title.
 Sec. 6042. Opioid use disorder treatment demonstration program.

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

- Sec. 6051. Short title.
 Sec. 6052. Grants to provide technical assistance to outlier prescribers of opioids.

Subtitle G—Preventing Addiction for Susceptible Seniors

- Sec. 6061. Short title.
 Sec. 6062. Electronic prior authorization for covered part D drugs.
 Sec. 6063. Program integrity transparency measures under Medicare parts C and D.
 Sec. 6064. Expanding eligibility for medication therapy management programs under part D.
 Sec. 6065. Medicare notifications to outlier prescribers of opioids.
 Sec. 6066. No additional funds authorized.

Subtitle H—Expanding Oversight of Opioid Prescribing and Payment

- Sec. 6071. Short title.
 Sec. 6072. Medicare Payment Advisory Commission report on opioid payment, adverse incentives, and data under the Medicare program.
 Sec. 6073. No additional funds authorized.

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

- Sec. 6081. Short title.
 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.
 Sec. 6083. Expanding access under the Medicare program to addiction treatment in Federally qualified health centers and rural health clinics.
 Sec. 6084. Studying the availability of supplemental benefits designed to treat or prevent substance use disorders under Medicare Advantage plans.
 Sec. 6085. Clinical psychologist services models under the Center for Medicare and Medicaid Innovation; GAO study and report.
 Sec. 6086. Pain management study.

Subtitle J—Combating Opioid Abuse for Care in Hospitals

- Sec. 6091. Short title.
 Sec. 6092. Developing guidance on pain management and opioid use disorder prevention for hospitals receiving payment under part A of the Medicare program.

- Sec. 6093. Requiring the review of quality measures relating to opioids and opioid use disorder treatments furnished under the medicare program and other federal health care programs.
- Sec. 6094. Technical expert panel on reducing surgical setting opioid use; Data collection on perioperative opioid use.
- Sec. 6095. Requiring the posting and periodic update of opioid prescribing guidance for Medicare beneficiaries.

Subtitle K—Stop Excessive Narcotics in Our Retirement Communities
Protection

- Sec. 6101. Short title.
- Sec. 6102. Suspension of payments by Medicare prescription drug plans and MA–PD plans pending investigations of credible allegations of fraud by pharmacies.

Subtitle L—Providing Reliable Options for Patients and Educational
Resources

- Sec. 6111. Short title.
- Sec. 6112. Requiring Medicare Advantage plans and part D prescription drug plans to include information on risks associated with opioids and coverage of nonpharmacological therapies and nonopioid medications or devices used to treat pain.
- Sec. 6113. Requiring Medicare Advantage plans and prescription drug plans to provide information on the safe disposal of prescription drugs.
- Sec. 6114. Revising measures used under the Hospital Consumer Assessment of Healthcare Providers and Systems survey relating to pain management.

TITLE VII—OTHER HEALTH PROVISIONS

Subtitle A—Synthetic Drug Awareness

- Sec. 7001. Short title.
- Sec. 7002. Report on effects on public health of synthetic drug use.

Subtitle B—Empowering Pharmacists in the Fight Against Opioid Abuse

- Sec. 7011. Short title.
- Sec. 7012. Programs and materials for training on certain circumstances under which a pharmacist may decline to fill a prescription.

Subtitle C—Indexing Narcotics, Fentanyl, and Opioids

- Sec. 7021. Short title.
- Sec. 7022. Establishment of substance use disorder information dashboard.
- Sec. 7023. Interagency Substance Use Disorder Coordinating Committee.

Subtitle D—Ensuring Access to Quality Sober Living

- Sec. 7031. Short title.
- Sec. 7032. National recovery housing best practices.

Subtitle E—Advancing Cutting Edge Research

- Sec. 7041. Short title.
- Sec. 7042. Unique research initiatives.

Subtitle F—Jessie’s Law

- Sec. 7051. Short title.
- Sec. 7052. Inclusion of opioid addiction history in patient records.
- Sec. 7053. Communication with families during emergencies.

Subtitle G—Safe Disposal of Unused Medication

- Sec. 7061. Short title.
- Sec. 7062. Disposal of controlled substances of a deceased hospice patient by employees of a qualified hospice program.

Subtitle H—Substance Use Disorder Workforce Loan Repayment

- Sec. 7071. Short title.
- Sec. 7072. Loan repayment program for substance use disorder treatment employees.

Subtitle I—Preventing Overdoses While in Emergency Rooms

- Sec. 7081. Short title.
- Sec. 7082. Program to support emergency room discharge and care coordination for drug overdose patients.

Subtitle J—Alternatives to Opioids in the Emergency Department

- Sec. 7091. Short title.
- Sec. 7092. Emergency department alternatives to opioids demonstration program.

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

- Sec. 7101. Short title.
- Sec. 7102. Detention, refusal, and destruction of drugs offered for importation.
- Sec. 7103. Notification, nondistribution, and recall of adulterated or misbranded drug products.
- Sec. 7104. Single source pattern of shipments of adulterated or misbranded drugs.
- Sec. 7105. Fund to strengthen efforts of FDA to combat the opioid and substance use epidemic.
- Sec. 7106. Consideration of potential for misuse and abuse required for drug approval.

Subtitle L—Treatment, Education, and Community Help to Combat Addiction

- Sec. 7111. Short title.
- Sec. 7112. Establishment of Regional Centers of Excellence in Substance Use Disorder Education.

Subtitle M—Guidance From National Mental Health and Substance Use Policy Laboratory

- Sec. 7121. Guidance from National Mental Health and Substance Use Policy Laboratory.

Subtitle N—Comprehensive Opioid Recovery Centers

- Sec. 7131. Short title.
- Sec. 7132. Comprehensive opioid recovery centers.

Subtitle O—Poison Center Network Enhancement

- Sec. 7141. Short title.
- Sec. 7142. Reauthorization of poison control centers national toll-free number.
- Sec. 7143. Reauthorization of nationwide public awareness campaign to promote poison control center utilization.
- Sec. 7144. Reauthorization of the poison control center grant program.

Subtitle P—Eliminating Opioid Related Infectious Diseases

- Sec. 7151. Short title.
- Sec. 7152. Reauthorization and expansion of program of surveillance and education regarding infections associated with illicit drug use and other risk factors.

Subtitle Q—Better Pain Management Through Better Data

- Sec. 7161. Short title.
- Sec. 7162. Guidance addressing alternative approaches to data collection and labeling claims for opioid sparing.

Subtitle R—Special Registration for Telemedicine Clarification

- Sec. 7171. Short title.
- Sec. 7172. Deadline for interim final regulations for a special registration To engage in the practice of telemedicine.

Subtitle S—Peer Support Communities of Recovery

- Sec. 7181. Short title.
- Sec. 7182. Building communities of recovery.

Subtitle T—Stop Illicit Drug Importation

- Sec. 7191. Short title.
- Sec. 7192. Detention, refusal, and destruction of drugs offered for importation.
- Sec. 7193. Seizure.
- Sec. 7194. Debarring violative individuals or companies.

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

- Sec. 7201. Short title.
- Sec. 7202. Preventing overdoses of controlled substances.
- Sec. 7203. Prescription drug monitoring program.

Subtitle V—Securing Opioids and Unused Narcotics With Deliberate Disposal and Packaging

- Sec. 7211. Short title.
- Sec. 7212. Improved technologies, controls, or measures with respect to the packaging or disposal of certain drugs.

Subtitle W—Postapproval Study Requirements

- Sec. 7221. Postapproval study requirements.

TITLE VIII—MISCELLANEOUS

Subtitle A—Synthetics Trafficking and Overdose Prevention

- Sec. 8001. Short title; table of contents.
- Sec. 8002. Customs fees.
- Sec. 8003. Mandatory advance electronic information for postal shipments.
- Sec. 8004. International postal agreements.
- Sec. 8005. Cost recoupment.
- Sec. 8006. Development of technology to detect illicit narcotics.
- Sec. 8007. Civil penalties for postal shipments.
- Sec. 8008. Report on violations of arrival, reporting, entry, and clearance requirements and falsity or lack of manifest.
- Sec. 8009. Effective date; regulations.

Subtitle B—Recognizing Early Childhood Trauma Related to Substance Abuse

- Sec. 8011. Short title.
- Sec. 8012. Recognizing Early Childhood Trauma Related to Substance Abuse.

Subtitle C—Assisting States' Implementation of Plans of Safe Care

- Sec. 8021. Short title.
- Sec. 8022. Assisting States with implementation of plans of safe care.

Subtitle D—Improving the Federal Response to Families Impacted by Substance Use Disorder

- Sec. 8031. Short title.
- Sec. 8032. Interagency Task Force to Improve the Federal Response to Families Impacted by Substance Use Disorders.

Subtitle E—Establishment of an Advisory Committee on Opioids and the Workplace

- Sec. 8041. Establishment of an Advisory Committee on Opioids and the Workplace.

Subtitle F—Veterans Treatment Court Improvement

- Sec. 8051. Short title.
- Sec. 8052. Hiring by Department of Veterans Affairs of additional Veterans Justice Outreach Specialists.

Subtitle G—Peer Support Counseling Program for Women Veterans

- Sec. 8061. Peer support counseling program for women veterans.

Subtitle H—Treating Barriers to Prosperity

- Sec. 8071. Short title.
- Sec. 8072. Drug abuse mitigation initiative.

Subtitle I—Supporting Grandparents Raising Grandchildren

- Sec. 8081. Short title.
- Sec. 8082. Findings.
- Sec. 8083. Advisory Council To Support Grandparents Raising Grandchildren.

Sec. 8084. Definitions.

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

Sec. 8091. Short title.

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

TITLE IX—SITSA ACT

Sec. 9001. Short title.

Sec. 9002. Establishment of schedule A.

Sec. 9003. Temporary and permanent scheduling of schedule A substances.

Sec. 9004. Penalties.

Sec. 9005. False labeling of schedule A controlled substances.

Sec. 9006. Registration requirements for handlers of schedule A substances.

Sec. 9007. Additional conforming amendments.

Sec. 9008. Controlled substance analogues.

Sec. 9009. Rules of construction.

Sec. 9010. Study by Comptroller General.

Sec. 9011. Report on controlled substance analogues sold by means of the Internet.

Sec. 9012. Controlled substance analogues.

TITLE X—THRIVE ACT

Sec. 10001. Short title.

Sec. 10002. Demonstration program to study the impact of using rental vouchers for supportive housing for individuals recovering from opioid use disorders or other substance use disorders.

Sec. 10003. Repeal of Rental Voucher Demonstration Program.

Sec. 10004. Demonstration Close-Out.

Sec. 10005. No additional funds authorized.

TITLE XI—IMD CARE ACT

Sec. 11001. Short title.

Sec. 11002. Medicaid State plan option to provide services for certain individuals with targeted SUDs in institutions for mental diseases.

Sec. 11003. Promoting value in Medicaid managed care.

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 Act (42 U.S.C. 1396a) is amended—

6 (1) in subsection (a)—

7 (A) by striking “and” at the end of paragraph (82);

1 (B) by striking the period at the end of
2 paragraph (83) and inserting “; and”; and

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

5 “(84) provide that—

6 “(A) the State shall not terminate eligi-
7 bility for medical assistance under the State
8 plan for an individual who is an eligible juvenile
9 (as defined in subsection (nn)(2)) because the
10 juvenile is an inmate of a public institution (as
11 defined in subsection (nn)(3)), but may suspend
12 coverage during the period the juvenile is such
13 an inmate;

14 “(B) in the case of an individual who is an
15 eligible juvenile described in paragraph (2)(A)
16 of subsection (nn), the State shall, prior to the
17 individual’s release from such a public institu-
18 tion, conduct a redetermination of eligibility for
19 such individual with respect to such medical as-
20 sistance (without requiring a new application
21 from the individual) and, if the State deter-
22 mines pursuant to such redetermination that
23 the individual continues to meet the eligibility
24 requirements for such medical assistance, the
25 State shall restore coverage for such medical

1 assistance to such an individual upon the indi-
 2 vidual's release from such public institution;
 3 and

4 “(C) in the case of an individual who is an
 5 eligible juvenile described in paragraph (2)(B)
 6 of subsection (nn), the State shall process any
 7 application for medical assistance submitted by,
 8 or on behalf of, such individual such that the
 9 State makes a determination of eligibility for
 10 such individual with respect to such medical as-
 11 sistance upon release of such individual from
 12 such public institution.”; and

13 (2) by adding at the end the following new sub-
 14 section:

15 “(nn) JUVENILE; ELIGIBLE JUVENILE; PUBLIC IN-
 16 STITUTION.—For purposes of subsection (a)(84) and this
 17 subsection:

18 “(1) JUVENILE.—The term ‘juvenile’ means an
 19 individual who is—

20 “(A) under 21 years of age; or

21 “(B) described in subsection
 22 (a)(10)(A)(i)(IX).

23 “(2) ELIGIBLE JUVENILE.—The term ‘eligible
 24 juvenile’ means a juvenile who is an inmate of a
 25 public institution and who—

1 “(A) was determined eligible for medical
2 assistance under the State plan immediately be-
3 fore becoming an inmate of such a public insti-
4 tution; or

5 “(B) is determined eligible for such med-
6 ical assistance while an inmate of a public insti-
7 tution.

8 “(3) INMATE OF A PUBLIC INSTITUTION.—The
9 term ‘inmate of a public institution’ has the meaning
10 given such term for purposes of applying the sub-
11 division (A) following paragraph (29) of section
12 1905(a), taking into account the exception in such
13 subdivision for a patient of a medical institution.”.

14 (b) NO CHANGE IN EXCLUSION FROM MEDICAL AS-
15 SISTANCE FOR INMATES OF PUBLIC INSTITUTIONS.—
16 Nothing in this section shall be construed as changing the
17 exclusion from medical assistance under the subdivision
18 (A) following paragraph (29) of section 1905(a) of the So-
19 cial Security Act (42 U.S.C. 1396d(a)), including any ap-
20 plicable restrictions on a State submitting claims for Fed-
21 eral financial participation under title XIX of such Act
22 for such assistance.

23 (c) NO CHANGE IN CONTINUITY OF ELIGIBILITY BE-
24 FORE ADJUDICATION OR SENTENCING.—Nothing in this
25 section shall be construed to mandate, encourage, or sug-

1 gest that a State suspend or terminate coverage for indi-
2 viduals before they have been adjudicated or sentenced.

3 (d) EFFECTIVE DATE.—

4 (1) IN GENERAL.—Except as provided in para-
5 graph (2), the amendments made by subsection (a)
6 shall apply to eligibility of juveniles who become in-
7 mates of public institutions on or after the date that
8 is 1 year after the date of the enactment of this Act.

9 (2) RULE FOR CHANGES REQUIRING STATE
10 LEGISLATION.—In the case of a State plan for med-
11 ical assistance under title XIX of the Social Security
12 Act which the Secretary of Health and Human Serv-
13 ices determines requires State legislation (other than
14 legislation appropriating funds) in order for the plan
15 to meet the additional requirements imposed by the
16 amendments made by subsection (a), the State plan
17 shall not be regarded as failing to comply with the
18 requirements of such title solely on the basis of its
19 failure to meet these additional requirements before
20 the first day of the first calendar quarter beginning
21 after the close of the first regular session of the
22 State legislature that begins after the date of the en-
23 actment of this Act. For purposes of the previous
24 sentence, in the case of a State that has a 2-year
25 legislative session, each year of such session shall be

1 deemed to be a separate regular session of the State
2 legislature.

3 **SEC. 1002. HEALTH INSURANCE FOR FORMER FOSTER**
4 **YOUTH.**

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

7 (1) IN GENERAL.—Section
8 1902(a)(10)(A)(i)(IX) of the Social Security Act (42
9 U.S.C. 1396a(a)(10)(A)(i)(IX)) is amended—

10 (A) in item (bb), by striking “are not de-
11 scribed in or enrolled under” and inserting “are
12 not described in and are not enrolled under”;

13 (B) in item (cc), by striking “responsibility
14 of the State” and inserting “responsibility of a
15 State”; and

16 (C) in item (dd), by striking “the State
17 plan under this title or under a waiver of the”
18 and inserting “a State plan under this title or
19 under a waiver of such a”.

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

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

1 Human Services shall issue guidance to States, with re-
2 spect to the State Medicaid programs of such States—

3 (1) on best practices for—

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

7 (B) conducting outreach and raising
8 awareness among such youth regarding Med-
9 icaid coverage options for such youth; and

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

13 **SEC. 1003. DEMONSTRATION PROJECT TO INCREASE SUB-**
14 **STANCE USE PROVIDER CAPACITY UNDER**
15 **THE MEDICAID PROGRAM.**

16 Section 1903 of the Social Security Act (42 U.S.C.
17 1396b) is amended by adding at the end the following new
18 subsection:

19 “(aa) DEMONSTRATION PROJECT TO INCREASE SUB-
20 STANCE USE PROVIDER CAPACITY.—

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

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

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

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

12 “(2) PURPOSE.—The purpose described in this
13 paragraph is for each State selected under para-
14 graph (4) to increase the treatment capacity of pro-
15 viders participating under the State plan (or a waiv-
16 er of such plan) to provide substance use disorder
17 treatment or recovery services under such plan (or
18 waiver) through the following activities:

19 “(A) For the purpose described in para-
20 graph (3)(C)(i), activities that support an ongo-
21 ing assessment of the behavioral health treat-
22 ment needs of the State, taking into account
23 the matters described in subclauses (I) through
24 (IV) of such paragraph.

1 “(B) Activities that, taking into account
2 the results of the assessment described in sub-
3 paragraph (A), support the recruitment, train-
4 ing, and provision of technical assistance for
5 providers participating under the State plan (or
6 a waiver of such plan) that offer substance use
7 disorder treatment or recovery services.

8 “(C) Improved reimbursement for and ex-
9 pansion of, through the provision of education,
10 training, and technical assistance, the number
11 or treatment capacity of providers participating
12 under the State plan (or waiver) that—

13 “(i) are authorized to dispense drugs
14 approved by the Food and Drug Adminis-
15 tration for individuals with a substance use
16 disorder who need withdrawal management
17 or maintenance treatment for such dis-
18 order;

19 “(ii) have in effect a registration or
20 waiver under section 303(g) of the Con-
21 trolled Substances Act for purposes of dis-
22 pensing narcotic drugs to individuals for
23 maintenance treatment or detoxification
24 treatment and are in compliance with any
25 regulation promulgated by the Assistant

1 Secretary for Mental Health and Sub-
2 stance Use for purposes of carrying out
3 the requirements of such section 303(g);
4 and

5 “(iii) are qualified under applicable
6 State law to provide substance use disorder
7 treatment or recovery services.

8 “(D) Improved reimbursement for and ex-
9 pansion of, through the provision of education,
10 training, and technical assistance, the number
11 or treatment capacity of providers participating
12 under the State plan (or waiver) that have the
13 qualifications to address the treatment or recov-
14 ery needs of—

15 “(i) individuals enrolled under the
16 State plan (or a waiver of such plan) who
17 have neonatal abstinence syndrome, in ac-
18 cordance with guidelines issued by the
19 American Academy of Pediatrics and
20 American College of Obstetricians and
21 Gynecologists relating to maternal care
22 and infant care with respect to neonatal
23 abstinence syndrome;

24 “(ii) pregnant women, postpartum
25 women, and infants, particularly the con-

1 current treatment, as appropriate, and
2 comprehensive case management of preg-
3 nant women, postpartum women and in-
4 fants, enrolled under the State plan (or a
5 waiver of such plan);

6 “(iii) adolescents and young adults be-
7 tween the ages of 12 and 21 enrolled
8 under the State plan (or a waiver of such
9 plan); or

10 “(iv) American Indian and Alaska Na-
11 tive individuals enrolled under the State
12 plan (or a waiver of such plan).

13 “(3) PLANNING GRANTS.—

14 “(A) IN GENERAL.—The Secretary shall,
15 with respect to the first 18-month period of the
16 demonstration project conducted under para-
17 graph (1), award planning grants to at least 10
18 States selected in accordance with subpara-
19 graph (B) for purposes of preparing an applica-
20 tion described in paragraph (4)(C) and carrying
21 out the activities described in subparagraph
22 (C).

23 “(B) SELECTION.—In selecting States for
24 purposes of this paragraph, the Secretary
25 shall—

1 “(i) select States that have a State
2 plan (or waiver of the State plan) approved
3 under this title;

4 “(ii) select States in a manner that
5 ensures geographic diversity; and

6 “(iii) give preference to States with a
7 prevalence of substance use disorders (in
8 particular opioid use disorders) that is
9 comparable to or higher than the national
10 average prevalence, as measured by aggre-
11 gate per capita drug overdoses, or any
12 other measure that the Secretary deems
13 appropriate.

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

17 “(i) Activities that support the devel-
18 opment of an initial assessment of the be-
19 havioral health treatment needs of the
20 State to determine the extent to which pro-
21 viders are needed (including the types of
22 such providers and geographic area of
23 need) to improve the network of providers
24 that treat substance use disorders under

1 the State plan (or waiver), including the
2 following:

3 “(I) An estimate of the number
4 of individuals enrolled under the State
5 plan (or a waiver of such plan) who
6 have a substance use disorder.

7 “(II) Information on the capacity
8 of providers to provide substance use
9 disorder treatment or recovery serv-
10 ices to individuals enrolled under the
11 State plan (or waiver), including in-
12 formation on providers who provide
13 such services and their participation
14 under the State plan (or waiver).

15 “(III) Information on the gap in
16 substance use disorder treatment or
17 recovery services under the State plan
18 (or waiver) based on the information
19 described in subclauses (I) and (II).

20 “(IV) Projections regarding the
21 extent to which the State partici-
22 pating under the demonstration
23 project would increase the number of
24 providers offering substance use dis-
25 order treatment or recovery services

1 under the State plan (or waiver) dur-
2 ing the period of the demonstration
3 project.

4 “(ii) Activities that, taking into ac-
5 count the results of the assessment de-
6 scribed in clause (i), support the develop-
7 ment of State infrastructure to, with re-
8 spect to the provision of substance use dis-
9 order treatment or recovery services under
10 the State plan (or a waiver of such plan),
11 recruit prospective providers and provide
12 training and technical assistance to such
13 providers.

14 “(D) FUNDING.—For purposes of subpara-
15 graph (A), there is appropriated, out of any
16 funds in the Treasury not otherwise appro-
17 priated, \$50,000,000, to remain available until
18 expended.

19 “(4) POST-PLANNING STATES.—

20 “(A) IN GENERAL.—The Secretary shall,
21 with respect to the remaining 36-month period
22 of the demonstration project conducted under
23 paragraph (1), select not more than 5 States in
24 accordance with subparagraph (B) for purposes
25 of carrying out the activities described in para-

1 graph (2) and receiving payments in accordance
2 with paragraph (5).

3 “(B) SELECTION.—In selecting States for
4 purposes of this paragraph, the Secretary
5 shall—

6 “(i) select States that received a plan-
7 ning grant under paragraph (3);

8 “(ii) select States that submit to the
9 Secretary an application in accordance
10 with the requirements in subparagraph
11 (C), taking into consideration the quality
12 of each such application;

13 “(iii) select States in a manner that
14 ensures geographic diversity; and

15 “(iv) give preference to States with a
16 prevalence of substance use disorders (in
17 particular opioid use disorders) that is
18 comparable to or higher than the national
19 average prevalence, as measured by aggre-
20 gate per capita drug overdoses, or any
21 other measure that the Secretary deems
22 appropriate.

23 “(C) APPLICATIONS.—

24 “(i) IN GENERAL.—A State seeking to
25 be selected for purposes of this paragraph

1 shall submit to the Secretary, at such time
2 and in such form and manner as the Sec-
3 retary requires, an application that in-
4 cludes such information, provisions, and
5 assurances, as the Secretary may require,
6 in addition to the following:

7 “(I) A proposed process for car-
8 rying out the ongoing assessment de-
9 scribed in paragraph (2)(A), taking
10 into account the results of the initial
11 assessment described in paragraph
12 (3)(C)(i).

13 “(II) A review of reimbursement
14 methodologies and other policies re-
15 lated to substance use disorder treat-
16 ment or recovery services under the
17 State plan (or waiver) that may create
18 barriers to increasing the number of
19 providers delivering such services.

20 “(III) The development of a plan,
21 taking into account activities carried
22 out under paragraph (3)(C)(ii), that
23 will result in long-term and sustain-
24 able provider networks under the
25 State plan (or waiver) that will offer

1 a continuum of care for substance use
2 disorders. Such plan shall include the
3 following:

4 “(aa) Specific activities to
5 increase the number of providers
6 (including providers that spe-
7 cialize in providing substance use
8 disorder treatment or recovery
9 services, hospitals, health care
10 systems, Federally qualified
11 health centers, and, as applicable,
12 certified community behavioral
13 health clinics) that offer sub-
14 stance use disorder treatment, re-
15 covery, or support services, in-
16 cluding short-term detoxification
17 services, outpatient substance use
18 disorder services, and evidence-
19 based peer recovery services.

20 “(bb) Strategies that will
21 incentivize providers described in
22 subparagraphs (C) and (D) of
23 paragraph (2) to obtain the nec-
24 essary training, education, and
25 support to deliver substance use

1 disorder treatment or recovery
2 services in the State.

3 “(cc) Milestones and timeli-
4 ness for implementing activities
5 set forth in the plan.

6 “(dd) Specific measurable
7 targets for increasing the sub-
8 stance use disorder treatment
9 and recovery provider network
10 under the State plan (or a waiver
11 of such plan).

12 “(IV) A proposed process for re-
13 porting the information required
14 under paragraph (6)(A), including in-
15 formation to assess the effectiveness
16 of the efforts of the State to expand
17 the capacity of providers to deliver
18 substance use disorder treatment or
19 recovery services during the period of
20 the demonstration project under this
21 subsection.

22 “(V) The expected financial im-
23 pact of the demonstration project
24 under this subsection on the State.

1 “(VI) A description of all funding
2 sources available to the State to pro-
3 vide substance use disorder treatment
4 or recovery services in the State.

5 “(VII) A preliminary plan for
6 how the State will sustain any in-
7 crease in the capacity of providers to
8 deliver substance use disorder treat-
9 ment or recovery services resulting
10 from the demonstration project under
11 this subsection after the termination
12 of such demonstration project.

13 “(VIII) A description of how the
14 State will coordinate the goals of the
15 demonstration project with any waiver
16 granted (or submitted by the State
17 and pending) pursuant to section
18 1115 for the delivery of substance use
19 services under the State plan, as ap-
20 plicable.

21 “(ii) CONSULTATION.—In completing
22 an application under clause (i), a State
23 shall consult with relevant stakeholders, in-
24 cluding Medicaid managed care plans,
25 health care providers, and Medicaid bene-

1 fiary advocates, and include in such ap-
2 plication a description of such consultation.

3 “(5) PAYMENT.—

4 “(A) IN GENERAL.—For each quarter oc-
5 curring during the period for which the dem-
6 onstration project is conducted (after the first
7 18 months of such period), the Secretary shall
8 pay under this subsection, subject to subpara-
9 graph (C), to each State selected under para-
10 graph (4) an amount equal to 80 percent of so
11 much of the qualified sums expended during
12 such quarter.

13 “(B) QUALIFIED SUMS DEFINED.—For
14 purposes of subparagraph (A), the term ‘quali-
15 fied sums’ means, with respect to a State and
16 a quarter, the amount equal to the amount (if
17 any) by which the sums expended by the State
18 during such quarter attributable to substance
19 use treatment or recovery services furnished by
20 providers participating under the State plan (or
21 a waiver of such plan) exceeds 1/4 of such sums
22 expended by the State during fiscal year 2018
23 attributable to substance use treatment or re-
24 covery services.

1 “(C) NON-DUPLICATION OF PAYMENT.—In
2 the case that payment is made under subpara-
3 graph (A) with respect to expenditures for sub-
4 stance use treatment or recovery services fur-
5 nished by providers participating under the
6 State plan (or a waiver of such plan), payment
7 may not also be made under subsection (a) with
8 respect to expenditures for the same services so
9 furnished.

10 “(6) REPORTS.—

11 “(A) STATE REPORTS.—A State receiving
12 payments under paragraph (5) shall, for the pe-
13 riod of the demonstration project under this
14 subsection, submit to the Secretary a quarterly
15 report, with respect to expenditures for sub-
16 stance use treatment or recovery services for
17 which payment is made to the State under this
18 subsection, on the following:

19 “(i) The specific activities with re-
20 spect to which payment under this sub-
21 section was provided.

22 “(ii) The number of providers that de-
23 livered substance use disorder treatment or
24 recovery services in the State under the
25 demonstration project compared to the es-

1 timated number of providers that would
2 have otherwise delivered such services in
3 the absence of such demonstration project.

4 “(iii) The number of individuals en-
5 rolled under the State plan (or a waiver of
6 such plan) who received substance use dis-
7 order treatment or recovery services under
8 the demonstration project compared to the
9 estimated number of such individuals who
10 would have otherwise received such services
11 in the absence of such demonstration
12 project.

13 “(iv) Other matters as determined by
14 the Secretary.

15 “(B) CMS REPORTS.—

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

24 “(I) the States awarded planning
25 grants under paragraph (3);

1 “(II) the criteria used in such se-
2 lection; and

3 “(III) the activities carried out
4 by such States under such planning
5 grants.

6 “(ii) INTERIM REPORT.—Not later
7 than October 1, 2022, the Administrator
8 of the Centers for Medicare & Medicaid
9 Services shall, in consultation with the Di-
10 rector of the Agency for Healthcare Re-
11 search and Quality and the Assistant Sec-
12 retary for Mental Health and Substance
13 Use, submit to Congress an interim re-
14 port—

15 “(I) on activities carried out
16 under the demonstration project
17 under this subsection;

18 “(II) on the extent to which
19 States selected under paragraph (4)
20 have achieved the stated goals sub-
21 mitted in their applications under sub-
22 paragraph (C) of such paragraph;

23 “(III) with a description of the
24 strengths and limitations of such dem-
25 onstration project; and

1 “(IV) with a plan for the sustain-
2 ability of such project.

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

11 “(I) providing updates on the
12 matters reported in the interim report
13 under clause (ii);

14 “(II) including a description of
15 any changes made with respect to the
16 demonstration project under this sub-
17 section after the submission of such
18 interim report; and

19 “(III) evaluating such dem-
20 onstration project.

21 “(C) AHRQ REPORT.—Not later than 3
22 years after the date of the enactment of this
23 subsection, the Director of the Agency for
24 Healthcare Research and Quality, on consulta-
25 tion with the Administrator of the Centers for

1 Medicare & Medicaid Services, shall submit to
2 Congress a summary on the experiences of
3 States awarded planning grants under para-
4 graph (3) and States selected under paragraph
5 (4).

6 “(7) DATA SHARING AND BEST PRACTICES.—
7 During the period of the demonstration project
8 under this subsection, the Secretary shall, in collabo-
9 ration with States selected under paragraph (4), fa-
10 cilitate data sharing and the development of best
11 practices between such States and States that were
12 not so selected.

13 “(8) CMS FUNDING.—There is appropriated,
14 out of any funds in the Treasury not otherwise ap-
15 propriated, \$5,000,000 to the Centers for Medicare
16 & Medicaid Services for purposes of implementing
17 this subsection. Such amount shall remain available
18 until expended.”.

19 **SEC. 1004. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
20 **BENEFICIARIES.**

21 (a) IN GENERAL.—Title XIX of the Social Security
22 Act is amended by inserting after section 1927 (42 U.S.C.
23 1396r–8) the following new section:

1 **“SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK**
2 **BENEFICIARIES.**

3 “(a) IN GENERAL.—Beginning January 1, 2020, a
4 State shall operate a qualified drug management program
5 under which a State may enroll certain at-risk bene-
6 ficiaries identified by the State under the program.

7 “(b) QUALIFIED DRUG MANAGEMENT PROGRAM.—
8 For purposes of this section, the term ‘qualified drug man-
9 agement program’ means, with respect to a State, a pro-
10 gram carried out by the State (including through a con-
11 tract with a pharmacy benefit manager) that provides at
12 least for the following:

13 “(1) IDENTIFICATION OF AT-RISK INDIVID-
14 UALS.—Under the program, the State identifies, in
15 accordance with subsection (c), individuals enrolled
16 under the State plan (or waiver of the State plan)
17 who are at-risk beneficiaries.

18 “(2) ELEMENTS OF PROGRAM.—

19 “(A) IN GENERAL.—Under the program,
20 the State, with respect to each individual identi-
21 fied under paragraph (1) and enrolled under
22 the program under paragraph (5)—

23 “(i) subject to subparagraphs (B) and
24 (C), selects at least one, but not more than
25 three, health care providers and at least
26 one, but not more than three, pharmacies

1 for each such individual for purposes of
2 clause (ii), in accordance with a selection
3 process that takes into account reasonable
4 factors such as the individual’s previous
5 utilization of items and services from
6 health care providers and pharmacies, geo-
7 graphic proximity of the individual to such
8 health care providers and pharmacies, ac-
9 cess of the individual to health care, rea-
10 sonable travel time, information regarding
11 housing status, and any known preference
12 of the individual for a certain health care
13 provider or pharmacy; and

14 “(ii) requires that any controlled sub-
15 stance furnished to such individual during
16 the period for which such individual is en-
17 rolled under the program be prescribed by
18 a health care provider selected under
19 clause (i) for such individual and dispensed
20 by a pharmacy selected under clause (i) for
21 such individual in order for such controlled
22 substance to be covered under the State
23 plan (or waiver).

24 “(B) BENEFICIARY PREFERENCE.—In the
25 case of an individual receiving a notice under

1 paragraph (3)(A) of being identified as poten-
2 tially being an at-risk beneficiary described in
3 such paragraph, such individual may submit,
4 during the 30-day period following receipt of
5 such notice, preferences for which health care
6 providers and pharmacies the individual would
7 prefer the State to select under subparagraph
8 (A). The State shall select or change the selec-
9 tion of health care providers and pharmacies
10 under subparagraph (A) for the individuals
11 based on such preferences, except that in the
12 case that State determines that such selection
13 (or change of selection) of a health care pro-
14 vider or pharmacy under subparagraph (A) is
15 contributing or would contribute to prescription
16 drug abuse or drug diversion by the individual,
17 the State may select or change the selection of
18 health care provider or pharmacy for the indi-
19 vidual without regard to the preferences of the
20 individual described in this subparagraph. If the
21 State selects or changes the selection pursuant
22 to the preceding sentence without regard to the
23 preferences of the individual, the State shall
24 provide the individual with at least 30 days
25 written notice of the selection or change of se-

1 lection and a rationale for the selection or
2 change.

3 “(C) TREATMENT OF PHARMACY WITH
4 MULTIPLE LOCATIONS.—For purposes of sub-
5 paragraph (A)(i), in the case of a pharmacy
6 that has multiple locations that share real-time
7 electronic prescription data, all such locations
8 of the pharmacy shall collectively be treated as
9 one pharmacy.

10 “(D) TREATMENT OF EXISTING FFS DRUG
11 MANAGEMENT PROGRAMS.—In the case of a pa-
12 tient review and restriction program (as identi-
13 fied in the annual report submitted to the Sec-
14 retary under section 1927(g)(3)(D)) operated
15 by a State pursuant to section 1915(a)(2) be-
16 fore the date of the enactment of this section,
17 such program shall be treated as a qualified
18 drug management program.

19 “(E) REASONABLE ACCESS.—The program
20 shall ensure, including through waiver of ele-
21 ments of the program (including under sub-
22 paragraph (A)(ii)), reasonable access to health
23 care (including access to health care providers
24 and pharmacies with respect to prescription
25 drugs described in subparagraph (A)) in the

1 case of individuals with multiple residences, in
2 the case of natural disasters and similar situa-
3 tions, and in the case of the provision of emer-
4 gency services (as defined for purposes of sec-
5 tion 1860D–4(c)(5)(D)(ii)(II)).

6 “(3) NOTIFICATION TO IDENTIFIED INDIVID-
7 UALS.—Under the program, the State provides each
8 individual who is identified under paragraph (1),
9 prior to enrolling such individual under the program,
10 at least one notification of each of the following:

11 “(A) Notice that the State has identified
12 the individual as potentially being an at-risk
13 beneficiary for abuse or misuse of a controlled
14 substance.

15 “(B) The name, address, and contact in-
16 formation of each health care provider and
17 pharmacy that may be selected for the indi-
18 vidual under paragraph (2)(A).

19 “(C) Information describing all State and
20 Federal public health resources that are de-
21 signed to address such abuse or misuse to
22 which the individual has access, including men-
23 tal health services, substance use disorder and
24 recovery services, and other counseling services.

1 “(D) Notice of, and information about, the
2 right of the individual to—

3 “(i) submit preferences of the indi-
4 vidual for health care providers and phar-
5 macies to be selected under paragraph
6 (2)(A), including as described in paragraph
7 (2)(B);

8 “(ii) appeal under paragraph (4)—

9 “(I) such identification described
10 in subparagraph (A); and

11 “(II) the selection of health care
12 providers and pharmacies under para-
13 graph (2)(A).

14 “(E) An explanation of the meaning and
15 consequences of the identification of the indi-
16 vidual as potentially being an at-risk beneficiary
17 for abuse or misuse of a controlled substance,
18 including an explanation of the program.

19 “(F) Information, including a contact list
20 and clear instructions, that explain how the in-
21 dividual can contact the appropriate entities ad-
22 ministering the program in order to submit
23 preferences described in paragraph (2)(B) and
24 any other communications relating to the pro-
25 gram.

1 “(4) APPEALS PROCESS.—Under the program,
2 the State provides for an appeals process under
3 which, with respect to an individual identified under
4 paragraph (1)—

5 “(A) such individual may appeal—

6 “(i) such identification; and

7 “(ii) the selection of a health care pro-
8 vider or pharmacy under paragraph (2)(A);

9 “(B) in the case of an appeal described in
10 subparagraph (A)(ii), the State shall accommo-
11 date the health care provider or pharmacy pre-
12 ferred by the individual for selection for pur-
13 poses of paragraph (2)(A), unless the State de-
14 termines that a change to the selection of
15 health care provider or pharmacy under such
16 paragraph is contributing or would contribute
17 to prescription drug abuse or drug diversion by
18 the individual;

19 “(C) such individual is provided a period of
20 not less than 30 days following the date of re-
21 ceipt of the notice described in paragraph (3) to
22 submit such appeal; and

23 “(D) the State must make a determination
24 with respect to an appeal described in subpara-
25 graph (A), and notify the individual of such de-

1 termination, prior to enrollment of such indi-
2 vidual in the program.

3 “(5) ENROLLMENT.—Under the program, the
4 State initially enrolls individuals who are identified
5 under paragraph (1) in the program for a 12-month
6 period—

7 “(A) in the case of such an individual who
8 does not submit an appeal under paragraph (4)
9 within the period applied by the State pursuant
10 to subparagraph (C) of such paragraph, begin-
11 ning on the day after the last day of such pe-
12 riod; and

13 “(B) in the case of such an individual who
14 does submit an appeal under paragraph (4)
15 within the period applied by the State pursuant
16 to subparagraph (C) of such paragraph but
17 such appeal is denied, beginning not later than
18 30 days after the date of such denial.

19 “(6) NOTIFICATION OF HEALTH CARE PRO-
20 VIDERS AND PHARMACIES.—Under the program, the
21 State provides to each health care provider and
22 pharmacy selected for an individual under paragraph
23 (2)—

24 “(A) notification that the individual is an
25 at-risk beneficiary enrolled under the program

1 and that the provider or pharmacy has been se-
2 lected for the individual under paragraph (2);

3 “(B) information on such program and the
4 role of being so selected; and

5 “(C) a process through which the provider
6 or pharmacy can submit a concern or complaint
7 with respect to being so selected.

8 “(7) CONTINUATION OF ENROLLMENT.—Under
9 the program, the State, with respect to an individual
10 enrolled under the program, provides for a process
11 to—

12 “(A) not later than 30 days before the end
13 of the 12-month period for which the individual
14 is so enrolled pursuant to paragraph (5)—

15 “(i) assess, in accordance with pub-
16 licly available evidence-based guidelines,
17 whether or not such individual should con-
18 tinue to be enrolled under the program;
19 and

20 “(ii) notify such individual of the re-
21 sults of the assessment under clause (i);

22 “(B) continue, subject to subparagraph
23 (C), enrollment of such individual if such as-
24 sessment recommends such continuation; and

1 “(C) appeal the continuation of enrollment
2 in accordance with the appeals process de-
3 scribed in paragraph (4).

4 “(c) AT-RISK BENEFICIARY.—

5 “(1) IDENTIFICATION.—For purposes of this
6 section, a State shall identify an individual enrolled
7 under the State plan (or waiver of the State plan)
8 as an at-risk beneficiary if the individual is not an
9 exempted individual described in paragraph (2)
10 and—

11 “(A) is identified as such an at-risk bene-
12 ficiary through the use of publicly available evi-
13 dence-based guidelines that indicate misuse or
14 abuse of a controlled substance; or

15 “(B) the State received notification from a
16 PDP sponsor or Medicare Advantage organiza-
17 tion that such individual was identified as being
18 an at-risk beneficiary for prescription drug
19 abuse for enrollment in a drug management
20 program established by the sponsor or organiza-
21 tion pursuant to section 1860D–4(c)(5) and
22 such identification has not been terminated
23 under subparagraph (F) of such section.

1 “(2) EXEMPTED INDIVIDUAL DESCRIBED.—For
2 purposes of paragraph (1), an exempted individual
3 described in this paragraph is an individual who—

4 “(A) is receiving—

5 “(i) hospice or palliative care; or

6 “(ii) treatment for cancer;

7 “(B) is a resident of a long-term care facil-
8 ity, of a facility described in section 1905(d), or
9 of another facility for which frequently abused
10 drugs are dispensed for residents through a
11 contract with a single pharmacy; or

12 “(C) the State elects to treat as an ex-
13 empted individual for purposes of paragraph
14 (1).

15 “(d) APPLICATION OF PRIVACY RULES CLARIFICA-
16 TION.—The Secretary shall clarify privacy requirements,
17 including requirements under the regulations promulgated
18 pursuant to section 264(c) of the Health Insurance Port-
19 ability and Accountability Act of 1996 (42 U.S.C. 1320d-
20 2 note), related to the sharing of data under subsection
21 (b)(6) in the same manner as the Secretary is required
22 under subparagraph (J) of section 1860D-4(c)(5) to clar-
23 ify privacy requirements related to the sharing of data de-
24 scribed in such subparagraph.

25 “(e) REPORTS.—

1 “(1) ANNUAL REPORTS.—A State operating a
2 qualified drug management program shall include in
3 the annual report submitted to the Secretary under
4 section 1927(g)(3)(D), beginning with such reports
5 submitted for 2021, the following information:

6 “(A) The number of individuals enrolled
7 under the State plan (or waiver of the State
8 plan) who are enrolled under the program and
9 the percentage of individuals enrolled under the
10 State plan (or waiver) who are enrolled under
11 such program.

12 “(B) The number of prescriptions for con-
13 trolled substances that were dispensed per
14 month during each such year per individual en-
15 rolled under the program, including the daily
16 morphine milligram equivalents and the quan-
17 tity prescribed for each such prescription.

18 “(C) The number of pharmacies filling pre-
19 scriptions for controlled substances for individ-
20 uals enrolled under such program.

21 “(D) The number of health care providers
22 writing prescriptions for controlled substances
23 (other than prescriptions for a refill) for indi-
24 viduals enrolled under such program.

1 “(E) Any other data that the Secretary
2 may require.

3 “(F) Any report submitted by a managed
4 care entity under subsection (f)(1)(B) with re-
5 spect to the year involved.

6 For each such report for a year after 2021, the in-
7 formation described in this paragraph shall be pro-
8 vided in a manner that compares such information
9 with respect to the prior calendar year to such infor-
10 mation with respect to the second prior calendar
11 year.

12 “(2) MACPAC REPORTS AND REVIEW.—Not
13 later than 2 years after the date of the enactment
14 of this section, the Medicaid and CHIP Payment
15 and Access Commission (in this section referred to
16 as ‘MACPAC’), in consultation with the National
17 Association of Medicaid Directors, pharmacy benefit
18 managers, managed care organizations, health care
19 providers (including pharmacists), beneficiary advo-
20 cates, and other stakeholders, shall publish a report
21 that includes—

22 “(A) best practices for operating drug
23 management programs, based on a review of a
24 representative sample of States administering
25 such a program;

1 “(B) a summary of the experience of the
2 appeals process under drug management pro-
3 grams operated by several States, such as the
4 frequency at which individuals appealed the
5 identification of being an at-risk individual, the
6 frequency at which individuals appealed the se-
7 lection of a health care provider or pharmacy
8 under such a program, the timeframes for such
9 appeals, a summary of the reasons for such ap-
10 peals, and the design of such appeals processes;

11 “(C) a summary of trends and the effec-
12 tiveness of qualified drug management pro-
13 grams operated under this section; and

14 “(D) recommendations to States on how
15 improvements can be made with respect to the
16 operation of such programs.

17 In reporting on State practices, the MACPAC shall
18 consider how such programs have been implemented
19 in rural areas, under fee-for-service as well as man-
20 aged care arrangements, and the extent to which
21 such programs have resulted in increased efficiencies
22 to such States or to the Federal Government under
23 this title.

24 “(3) REPORT ON PLAN FOR COORDINATED
25 CARE.—Not later than January 1, 2021, each State

1 operating a qualified drug management program
2 shall submit to the Administrator of the Centers for
3 Medicare & Medicaid Services a report on how such
4 State plans to provide coordinated care for individ-
5 uals enrolled under the State plan (or waiver of the
6 State plan) and—

7 “(A) who are enrolled under the program;

8 or

9 “(B) who are enrolled with a managed care
10 entity and enrolled under such a qualified drug
11 management program operated by such entity.

12 “(f) APPLICABILITY TO MANAGED CARE ENTI-
13 TIES.—

14 “(1) IN GENERAL.—With respect to any con-
15 tract that a State enters into on or after January
16 1, 2020, with a managed care entity (as defined in
17 section 1932(a)(1)(B)) pursuant to section 1903(m),
18 the State shall, as a condition of the contract, re-
19 quire the managed care entity—

20 “(A) to operate a qualified drug manage-
21 ment program (as defined in subsection (b)) for
22 at-risk beneficiaries who are enrolled with such
23 entity and identified by the managed care entity
24 by means of application of paragraph (2);

1 “(B) to submit to the State an annual re-
2 port on the matters described in subparagraphs
3 (A) through (E) of subsection (e)(1); and

4 “(C) to submit to the State a list (and as
5 necessary update such list) of individuals en-
6 rolled with such entity under the qualified drug
7 management program operated by such entity
8 under subparagraph (A) for purposes of allow-
9 ing State plans for which medical assistance is
10 paid on a fee-for-service basis to have access to
11 such information.

12 “(2) APPLICATION.—For purposes of applying,
13 with respect to a managed care entity—

14 “(A) under paragraph (1)(A)—

15 “(i) the definition of the term ‘quali-
16 fied drug management program’ under
17 subsection (b), other than paragraph
18 (2)(D) of such subsection; and

19 “(ii) the provisions of paragraphs (1)
20 and (2) of subsection (c); and

21 “(B) under paragraph (1)(B), the report
22 requirements described in subparagraphs (A)
23 through (E) of subsection (e)(1);

24 each reference in such subsection (b) and para-
25 graphs of subsection (c) to ‘a State’ or ‘the State’

1 (other than to ‘a State plan’ or ‘the State plan’)
2 shall be deemed a reference to the managed care en-
3 tity, each reference under such subsection, para-
4 graphs, or subparagraphs to individuals enrolled
5 under the State plan (or waiver of the State plan)
6 shall be deemed a reference to individuals enrolled
7 with such entity, and each reference under such sub-
8 section, paragraphs, or subparagraphs to individuals
9 enrolled under the qualified drug management pro-
10 gram operated by the State shall be deemed a ref-
11 erence to individuals enrolled under the qualified
12 drug management program operated by the man-
13 aged care entity.

14 “(g) CONTROLLED SUBSTANCE DEFINED.—For pur-
15 poses of this section, the term ‘controlled substance’
16 means a drug that is included in schedule II, III, or IV
17 of section 202(e) of the Controlled Substances Act, or any
18 combination thereof, as specified by the State.”.

19 (b) GUIDANCE ON AT-RISK POPULATION
20 TRANSITIONING BETWEEN MEDICAID FFS AND MAN-
21 AGED CARE.—Not later than October 1, 2019, the Sec-
22 retary of Health and Human Services shall issue guidance
23 for State Medicaid programs, with respect to individuals
24 who are enrolled under a State plan (or waiver of such
25 plan) under title XIX of the Social Security Act and under

1 a drug management program, for purposes of providing
2 best practices—

3 (1) for transitioning, as applicable, such indi-
4 viduals from fee-for-service Medicaid (and such a
5 program operated by the State) to receiving medical
6 assistance under such title through a managed care
7 entity (as defined in section 1932(a)(1)(B) of the
8 Social Security Act) with a contract that with the
9 State pursuant to section 1903(m) of such Act (and
10 such a program operated by such entity); and

11 (2) for transitioning, as applicable, such indi-
12 viduals from receiving medical assistance under such
13 title through a managed care entity (as defined in
14 section 1932(a)(1)(B) of the Social Security Act)
15 with a contract that with the State pursuant to sec-
16 tion 1903(m) of such Act (and such a program oper-
17 ated by such entity) to fee-for-service Medicaid (and
18 such a program operated by the State).

19 (c) GUIDANCE ON AT-RISK POPULATION
20 TRANSITIONING TO MEDICARE.—

21 (1) IN GENERAL.—Not later than January 1,
22 2020, the Secretary of Health and Human Services,
23 after consultation with the Federal Coordinated
24 Health Care Office established under section 2602
25 of the Patient Protection and Affordable Care Act

1 (42 U.S.C. 1315b), shall issue guidance for State
2 Medicaid programs, with respect to transitioning in-
3 dividuals, providing for—

4 (A) notification to be submitted by the
5 State to the Centers for Medicare & Medicaid
6 Services and such individuals of the status of
7 such individuals as transitioning individuals;

8 (B) notification to such individuals about
9 enrollment under a prescription drug plan
10 under part D of such title or under a MA–PD
11 plan under part C of such title;

12 (C) best practices for transitioning such in-
13 dividuals to such a plan; and

14 (D) best practices for coordination between
15 the qualified drug management program (as de-
16 scribed in section 1927A(b) of the Social Secu-
17 rity Act, as added by subsection (a)) carried out
18 by the State and a drug management program
19 carried out under such a plan pursuant to sec-
20 tion 1860D–4(c)(5) of the Social Security Act
21 (42 U.S.C. 1395w–10(c)(5)).

22 (2) TRANSITIONING INDIVIDUALS.—For pur-
23 poses of paragraph (1), a transitioning individual is
24 an individual who, with respect to a month—

1 (A) is enrolled under the State plan (or
2 waiver of the State plan) and under the quali-
3 fied drug management program (as described in
4 section 1927A(b) of the Social Security Act, as
5 added by subsection (a)) carried out by the
6 State; and

7 (B) is expected to become eligible for the
8 Medicare program under title XVIII of such
9 Act during the subsequent 12-month period.

10 **SEC. 1005. MEDICAID DRUG REVIEW AND UTILIZATION.**

11 (a) MEDICAID DRUG UTILIZATION REVIEW.—

12 (1) STATE PLAN REQUIREMENT.—Section
13 1902(a) of the Social Security Act (42 U.S.C.
14 1396a(a)), as amended by section 101, is further
15 amended—

16 (A) in paragraph (83), at the end, by
17 striking “and”;

18 (B) in paragraph (84), at the end, by
19 striking the period and inserting “; and”; and

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

22 “(85) provide that the State is in compliance
23 with the drug review and utilization requirements
24 under subsection (oo)(1).”.

1 (2) DRUG REVIEW AND UTILIZATION REQUIRE-
2 MENTS.—Section 1902 of the Social Security Act
3 (42 U.S.C. 1396a), as amended by section 101, is
4 further amended by adding at the end the following
5 new subsection:

6 “(00) DRUG REVIEW AND UTILIZATION REQUIRE-
7 MENTS.—

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

12 “(A) CLAIMS REVIEW LIMITATIONS.—

13 “(i) IN GENERAL.—The State has in
14 place—

15 “(I) safety edits (as specified by
16 the State) for subsequent fills for
17 opioids and a claims review automated
18 process (as designed and implemented
19 by the State) that indicates when an
20 individual enrolled under the State
21 plan (or under a waiver of the State
22 plan) is prescribed a subsequent fill of
23 opioids in excess of any limitation
24 that may be identified by the State;

1 “(II) safety edits (as specified by
2 the State) on the maximum daily mor-
3 phine equivalent that can be pre-
4 scribed to an individual enrolled under
5 the State plan (or under a waiver of
6 the State plan) for treatment of
7 chronic pain and a claims review auto-
8 mated process (as designed and imple-
9 mented by the State) that indicates
10 when an individual enrolled under the
11 plan (or waiver) is prescribed the mor-
12 phine equivalent for such treatment in
13 excess of any limitation that may be
14 identified by the State; and

15 “(III) a claims review automated
16 process (as designed and implemented
17 by the State) that monitors when an
18 individual enrolled under the State
19 plan (or under a waiver of the State
20 plan) is concurrently prescribed
21 opioids and—

22 “(aa) benzodiazepines; or

23 “(bb) antipsychotics.

24 “(ii) MANAGED CARE ENTITIES.—The
25 State requires each managed care entity

1 (as defined in section 1932(a)(1)(B)) with
2 respect to which the State has a contract
3 under section 1903(m) or under section
4 1905(t)(3) to have in place, subject to
5 paragraph (3), with respect to individuals
6 who are eligible for medical assistance
7 under the State plan (or under a waiver of
8 the State plan) and who are enrolled with
9 the entity, the limitations described in sub-
10 clauses (I) and (II) of clause (i) and a
11 claims review automated process described
12 in subclause (III) of such clause.

13 “(iii) RULES OF CONSTRUCTION.—
14 Nothing in this subparagraph may be con-
15 strued as prohibiting a State or managed
16 care entity from designing and imple-
17 menting a claims review automated process
18 under this subparagraph that provides for
19 prospective or retrospective reviews of
20 claims. Nothing in this subparagraph shall
21 be understood as prohibiting the exercise
22 of clinical judgment from a provider en-
23 rolled as a participating provider in a
24 State plan (or waiver of the State plan) or
25 contracting with a managed care entity re-

1 garding the best items and services for an
2 individual enrolled under such State plan
3 (or waiver).

4 “(B) PROGRAM TO MONITOR
5 ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—
6 The State has in place a program (as designed
7 and implemented by the State) to monitor and
8 manage the appropriate use of antipsychotic
9 medications by children enrolled under the
10 State plan (or under a waiver of the State plan)
11 and submits annually to the Secretary such in-
12 formation as the Secretary may require on ac-
13 tivities carried out under such program for indi-
14 viduals not more than the age of 18 years gen-
15 erally and children in foster care specifically.

16 “(C) FRAUD AND ABUSE IDENTIFICA-
17 TION.—The State has in place a process (as de-
18 signed and implemented by the State) that
19 identifies potential fraud or abuse of controlled
20 substances by individuals enrolled under the
21 State plan (or under a waiver of the State
22 plan), health care providers prescribing drugs
23 to individuals so enrolled, and pharmacies dis-
24 pensing drugs to individuals so enrolled.

1 “(D) REPORTS.—The State shall include
2 in the annual report submitted to the Secretary
3 under section 1927(g)(3)(D) information on the
4 limitations, requirement, program, and proc-
5 esses applied by the State under subparagraphs
6 (A) through (C) in accordance with such man-
7 ner and time as specified by the Secretary.

8 “(E) CLARIFICATION.—Nothing shall pre-
9 vent a State from satisfying the requirement—

10 “(i) described in subparagraph (A) by
11 having safety edits or a claims review auto-
12 mated process described in such subpara-
13 graph that was in place before October 1,
14 2019;

15 “(ii) described in subparagraph (B)
16 by having a program described in such
17 subparagraph that was in place before
18 such date; or

19 “(iii) described in subparagraph (C)
20 by having a process described in such sub-
21 paragraph that was in place before such
22 date.

23 “(2) ANNUAL REPORT BY SECRETARY.—For
24 each fiscal year beginning with fiscal year 2020, the
25 Secretary shall submit to Congress a report on the

1 most recent information submitted by States under
2 paragraph (1)(D).

3 “(3) EXCEPTIONS.—

4 “(A) CERTAIN INDIVIDUALS EXEMPTED.—

5 The drug review and utilization requirements
6 under this subsection shall not apply with re-
7 spect to an individual who—

8 “(i) is receiving—

9 “(I) hospice or palliative care; or

10 “(II) treatment for cancer;

11 “(ii) is a resident of a long-term care
12 facility, of a facility described in section
13 1905(d), or of another facility for which
14 frequently abused drugs are dispensed for
15 residents through a contract with a single
16 pharmacy; or

17 “(iii) the State elects to treat as ex-
18 empted from such requirements.

19 “(B) EXCEPTION RELATING TO ENSURING
20 ACCESS.—In order to ensure reasonable access
21 to health care, the Secretary shall waive the
22 drug review and utilization requirements under
23 this subsection, with respect to a State, in the
24 case of natural disasters and similar situations,
25 and in the case of the provision of emergency

1 services (as defined for purposes of section
2 1860D–4(c)(5)(D)(ii)(II)).”.

3 (3) MANAGED CARE ENTITIES.—Section 1932
4 of the Social Security Act (42 U.S.C. 1396u–2) is
5 amended by adding at the end the following new
6 subsection:

7 “(i) DRUG UTILIZATION REVIEW ACTIVITIES AND
8 REQUIREMENTS.—Beginning not later than October 1,
9 2019, each contract under a State plan with a managed
10 care entity (other than a primary care case manager)
11 under section 1903(m) shall provide that the entity is in
12 compliance with the applicable provisions of section
13 438.3(s)(2) of title 42 of the Code of Federal Regulations,
14 section 483.3(s)(4) of such title, and section 483.3(s)(5)
15 of such title, as such provisions were in effect on March
16 31, 2018.”.

17 (b) IDENTIFYING AND ADDRESSING INAPPROPRIATE
18 PRESCRIBING AND BILLING PRACTICES UNDER MED-
19 ICAID.—

20 (1) IN GENERAL.—Section 1927(g) of the So-
21 cial Security Act (42 U.S.C. 1396r–8(g)) is amend-
22 ed—

23 (A) in paragraph (1)(A)—

1 (i) by striking “of section
2 1903(i)(10)(B)” and inserting “of section
3 1902(a)(54)”;

4 (ii) by striking “, by not later than
5 January 1, 1993,”;

6 (iii) by inserting after “gross over-
7 use,” the following: “excessive utilization,”;
8 and

9 (iv) by striking “or inappropriate or
10 medically unnecessary care” and inserting
11 “inappropriate or medically unnecessary
12 care, or prescribing or billing practices
13 that indicate abuse or excessive utiliza-
14 tion”; and

15 (B) in paragraph (2)(B)—

16 (i) by inserting after “gross overuse,”
17 the following: “excessive utilization,”; and

18 (ii) by striking “or inappropriate or
19 medically unnecessary care” and inserting
20 “inappropriate or medically unnecessary
21 care, or prescribing or billing practices
22 that indicate abuse or excessive utiliza-
23 tion”.

24 (2) EFFECTIVE DATE.—The amendments made
25 by paragraph (1) shall take effect with respect to

1 retrospective drug use reviews conducted on or after
2 October 1, 2020.

3 **SEC. 1006. GUIDANCE TO IMPROVE CARE FOR INFANTS**
4 **WITH NEONATAL ABSTINENCE SYNDROME**
5 **AND THEIR MOTHERS; GAO STUDY ON GAPS**
6 **IN MEDICAID COVERAGE FOR PREGNANT**
7 **AND POSTPARTUM WOMEN WITH SUBSTANCE**
8 **USE DISORDER.**

9 (a) GUIDANCE.—Not later than 1 year after the date
10 of the enactment of this Act, the Secretary of Health and
11 Human Services shall issue guidance to improve care for
12 infants with neonatal abstinence syndrome and their fami-
13 lies. Such guidance shall include—

14 (1) the types of services, including post-dis-
15 charge services and parenting supports, for families
16 of babies with neonatal abstinence syndrome that
17 States may cover under the Medicaid program under
18 title XIX of the Social Security Act;

19 (2) best practices from States with respect to
20 innovative or evidenced-based payment models that
21 focus on prevention, screening, treatment, plans of
22 safe care, and post-discharge services for mothers
23 and fathers with substance use disorders and babies
24 with neonatal abstinence syndrome that improve
25 care and clinical outcomes;

1 (3) recommendations for States on available fi-
2 nancing options under the Medicaid program under
3 title XIX of such Act and under the Children’s
4 Health Insurance Program under title XXI of such
5 Act for Children’s Health Insurance Program
6 Health Services Initiative funds for parents with
7 substance use disorders, infants with neonatal absti-
8 nence syndrome, and home visiting services; and

9 (4) guidance and technical assistance to State
10 Medicaid agencies regarding additional flexibilities
11 and incentives related to screening, prevention, and
12 post-discharge services, including parenting sup-
13 ports.

14 (b) GAO STUDY.—Not later than 1 year after the
15 date of the enactment of this Act, the Comptroller General
16 of the United States shall conduct a study, and submit
17 to Congress a report, addressing gaps in coverage for
18 pregnant women with substance use disorder under the
19 Medicaid program under title XIX of the Social Security
20 Act, and gaps in coverage for postpartum women with sub-
21 stance use disorder who had coverage during their preg-
22 nancy under the Medicaid program under such title.

1 **SEC. 1007. MEDICAID HEALTH HOMES FOR OPIOID-USE-DIS-**
2 **ORDER MEDICAID ENROLLEES.**

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

7 (1) in subsection (c)—

8 (A) in paragraph (1), by inserting “subject
9 to paragraph (4),” after “except that,”; and

10 (B) by adding at the end the following new
11 paragraph:

12 “(4) SPECIAL RULE RELATING TO SUBSTANCE
13 USE DISORDER HEALTH HOMES.—

14 “(A) IN GENERAL.—In the case of a State
15 with an SUD-focused State plan amendment
16 approved by the Secretary on or after October
17 1, 2018, the Secretary may, at the request of
18 the State, extend the application of the Federal
19 medical assistance percentage described in
20 paragraph (1) to payments for the provision of
21 health home services to SUD-eligible individuals
22 under such State plan amendment, in addition
23 to the first 8 fiscal year quarters the State plan
24 amendment is in effect, for the subsequent 2
25 fiscal year quarters that the State plan amend-
26 ment is in effect. Nothing in this section shall

1 be construed as prohibiting a State with a State
2 plan amendment that is approved under this
3 section and that is not an SUD-focused State
4 plan amendment from additionally having ap-
5 proved on or after such date an SUD-focused
6 State plan amendment under this section, in-
7 cluding for purposes of application of this para-
8 graph.

9 “(B) REPORT REQUIREMENTS.—In the
10 case of a State with an SUD-focused State plan
11 amendment for which the application of the
12 Federal medical assistance percentage has been
13 extended under subparagraph (A), such State
14 shall, at the end of the period of such State
15 plan amendment, submit to the Secretary a re-
16 port on the following, with respect to SUD-eli-
17 gible individuals provided health home services
18 under such State plan amendment:

19 “(i) The quality of health care pro-
20 vided to such individuals, with a focus on
21 outcomes relevant to the recovery of each
22 such individual.

23 “(ii) The access of such individuals to
24 health care.

1 “(iii) The total expenditures of such
2 individuals for health care.

3 For purposes of this subparagraph, the Sec-
4 retary shall specify all applicable measures for
5 determining quality, access, and expenditures.

6 “(C) BEST PRACTICES.—Not later than
7 October 1, 2020, the Secretary shall make pub-
8 licly available on the Internet website of the
9 Centers for Medicare & Medicaid Services best
10 practices for designing and implementing an
11 SUD-focused State plan amendment, based on
12 the experiences of States that have State plan
13 amendments approved under this section that
14 include SUD-eligible individuals.

15 “(D) DEFINITIONS.—For purposes of this
16 paragraph:

17 “(i) SUD-ELIGIBLE INDIVIDUALS.—
18 The term ‘SUD-eligible individual’ means,
19 with respect to a State, an individual who
20 satisfies all of the following:

21 “(I) The individual is an eligible
22 individual with chronic conditions.

23 “(II) The individual is an indi-
24 vidual with a substance use disorder.

1 “(III) The individual has not pre-
2 viously received health home services
3 under any other State plan amend-
4 ment approved for the State under
5 this section by the Secretary.

6 “(ii) SUD-FOCUSED STATE PLAN
7 AMENDMENT.—The term ‘SUD-focused
8 State plan amendment’ means a State plan
9 amendment under this section that is de-
10 signed to provide health home services pri-
11 marily to SUD-eligible individuals.”.

12 (b) REQUIREMENT FOR STATE MEDICAID PLANS TO
13 PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREAT-
14 MENT.—

15 (1) REQUIREMENT FOR STATE MEDICAID PLANS
16 TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED
17 TREATMENT.—Section 1902(a)(10)(A) of the Social
18 Security Act (42 U.S.C. 1396a(a)(10)(A)) is amend-
19 ed, in the matter preceding clause (i), by striking
20 “and (28)” and inserting “(28), and (29)”.

21 (2) INCLUSION OF MEDICATION-ASSISTED
22 TREATMENT AS MEDICAL ASSISTANCE.—Section
23 1905(a) of the Social Security Act (42 U.S.C.
24 1396d(a)) is amended—

1 (A) in paragraph (28), by striking “and”
2 at the end;

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

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

7 “(29) subject to paragraph (2) of subsection
8 (ee), for the period beginning October 1, 2020, and
9 ending September 30, 2025, medication-assisted
10 treatment (as defined in paragraph (1) of such sub-
11 section); and”.

12 (3) MEDICATION-ASSISTED TREATMENT DE-
13 FINED; WAIVERS.—Section 1905 of the Social Secu-
14 rity Act (42 U.S.C. 1396d) is amended by adding at
15 the end the following new subsection:

16 “(ee) MEDICATION-ASSISTED TREATMENT.—

17 “(1) DEFINITION.—For purposes of subsection
18 (a)(29), the term ‘medication-assisted treatment’—

19 “(A) means all drugs approved under sec-
20 tion 505 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 355), including metha-
22 done, and all biological products licensed under
23 section 351 of the Public Health Service Act
24 (42 U.S.C. 262) to treat opioid use disorders;
25 and

1 “(B) includes, with respect to the provision
2 of such drugs and biological products, coun-
3 seling services and behavioral therapy.

4 “(2) EXCEPTION.—The provisions of paragraph
5 (29) of subsection (a) shall not apply with respect to
6 a State for the period specified in such paragraph,
7 if before the beginning of such period the State cer-
8 tifies to the satisfaction of the Secretary that imple-
9 menting such provisions statewide for all individuals
10 eligible to enroll in the State plan (or waiver of the
11 State plan) would not be feasible by reason of a
12 shortage of qualified providers of medication-assisted
13 treatment, or facilities providing such treatment,
14 that will contract with the State or a managed care
15 entity with which the State has a contract under
16 section 1903(m) or under section 1905(t)(3).”.

17 (4) EFFECTIVE DATE.—

18 (A) IN GENERAL.—Subject to subpara-
19 graph (B), the amendments made by this sub-
20 section shall apply with respect to medical as-
21 sistance provided on or after October 1, 2020,
22 and before October 1, 2025.

23 (B) EXCEPTION FOR STATE LEGISLA-
24 TION.—In the case of a State plan under title
25 XIX of the Social Security Act (42 U.S.C. 1396

1 et seq.) that the Secretary of Health and
2 Human Services determines requires State leg-
3 islation in order for the respective plan to meet
4 any requirement imposed by the amendments
5 made by this subsection, the respective plan
6 shall not be regarded as failing to comply with
7 the requirements of such title solely on the
8 basis of its failure to meet such an additional
9 requirement before the first day of the first cal-
10 endar quarter beginning after the close of the
11 first regular session of the State legislature that
12 begins after the date of the enactment of this
13 Act. For purposes of the previous sentence, in
14 the case of a State that has a 2-year legislative
15 session, each year of the session shall be consid-
16 ered to be a separate regular session of the
17 State legislature.

1 **TITLE II—MEDICARE PROVI-**
2 **SIONS TO ADDRESS THE**
3 **OPIOID CRISIS**

4 **SEC. 2001. AUTHORITY NOT TO APPLY CERTAIN MEDICARE**
5 **TELEHEALTH REQUIREMENTS IN THE CASE**
6 **OF CERTAIN TREATMENT OF A SUBSTANCE**
7 **USE DISORDER OR CO-OCCURRING MENTAL**
8 **HEALTH DISORDER.**

9 Section 1834(m) of the Social Security Act (42
10 U.S.C. 1395m(m)) is amended—

11 (1) in paragraph (2)(B)(i), by inserting “and
12 paragraph (7)(E)” after “Subject to clause (ii)”;
13 and

14 (2) by adding at the end the following new
15 paragraphs:

16 “(7) AUTHORITY NOT TO APPLY CERTAIN RE-
17 QUIREMENTS IN THE CASE OF CERTAIN TREATMENT
18 OF SUBSTANCE USE DISORDER OR CO-OCCURRING
19 MENTAL HEALTH DISORDER.—

20 “(A) IN GENERAL.—For purposes of pay-
21 ment under this subsection, in the case of tele-
22 health services described in subparagraph (C)
23 furnished on or after January 1, 2020, to an el-
24 igible beneficiary (as defined in subparagraph
25 (F)) for the treatment of a substance use dis-

1 order or a mental health disorder that is co-oc-
2 ccurring with a substance use disorder, the Sec-
3 retary is authorized to, through rulemaking, not
4 apply any of the requirements described in sub-
5 paragraph (B).

6 “(B) REQUIREMENTS DESCRIBED.—For
7 purposes of this paragraph, the requirements
8 described in this subparagraph are any of the
9 following:

10 “(i) Qualifications for an originating
11 site under paragraph (4)(C)(ii).

12 “(ii) Geographic limitations under
13 paragraph (4)(C)(i).

14 “(C) TELEHEALTH SERVICES DE-
15 SCRIBED.—For purposes of this paragraph, the
16 telehealth services described in this subpara-
17 graph are services that are both telehealth serv-
18 ices (as described in paragraph (4)(F)) and
19 identified by the Secretary, through rulemaking,
20 as services that are the most commonly fur-
21 nished (as defined by the Secretary) under this
22 part to individuals diagnosed with a substance
23 use disorder or a mental health disorder that is
24 co-occurring with a substance use disorder.

1 “(D) CLARIFICATION.—Nothing in this
2 paragraph shall be construed as limiting or oth-
3 erwise affecting the authority of the Secretary
4 to limit or eliminate the non-application pursu-
5 ant to this paragraph of any of the require-
6 ments under subparagraph (B).

7 “(E) TREATMENT OF ORIGINATING SITE
8 FACILITY FEE.—No facility fee shall be paid
9 under paragraph (2)(B) to an originating site
10 with respect to a telehealth service described in
11 subparagraph (B) for which payment is made
12 under this subsection by reason of the non-ap-
13 plication of a requirement described in subpara-
14 graph (B) pursuant to this paragraph if pay-
15 ment for such service would not otherwise be
16 permitted under this subsection if such require-
17 ment were applied.

18 “(F) ELIGIBLE BENEFICIARY DEFINED.—
19 For purposes of this paragraph, the term ‘eligi-
20 ble beneficiary’ means an individual who—

21 “(i) is entitled to, or enrolled for, ben-
22 efits under part A and enrolled for benefits
23 under this part;

24 “(ii) has a diagnosis for a substance
25 use disorder; and

1 “(iii) meets such other criteria as the
2 Secretary determines appropriate.

3 “(G) REPORT.—Not later than 5 years
4 after the date of the enactment of this para-
5 graph, the Secretary shall submit to Congress a
6 report on the impact of any non-application
7 under this paragraph of any of the require-
8 ments described in subparagraph (B) on

9 “(i) the utilization of health care serv-
10 ices related to substance use disorder, such
11 as behavioral health services and emer-
12 gency department visits; and

13 “(ii) health outcomes related to sub-
14 stance use disorder, such as substance use
15 overdose deaths.

16 “(H) FUNDING.—For purposes of carrying
17 out this paragraph, in addition to funds other-
18 wise available, the Secretary shall provide for
19 the transfer, from the Federal Supplementary
20 Medical Insurance Trust Fund under section
21 1841, of \$3,000,000 to the Centers for Medi-
22 care & Medicaid Services Program Management
23 Account to remain available until expended.

24 “(8) RULE OF CONSTRUCTION.—Nothing in
25 this subsection may be construed as waiving require-

1 ments under this title to comply with applicable
2 State law, including State licensure requirements.”.

3 **SEC. 2002. ENCOURAGING THE USE OF NON-OPIOID ANAL-**
4 **GESICS FOR THE MANAGEMENT OF POST-**
5 **SURGICAL PAIN.**

6 Section 1833(t)(6) of the Social Security Act (42
7 U.S.C. 1395l(t)(6)) is amended—

8 (1) in subparagraph (C)(i), by inserting “or, in
9 the case of an eligible non-opioid analgesic (as de-
10 fined in subparagraph (J)), during a period of 5
11 years,” after “3 years,”; and

12 (2) by adding at the end the following new sub-
13 paragraph:

14 “(J) ELIGIBLE NON-OPIOID ANALGESIC
15 DEFINED.—In this paragraph, the term ‘eligible
16 non-opioid analgesic’ means a drug or biologi-
17 cal—

18 “(i) that is an analgesic that is not an
19 opioid;

20 “(ii) that demonstrated substantial
21 clinical improvement, as determined by the
22 Secretary; and

23 “(iii) for which payment—

24 “(I) as an outpatient hospital
25 service under this part was not being

1 made as of the date of the enactment
2 of this subparagraph; or

3 “(II) was being made under this
4 paragraph as of such date.”.

5 **SEC. 2003. REQUIRING A REVIEW OF CURRENT OPIOID PRE-**
6 **SCRIPTIONS FOR CHRONIC PAIN AND**
7 **SCREENING FOR OPIOID USE DISORDER TO**
8 **BE INCLUDED IN THE WELCOME TO MEDI-**
9 **CARE INITIAL PREVENTIVE PHYSICAL EXAM-**
10 **INATION.**

11 (a) IN GENERAL.—Section 1861(ww) of the Social
12 Security Act (42 U.S.C. 1395x(ww)) is amended—

13 (1) in paragraph (1), by inserting “and a re-
14 view of current opioid prescriptions and screening
15 for opioid use disorder (as defined in paragraph
16 (4)),” before “but does not include”; and

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

19 “(4)(A) For purposes of paragraph (1), the term ‘a
20 review of current opioid prescriptions and screening for
21 opioid use disorder’ means, with respect to an individual—

22 “(i) a review by a physician or qualified non-
23 physician practitioner of all current prescriptions of
24 the individual; and

1 “(ii) in the case of an individual determined by
2 the review of a physician or qualified non-physician
3 practitioner under subparagraph (A) to have a cur-
4 rent prescription for opioids for chronic pain that
5 has been prescribed for a minimum period of time
6 (as specified by the Secretary)—

7 “(I) a review by the physician or practi-
8 tioner of the potential risk factors to the indi-
9 vidual for opioid use disorder;

10 “(II) an evaluation by the physician or
11 practitioner of pain of the individual;

12 “(III) the provision of information regard-
13 ing non-opioid treatment options for the treat-
14 ment and management of any chronic pain of
15 the individual; and

16 “(IV) if determined necessary by the physi-
17 cian or practitioner based on the results of the
18 review and evaluation conducted as described in
19 this paragraph, an appropriate referral by the
20 physician or practitioner for additional treat-
21 ment.

22 “(B) For purposes of this paragraph, the term ‘quali-
23 fied non-physician practitioner’ means a physician assist-
24 ant, nurse practitioner, or clinical nurse specialist.”.

1 (b) CLARIFICATION.—Nothing in the amendments
2 made by subsection (a) shall be construed to prohibit sepa-
3 rate payment for structured assessment and intervention
4 services for substance abuse furnished to an individual on
5 the same day as an initial preventive physical examination.

6 (c) EFFECTIVE DATE.—The amendments made by
7 subsection (a) shall apply with respect to initial preventive
8 physical examinations furnished on or after January 1,
9 2020.

10 **SEC. 2004. MODIFICATION OF PAYMENT FOR CERTAIN OUT-**
11 **PATIENT SURGICAL SERVICES.**

12 (a) FREEZE OF PAYMENT FOR CERTAIN SERVICES
13 FURNISHED IN AMBULATORY SURGICAL CENTERS.—Sec-
14 tion 1833(i)(2) of the Social Security Act (42 U.S.C.
15 1395l(i)(2)) is amended by adding at the end the following
16 new subparagraph:

17 “(F)(i) With respect to a targeted procedure
18 (as defined in clause (ii)) furnished during 2020 or
19 a subsequent year (before 2024) to an individual in
20 an ambulatory surgical center, the payment amount
21 for such procedure that would otherwise be deter-
22 mined under the revised payment system under sub-
23 paragraph (D), without application of this subpara-
24 graph, shall be equal to the payment amount for
25 such procedure furnished in 2016.

1 “(ii) For purposes of clause (i), the term ‘tar-
2 geted procedure’ means a procedure to which
3 Healthcare Common Procedure Coding System code
4 62310 (or, for years beginning after 2016, 62321),
5 62311 (or, for years beginning after 2016, 62323),
6 62264, 64490, 64493, or G0260, or any successor
7 code, apply.

8 “(iii) This subparagraph shall not be applied in
9 a budget-neutral manner.”.

10 (b) DATA COLLECTION.—

11 (1) IN GENERAL.—The Comptroller General
12 shall collect data relating to the cost differential be-
13 tween targeted procedures (as defined in section
14 1833(i)(2)(F)(ii) of the Social Security Act, as
15 added by subsection (a)) that are performed in a
16 hospital operating room and such procedures that
17 are performed in an office setting within a hospital
18 in order to determine whether such procedures are
19 being properly coded for claims, based on setting, for
20 payment under section 1833(i)(2)(D) of the Social
21 Security Act (42 U.S.C. 1395l(i)(2)(D)) and to de-
22 termine if further changes are needed in the classi-
23 fication system for covered outpatient department
24 services (as described in section 1833(t)(2)(A) of the
25 Social Security Act (42 U.S.C. 1395l(t)(2)(A)).

1 (2) REPORT.—Not later than 4 years after the
2 date of the enactment of this Act, the Comptroller
3 General shall submit a report to the Committee on
4 Energy and Commerce and the Committee on Ways
5 and Means of the House of Representatives and the
6 Committee on Finance of the Senate containing—

7 (A) a determination of whether procedures
8 described in paragraph (1) are being properly
9 coded for claims, based on setting, for payment
10 under section 1833(i)(2)(D) of the Social Secu-
11 rity Act (42 U.S.C. 1395l(i)(2)(D)); and

12 (B) recommendations on any changes the
13 Comptroller General determines are needed in
14 the classification system for covered outpatient
15 department services (as described in section
16 1833(t)(2)(A) of the Social Security Act (42
17 U.S.C. 1395l(t)(2)(A)).

18 (c) STUDY.—Not later than 3 years after the date
19 of the enactment of this Act, the Secretary of Health and
20 Human Services shall conduct a study and submit to Con-
21 gress a report on the extent to which procedures described
22 in section 1833(i)(2)(F)(ii) of the Social Security Act, as
23 added by subsection (a), are effective at preventing the
24 need for opioids for individuals furnished such procedures.

1 **SEC. 2005. REQUIRING E-PRESCRIBING FOR COVERAGE OF**
2 **COVERED PART D CONTROLLED SUB-**
3 **STANCES.**

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

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

9 “(A) IN GENERAL.—Subject to subpara-
10 graph (B), a prescription for a covered part D
11 drug under a prescription drug plan (or under
12 an MA–PD plan) for a schedule II, III, IV, or
13 V controlled substance shall be transmitted by
14 a health care practitioner electronically in ac-
15 cordance with an electronic prescription drug
16 program that meets the requirements of para-
17 graph (2).

18 “(B) EXCEPTION FOR CERTAIN CIR-
19 CUMSTANCES.—The Secretary shall, pursuant
20 to rulemaking, specify circumstances with re-
21 spect to which the Secretary may waive the re-
22 quirement under subparagraph (A), with re-
23 spect to a covered part D drug, including in the
24 case of—

1 “(i) a prescription issued when the
2 practitioner and dispenser are the same
3 entity;

4 “(ii) a prescription issued that cannot
5 be transmitted electronically under the
6 most recently implemented version of the
7 National Council for Prescription Drug
8 Programs SCRIPT Standard;

9 “(iii) a prescription issued by a practi-
10 tioner who has received a waiver or a re-
11 newal thereof for a specified period deter-
12 mined by the Secretary, not to exceed 1
13 year, from the requirement to use elec-
14 tronic prescribing, pursuant to a process
15 established by regulation by the Secretary,
16 due to demonstrated economic hardship,
17 technological limitations that are not rea-
18 sonably within the control of the practi-
19 tioner, or other exceptional circumstance
20 demonstrated by the practitioner;

21 “(iv) a prescription issued by a practi-
22 tioner under circumstances in which, not-
23 withstanding the practitioner’s ability to
24 submit a prescription electronically as re-
25 quired by this subsection, such practitioner

1 reasonably determines that it would be im-
2 practical for the individual involved to ob-
3 tain substances prescribed by electronic
4 prescription in a timely manner, and such
5 delay would adversely impact the individ-
6 ual’s medical condition involved;

7 “(v) a prescription issued by a practi-
8 tioner allowing for the dispensing of a non-
9 patient specific prescription pursuant to a
10 standing order, approved protocol for drug
11 therapy, collaborative drug management,
12 or comprehensive medication management,
13 in response to a public health emergency,
14 or other circumstances where the practi-
15 tioner may issue a non-patient specific pre-
16 scription;

17 “(vi) a prescription issued by a practi-
18 tioner prescribing a drug under a research
19 protocol;

20 “(vii) a prescription issued by a prac-
21 titioner for a drug for which the Food and
22 Drug Administration requires a prescrip-
23 tion to contain elements that are not able
24 to be included in electronic prescribing,
25 such as a drug with risk evaluation and

1 mitigation strategies that include elements
2 to assure safe use; and

3 “(viii) a prescription issued by a prac-
4 titioner for an individual who—

5 “(I) receives hospice care under
6 this title; or

7 “(II) is a resident of a skilled
8 nursing facility (as defined in section
9 1819(a)), or a medical institution or
10 nursing facility for which payment is
11 made for an institutionalized indi-
12 vidual under section 1902(q)(1)(B),
13 for which frequently abused drugs are
14 dispensed for residents through a con-
15 tract with a single pharmacy, as de-
16 termined by the Secretary in accord-
17 ance with this paragraph.

18 “(C) DISPENSING.—Nothing in this para-
19 graph shall be construed as requiring a sponsor
20 of a prescription drug plan under this part, MA
21 organization offering an MA–PD plan under
22 part C, or a pharmacist to verify that a practi-
23 tioner, with respect to a prescription for a cov-
24 ered part D drug, has a waiver (or is otherwise
25 exempt) under subparagraph (B) from the re-

1 requirement under subparagraph (A). Nothing in
2 this paragraph shall be construed as affecting
3 the ability of the plan to cover or the phar-
4 macists' ability to continue to dispense covered
5 part D drugs from otherwise valid written, oral
6 or fax prescriptions that are consistent with
7 laws and regulations. Nothing in this paragraph
8 shall be construed as affecting the ability of the
9 beneficiary involved to designate a particular
10 pharmacy to dispense a prescribed drug to the
11 extent consistent with the requirements under
12 subsection (b)(1) and under this paragraph.

13 “(D) ENFORCEMENT.—The Secretary
14 shall, pursuant to rulemaking, have authority to
15 enforce and specify appropriate penalties for
16 non-compliance with the requirement under
17 subparagraph (A).”.

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

1 **SEC. 2006. REQUIRING PRESCRIPTION DRUG PLAN SPON-**
2 **SORS UNDER MEDICARE TO ESTABLISH**
3 **DRUG MANAGEMENT PROGRAMS FOR AT-**
4 **RISK BENEFICIARIES.**

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

7 (1) in paragraph (1), by inserting after sub-
8 paragraph (E) the following new subparagraph:

9 “(F) With respect to plan years beginning
10 on or after January 1, 2021, a drug manage-
11 ment program for at-risk beneficiaries described
12 in paragraph (5).”; and

13 (2) in paragraph (5)(A), by inserting “(and for
14 plan years beginning on or after January 1, 2021,
15 a PDP sponsor shall)” after “A PDP sponsor may”.

16 **SEC. 2007. MEDICARE COVERAGE OF CERTAIN SERVICES**
17 **FURNISHED BY OPIOID TREATMENT PRO-**
18 **GRAMS.**

19 (a) **COVERAGE.**—Section 1861(s)(2) of the Social Se-
20 curity Act (42 U.S.C. 1395x(s)(2)) is amended—

21 (1) in subparagraph (FF), by striking at the
22 end “and”;

23 (2) in subparagraph (GG), by inserting at the
24 end “; and”; and

25 (3) by adding at the end the following new sub-
26 paragraph:

1 “(HH) opioid use disorder treatment serv-
2 ices (as defined in subsection (jjj)).”.

3 (b) OPIOID USE DISORDER TREATMENT SERVICES
4 AND OPIOID TREATMENT PROGRAM DEFINED.—Section
5 1861 of the Social Security Act is amended by adding at
6 the end the following new subsection:

7 “(jjj) OPIOID USE DISORDER TREATMENT SERV-
8 ICES; OPIOID TREATMENT PROGRAM.—

9 “(1) OPIOID USE DISORDER TREATMENT SERV-
10 ICES.—The term ‘opioid use disorder treatment serv-
11 ices’ means items and services that are furnished by
12 an opioid treatment program for the treatment of
13 opioid use disorder, including—

14 “(A) opioid agonist and antagonist treat-
15 ment medications (including oral, injected, or
16 implanted versions) that are approved by the
17 Food and Drug Administration under section
18 505 of the Federal Food, Drug and Cosmetic
19 Act for use in the treatment of opioid use dis-
20 order;

21 “(B) dispensing and administration of
22 such medications, if applicable;

23 “(C) substance use counseling by a profes-
24 sional to the extent authorized under State law
25 to furnish such services;

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

5 “(E) toxicology testing, and

6 “(F) other items and services that the Sec-
7 retary determines are appropriate (but in no
8 event to include meals or transportation).

9 “(2) OPIOID TREATMENT PROGRAM.—The term
10 ‘opioid treatment program’ means an entity that is
11 opioid treatment program (as defined in section 8.2
12 of title 42 of the Code of Federal Regulations, or
13 any successor regulation) that—

14 “(A) is enrolled under section 1866(j);

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

18 “(C) is accredited by an accrediting body
19 approved by the Substance Abuse and Mental
20 Health Services Administration; and

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

23 “(i) the health and safety of individ-
24 uals being furnished services under such
25 program; and

1 “(ii) the effective and efficient fur-
2 nishing of such services.”.

3 (c) PAYMENT.—

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

7 (A) by striking “and (BB)” and inserting
8 “(BB)”; and

9 (B) by inserting before the semicolon at
10 the end the following “, and (CC) with respect
11 to opioid use disorder treatment services fur-
12 nished during an episode of care, the amount
13 paid shall be equal to the amount payable under
14 section 1834(w) less any copayment required as
15 specified by the Secretary”.

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

20 “(w) OPIOID USE DISORDER TREATMENT SERV-
21 ICES.—

22 “(1) IN GENERAL.—The Secretary shall pay to
23 an opioid treatment program (as defined in para-
24 graph (2) of section 1861(jjj)) an amount that is
25 equal to 100 percent of a bundled payment under

1 this part for opioid use disorder treatment services
2 (as defined in paragraph (1) of such section) that
3 are furnished by such program to an individual dur-
4 ing an episode of care (as defined by the Secretary)
5 beginning on or after January 1, 2020. The Sec-
6 retary shall ensure, as determined appropriate by
7 the Secretary, that no duplicative payments are
8 made under this part or part D for items and serv-
9 ices furnished by an opioid treatment program.

10 “(2) CONSIDERATIONS.—The Secretary may
11 implement this subsection through one or more bun-
12 dles based on the type of medication provided (such
13 as buprenorphine, methadone, naltrexone, or a new
14 innovative drug), the frequency of services, the scope
15 of services furnished, characteristics of the individ-
16 uals furnished such services, or other factors as the
17 Secretary determine appropriate. In developing such
18 bundles, the Secretary may consider payment rates
19 paid to opioid treatment programs for comparable
20 services under State plans under title XIX or under
21 the TRICARE program under chapter 55 of title 10
22 of the United States Code.

23 “(3) ANNUAL UPDATES.—The Secretary shall
24 provide an update each year to the bundled payment
25 amounts under this subsection.”.

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

4 (1) in paragraph (1), by striking at the end
5 “and”;

6 (2) in paragraph (2), by striking the period at
7 the end and inserting “; and”; and

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

10 “(3) opioid treatment programs (as defined in
11 paragraph (2) of section 1861(jjj)), but only with re-
12 spect to the furnishing of opioid use disorder treat-
13 ment services (as defined in paragraph (1) of such
14 section).”.

15 **TITLE III—OTHER HEALTH PRO-**
16 **VISIONS TO ADDRESS THE**
17 **OPIOID CRISIS**

18 **SEC. 3001. CLARIFYING FDA REGULATION OF NON-ADDICT-**
19 **IVE PAIN AND ADDICTION THERAPIES.**

20 (a) PUBLIC MEETINGS.—Not later than 1 year after
21 the date of enactment of this Act, the Secretary of Health
22 and Human Services, acting through the Commissioner of
23 Food and Drugs, shall hold not less than one public meet-
24 ing to address the challenges and barriers of developing

1 non-addictive medical products intended to treat pain or
2 addiction, which may include—

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

13 (2) the application of eligibility criteria under
14 sections 506 and 515B of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-
16 addictive medical products intended to treat pain or
17 addiction.

18 (b) GUIDANCE.—Not later than 1 year after the pub-
19 lic meetings are conducted under subsection (a) the Sec-
20 retary shall issue one or more final guidance documents,
21 or update existing guidance documents, to help address
22 challenges to developing non-addictive medical products to
23 treat pain or addiction. Such guidance documents shall in-
24 clude information regarding—

1 (1) how the Food and Drug Administration
2 may apply sections 506 and 515B of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 356,
4 360e–3) to non-addictive medical products intended
5 to treat pain or addiction, including the cir-
6 cumstances under which the Secretary—

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

11 (B) considers the risk of addiction of con-
12 trolled substances approved to treat pain when
13 establishing unmet medical need; and

14 (C) considers pain, pain control, or pain
15 management in assessing whether a disease or
16 condition is a serious or life-threatening disease
17 or condition; and

18 (2) the methods by which sponsors may evalu-
19 ate acute and chronic pain, endpoints for non-addict-
20 ive medical products intended to treat pain, the
21 manner in which endpoints and evaluations of effi-
22 cacy will be applied across and within review divi-
23 sions, taking into consideration the etiology of the
24 underlying disease, and the manner in which spon-

1 sors may use surrogate endpoints, intermediate
2 endpoints, and real world evidence.

3 (c) **MEDICAL PRODUCT DEFINED.**—In this section,
4 the term “medical product” means a drug (as defined in
5 section 201(g)(1) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 321(g)(1))), biological product (as
7 defined in section 351(i) of the Public Health Service Act
8 (42 U.S.C. 262(i))), or device (as defined in section
9 201(h) of the Federal Food, Drug, and Cosmetic Act (21
10 U.S.C. 321(h))).

11 **SEC. 3002. SURVEILLANCE AND TESTING OF OPIOIDS TO**
12 **PREVENT FENTANYL DEATHS.**

13 (a) **PUBLIC HEALTH LABORATORIES TO DETECT**
14 **FENTANYL.**—Part F of title III of the Public Health Serv-
15 ice Act (42 U.S.C. 262 et seq.) is amended—

16 (1) in the heading of part F, by striking “AND
17 CLINICAL LABORATORIES” and inserting “, CLIN-
18 ICAL LABORATORIES, AND PUBLIC HEALTH LAB-
19 ORATORIES”; and

20 (2) by adding at the end the following new sub-
21 part:

1 **“Subpart 4—Public Health Laboratories**

2 **“SEC. 355. PUBLIC HEALTH LABORATORIES TO DETECT**
3 **FENTANYL.**

4 “(a) IN GENERAL.—The Secretary shall establish a
5 program to award grants to Federal, State, and local
6 agencies to support the establishment or operation of pub-
7 lic health laboratories to detect fentanyl, its analogues,
8 and other synthetic opioids, as described in subsection (b).

9 “(b) STANDARDS.—The Secretary, in consultation
10 with the Director of the National Institute of Standards
11 and Technology, shall—

12 “(1) develop standards for safely and effectively
13 handling and testing fentanyl, its analogues, and
14 other synthetic opioids;

15 “(2) develop fentanyl and fentanyl analog ref-
16 erence materials and quality control standards and
17 protocols to calibrate instrumentation for clinical
18 diagnostics and postmortem surveillance; and

19 “(3) include in the standards developed pursu-
20 ant to paragraph (1) procedures for encountering
21 new and emerging synthetic opioid formulations and
22 reporting those findings to other Federal, State, and
23 local public health laboratories.

24 “(c) LABORATORIES.—The Secretary shall require
25 grantees under subsection (a) to—

1 “(1) follow the standards established under
2 subsection (b) and be capable of providing system-
3 atic and routine laboratory testing of drugs for the
4 purposes of obtaining and disseminating public
5 health information to Federal, State, and local pub-
6 lic health officials, laboratories, and other entities
7 the Secretary deems appropriate;

8 “(2) work with law enforcement agencies and
9 public health authorities, as feasible, to develop real-
10 time information on the purity and movement of
11 fentanyl, its analogues, and other synthetic opioids;

12 “(3) assist State and local law enforcement
13 agencies in testing seized drugs when State and local
14 forensic laboratories request additional assistance;

15 “(4) provide early warning information and ad-
16 vice to Federal, State, and local law enforcement
17 agencies and public health authorities regarding po-
18 tential significant changes in the supply of fentanyl,
19 its analogues, and other synthetic opioids;

20 “(5) provide biosurveillance for non-fatal expo-
21 sures; and

22 “(6) provide diagnostic testing for non-fatal ex-
23 posures of emergency personnel.

24 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
25 carry out this section, there is authorized to be appro-

1 priated \$15,000,000 for each of fiscal years 2019 through
2 2023.”.

3 (b) ENHANCED FENTANYL SURVEILLANCE.—Title
4 III of the Public Health Service Act is amended by insert-
5 ing after section 317T of such Act (42 U.S.C. 247b–22)
6 the following new section:

7 **“SEC. 317U. ENHANCED FENTANYL SURVEILLANCE.**

8 “(a) IN GENERAL.—The Director of the Centers for
9 Disease Control and Prevention shall enhance its drug
10 surveillance program by—

11 “(1) expanding its surveillance program to in-
12 clude all 50 States and the territories of the United
13 States;

14 “(2) increasing and accelerating the collection
15 of data on fentanyl, its analogues, and other syn-
16 thetic opioids and new emerging drugs of abuse, in-
17 cluding related overdose data from medical exam-
18 iners and drug treatment admissions; and

19 “(3) utilizing available and emerging informa-
20 tion on fentanyl, its analogues, and other synthetic
21 opioids and new emerging drugs of abuse, including
22 information from—

23 “(A) the National Drug Early Warning
24 System;

1 “(3) based on such metrics, conduct an annual
2 evaluation of the pilot program and submit an an-
3 nual report to the Congress containing the results of
4 such evaluation.

5 “(b) AUTHORIZATION OF APPROPRIATIONS.—To
6 carry out this section, there is authorized to be appro-
7 priated \$5,000,000 for each of fiscal years 2019 through
8 2023.”.

9 **SEC. 3003. ALLOWING FOR MORE FLEXIBILITY WITH RE-**
10 **SPECT TO MEDICATION-ASSISTED TREAT-**
11 **MENT FOR OPIOID USE DISORDERS.**

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

16 “(II) The applicable number is—

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

23 “(bb) 100 if the practitioner holds addi-
24 tional credentialing, as defined in section 8.2 of

1 title 42, Code of Federal Regulations (or suc-
2 cessor regulations); or

3 “(cc) 100 if the practitioner provides medi-
4 cation-assisted treatment (MAT) using covered
5 medications (as such terms are defined in sec-
6 tion 8.2 of title 42, Code of Federal Regula-
7 tions (or successor regulations)) in a qualified
8 practice setting (as described in section 8.615
9 of title 42, Code of Federal Regulations (or suc-
10 cessor regulations)).”.

11 (b) ELIMINATING ANY TIME LIMITATION FOR NURSE
12 PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BE-
13 COME QUALIFYING PRACTITIONERS.—Clause (iii) of sec-
14 tion 303(g)(2)(G) of the Controlled Substances Act (21
15 U.S.C. 823(g)(2)(G)) is amended—

16 (1) in subclause (I), by striking “or” at the
17 end; and

18 (2) by amending subclause (II) to read as fol-
19 lows:

20 “(II) a qualifying other practitioner, as de-
21 fined in clause (iv), who is a nurse practitioner
22 or physician assistant; or”.

23 (c) IMPOSING A TIME LIMITATION FOR CLINICAL
24 NURSE SPECIALISTS, CERTIFIED REGISTERED NURSE
25 ANESTHETISTS, AND CERTIFIED NURSE MIDWIVES TO

1 BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of
2 section 303(g)(2)(G) of the Controlled Substances Act (21
3 U.S.C. 823(g)(2)(G)), as amended by subsection (b), is
4 further amended by adding at the end the following:

5 “(III) for the period beginning on October
6 1, 2018, and ending on October 1, 2023, a
7 qualifying other practitioner, as defined in
8 clause (iv), who is a clinical nurse specialist,
9 certified registered nurse anesthetist, or cer-
10 tified nurse midwife.”.

11 (d) DEFINITION OF QUALIFYING OTHER PRACTI-
12 TIONER.—Section 303(g)(2)(G)(iv) of the Controlled Sub-
13 stances Act (21 U.S.C. 823(g)(2)(G)(iv)) is amended by
14 striking “nurse practitioner or physician assistant” each
15 place it appears and inserting “nurse practitioner, clinical
16 nurse specialist, certified registered nurse anesthetist, cer-
17 tified nurse midwife, or physician assistant”.

18 (e) REPORT BY SECRETARY.—Not later than 2 years
19 after the date of the enactment of this Act, the Secretary
20 of Health and Human Services, in consultation with the
21 Drug Enforcement Administration, shall submit to Con-
22 gress a report that assesses the care provided by quali-
23 fying practitioners (as defined in section 303(g)(2)(G)(iii)
24 of the Controlled Substances Act (21 U.S.C.
25 823(g)(2)(G)(iii))) who are treating, in the case of physi-

1 cians, more than 100 patients, and in the case of quali-
2 fying practitioners who are not physicians, more than 30
3 patients. Such report shall include recommendations on
4 future applicable patient number levels and limits. In pre-
5 paring such report, the Secretary shall study, with respect
6 to opioid use disorder treatment—

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

9 (2) the average frequency with which patients
10 receive counseling, including the rates by which such
11 counseling is provided by such a qualifying practi-
12 tioner directly, or by referral;

13 (3) the frequency of toxicology testing, includ-
14 ing the average frequency with which random toxi-
15 cology testing is administered;

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

18 (5) the treatment retention rates for patients;

19 (6) overdose and mortality rates; and

20 (7) any available information regarding the di-
21 version of drugs by patients receiving such treat-
22 ment from such a qualifying practitioner.

1 **SEC. 3004. HIGH-QUALITY, EVIDENCE-BASED OPIOID AN-**
2 **ALGESIC PRESCRIBING GUIDELINES AND RE-**
3 **PORT.**

4 (a) **GUIDELINES.**—The Commissioner of Food and
5 Drugs shall develop high-quality, evidence-based opioid
6 analgesic prescribing guidelines for the indication-specific
7 treatment of acute pain in the relevant therapeutic areas
8 where such guidelines do not exist.

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

12 (1) conduct a public workshop, open to rep-
13 resentatives of State medical societies and medical
14 boards, various medical specialties including pain
15 medicine specialty societies, patient groups, phar-
16 macists, universities, and others; and

17 (2) provide a period for the submission of com-
18 ments by the public.

19 (c) **REPORT.**—Not later than the date that is 2 years
20 after the date of enactment of this Act, the Commissioner
21 of Food and Drugs shall submit to the Committee on En-
22 ergy and Commerce of the House of Representatives and
23 the Committee on Health, Education, Labor, and Pen-
24 sions of the Senate, and post on the public website of the
25 Food and Drug Administration, a report on how the

1 guidelines under subsection (a) will be utilized to protect
2 the public health.

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

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

8 (2) submit to the committees specified in sub-
9 section (c) and post on the public website of the
10 Food and Drug Administration an updated report
11 under subsection (c).

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

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

20 (2) should not be used by other parties, includ-
21 ing pharmacy benefit management companies, retail
22 or community pharmacies, or public and private
23 payors, for the purposes of restricting, limiting, de-
24 laying, or denying coverage for or access to a pre-
25 scription issued for a legitimate medical purpose by

1 an individual practitioner acting in the usual course
2 of professional practice.

3 (f) DEFINITION.—In this section, the term “evidence-
4 based” means informed by a robust and systemic review
5 of treatment efficacy and clinical evidence.

6 **SEC. 3005. REPORT ON OPIOIDS PRESCRIBING PRACTICES**
7 **FOR PREGNANT WOMEN.**

8 (a) IN GENERAL.—Not later than 180 days after the
9 date of the enactment of this Act, the Secretary of Health
10 and Human Services, in coordination with the Centers for
11 Disease Control and Prevention, the National Institutes
12 of Health, and the Substance Abuse and Mental Health
13 Services Administration shall develop and submit to the
14 Congress a report—

15 (1) on opioids prescribing practices for preg-
16 nant women and recommendations for such prac-
17 tices;

18 (2) that provides recommendations for identi-
19 fying and reducing opioids misuse during pregnancy;

20 (3) on prescription opioid misuse during preg-
21 nancy in urban and rural areas;

22 (4) on prescription opioid use during pregnancy
23 for the purpose of medication-assisted treatment in
24 urban and rural areas;

1 (5) evaluating current utilization of non-opiate
2 pain management practices in place of prescription
3 opioids during pregnancy;

4 (6) providing guidelines encouraging the use of
5 non-opioid pain management practices during preg-
6 nancy when safe and effective; and

7 (7) that provides recommendations for increas-
8 ing public awareness and education of opioid use dis-
9 order in pregnancy, including available treatment re-
10 sources in urban and rural areas.

11 (b) NO ADDITIONAL FUNDS.—No additional funds
12 are authorized to be appropriated for purposes of carrying
13 out subsection (a).

14 **SEC. 3006. GUIDELINES FOR PRESCRIBING NALOXONE.**

15 (a) IN GENERAL.—Not later than 180 days after the
16 date of the enactment of this Act, the Secretary of Health
17 and Human Services shall issue guidelines for prescribing
18 an opioid overdose reversal drug.

19 (b) CONTENTS.—In issuing guidelines under sub-
20 section (a), the Secretary shall address the following:

21 (1) Co-prescribing an opioid overdose reversal
22 drug in conjunction with any prescribed opioid.

23 (2) Dosage safety.

24 (3) Prescribing an opioid overdose reversal drug
25 to an individual other than a patient.

1 (4) Standing orders.

2 (5) Other distribution, education, and safety
3 measures as determined necessary.

4 **SEC. 3007. REQUIRING A SURVEY OF SUBSTANCE USE DIS-**
5 **ORDER TREATMENT PROVIDERS RECEIVING**
6 **FEDERAL FUNDING.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services (in this section referred to as the “Sec-
9 retary”) shall conduct a survey of all entities that receive
10 Federal funding for the purpose of providing substance
11 use disorder treatment services. The survey shall direct
12 such entities to provide the following information:

13 (1) The length of time the entity has provided
14 substance use disorder treatment services.

15 (2) A detailed description of the patient popu-
16 lation served by the entity, including but not limited
17 to the number of patients, type of addictions, geo-
18 graphic area served, as well as gender, racial, ethnic
19 and socioeconomic demographics of such patients.

20 (3) A detailed description of the types of addic-
21 tion for which the entity has the experience, capa-
22 bility, and capacity to provide such services.

23 (4) An explanation of how the entity handles
24 patients requiring treatment for a substance use dis-
25 order that the organization is not able to treat.

1 (5) A description of what is needed, in the opin-
2 ion of the entity, in order to improve the entity's
3 ability to meet the addiction treatment needs of the
4 communities served by that entity.

5 (6) Based on the identified needs of the com-
6 munities served, a description of unmet needs and
7 inadequate services and how such needs and services
8 could be better addressed through additional Fed-
9 eral, State, or local government resources or funding
10 to treat addiction to methamphetamine, crack co-
11 caine, other types of cocaine, heroin, opioids, and
12 other commonly abused drugs.

13 (b) REPORT.—Not later than 1 year after the date
14 of the enactment of this Act, the Secretary shall develop
15 and submit to Congress a plan to direct appropriate re-
16 sources to entities that provide substance use disorder
17 treatment services in order to address inadequacies in
18 services or funding identified through the survey described
19 in subsection (a).

20 **TITLE IV—OFFSETS**

21 **SEC. 4001. PROMOTING VALUE IN MEDICAID MANAGED** 22 **CARE.**

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

1 “(7)(A) With respect to expenditures described in
2 subparagraph (B) that are incurred by a State for any
3 fiscal year after fiscal year 2020 (and before fiscal year
4 2024), in determining the pro rata share to which the
5 United States is equitably entitled under subsection
6 (d)(3), the Secretary shall substitute the Federal medical
7 assistance percentage that applies for such fiscal year to
8 the State under section 1905(b) (without regard to any
9 adjustments to such percentage applicable under such sec-
10 tion or any other provision of law) for the percentage that
11 applies to such expenditures under section 1905(y).

12 “(B) Expenditures described in this subparagraph,
13 with respect to a fiscal year to which subparagraph (A)
14 applies, are expenditures incurred by a State for payment
15 for medical assistance provided to individuals described in
16 subclause (VIII) of section 1902(a)(10)(A)(i) by a man-
17 aged care entity, or other specified entity (as defined in
18 subparagraph (D)(iii)), that are treated as remittances be-
19 cause the State—

20 “(i) has satisfied the requirement of section
21 438.8 of title 42, Code of Federal Regulations (or
22 any successor regulation), by electing—

23 “(I) in the case of a State described in
24 subparagraph (C), to apply a minimum medical
25 loss ratio (as defined in subparagraph (D)(ii))

1 that is at least 85 percent but not greater than
2 the minimum medical loss ratio (as so defined)
3 that such State applied as of May 31, 2018; or

4 “(II) in the case of a State not described
5 in subparagraph (C), to apply a minimum med-
6 ical loss ratio that is equal to 85 percent; and

7 “(ii) recovered all or a portion of the expendi-
8 tures as a result of the entity’s failure to meet such
9 ratio.

10 “(C) For purposes of subparagraph (B), a State de-
11 scribed in this subparagraph is a State that as of May
12 31, 2018, applied a minimum medical loss ratio (as cal-
13 culated under subsection (d) of section 438.8 of title 42,
14 Code of Federal Regulations (as in effect on June 1,
15 2018)) for payment for services provided by entities de-
16 scribed in such subparagraph under the State plan under
17 this title (or a waiver of the plan) that is equal to or great-
18 er than 85 percent.

19 “(D) For purposes of this paragraph:

20 “(i) The term ‘managed care entity’ means a
21 medicaid managed care organization described in
22 section 1932(a)(1)(B)(i).

23 “(ii) The term ‘minimum medical loss ratio’
24 means, with respect to a State, a minimum medical
25 loss ratio (as calculated under subsection (d) of sec-

1 tion 438.8 of title 42, Code of Federal Regulations
2 (as in effect on June 1, 2018)) for payment for serv-
3 ices provided by entities described in subparagraph
4 (B) under the State plan under this title (or a waiv-
5 er of the plan).

6 “(iii) The term ‘other specified entity’ means—

7 “(I) a prepaid inpatient health plan, as de-
8 fined in section 438.2 of title 42, Code of Fed-
9 eral Regulations (or any successor regulation);
10 and

11 “(II) a prepaid ambulatory health plan, as
12 defined in such section (or any successor regu-
13 lation).”.

14 **SEC. 4002. EXTENDING PERIOD OF APPLICATION OF MEDI-**
15 **CARE SECONDARY PAYER RULES FOR INDI-**
16 **VIDUALS WITH END STAGE RENAL DISEASE.**

17 Section 1862(b)(1)(C) of the Social Security Act (42
18 U.S.C. 1395y(b)(1)(C)) is amended—

19 (1) in the last sentence, by inserting “and be-
20 fore January 1, 2020” after “date of enactment of
21 the Balanced Budget Act of 1997”; and

22 (2) by adding at the end the following new sen-
23 tence: “Effective for items and services furnished on
24 or after January 1, 2020 (with respect to periods
25 beginning on or after July 1, 2018), clauses (i) and

1 (ii) shall be applied by substituting ‘33-month’ for
2 ‘12-month’ each place it appears.”.

3 **SEC. 4003. REQUIRING REPORTING BY GROUP HEALTH**
4 **PLANS OF PRESCRIPTION DRUG COVERAGE**
5 **INFORMATION FOR PURPOSES OF IDENTI-**
6 **FYING PRIMARY PAYER SITUATIONS UNDER**
7 **THE MEDICARE PROGRAM.**

8 Clause (i) of section 1862(b)(7)(A) of the Social Se-
9 curity Act (42 U.S.C. 1395y(b)(7)(A)) is amended to read
10 as follows:

11 “(i) secure from the plan sponsor and
12 plan participants such information as the
13 Secretary shall specify for the purpose of
14 identifying situations where the group
15 health plan is or has been—

16 “(I) a primary plan to the pro-
17 gram under this title; or

18 “(II) for calendar quarters begin-
19 ning on or after January 1, 2020, a
20 primary payer with respect to benefits
21 relating to prescription drug coverage
22 under part D; and”.

1 **TITLE V—OTHER MEDICAID**
2 **PROVISIONS**
3 **Subtitle A—Mandatory Reporting**
4 **With Respect to Adult Behav-**
5 **ioral Health Measures**

6 **SEC. 5001. MANDATORY REPORTING WITH RESPECT TO**
7 **ADULT BEHAVIORAL HEALTH MEASURES.**

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

10 (1) in subsection (b)—

11 (A) in paragraph (3)—

12 (i) by striking “Not later than Janu-
13 ary 1, 2013” and inserting the following:

14 “(A) VOLUNTARY REPORTING.—Not later
15 than January 1, 2013”; and

16 (ii) by adding at the end the fol-
17 lowing:

18 “(B) MANDATORY REPORTING WITH RE-
19 SPECT TO BEHAVIORAL HEALTH MEASURES.—

20 Beginning with the State report required under
21 subsection (d)(1) for 2024, the Secretary shall
22 require States to use all behavioral health meas-
23 ures included in the core set of adult health
24 quality measures and any updates or changes to
25 such measures to report information, using the

1 standardized format for reporting information
2 and procedures developed under subparagraph
3 (A), regarding the quality of behavioral health
4 care for Medicaid eligible adults.”; and

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

7 “(C) BEHAVIORAL HEALTH MEASURES.—
8 Beginning with respect to State reports re-
9 quired under subsection (d)(1) for 2024, the
10 core set of adult health quality measures main-
11 tained under this paragraph (and any updates
12 or changes to such measures) shall include be-
13 havioral health measures.”; and

14 (2) in subsection (d)(1)(A)—

15 (A) by striking “the such plan” and insert-
16 ing “such plan”; and

17 (B) by striking “subsection (a)(5)” and in-
18 serting “subsection (b)(5) and, beginning with
19 the report for 2024, all behavioral health meas-
20 ures included in the core set of adult health
21 quality measures maintained under such sub-
22 section (b)(5) and any updates or changes to
23 such measures (as required under subsection
24 (b)(3))”.

1 **Subtitle B—Medicaid IMD**
2 **Additional Info**

3 **SEC. 5011. SHORT TITLE.**

4 This subtitle may be cited as the “Medicaid Institutes
5 for Mental Disease Are Decisive in Delivering Inpatient
6 Treatment for Individuals but Opportunities for Needed
7 Access are Limited without Information Needed about Fa-
8 cility Obligations Act” or the “Medicaid IMD ADDI-
9 TIONAL INFO Act”.

10 **SEC. 5012. MACPAC EXPLORATORY STUDY AND REPORT ON**
11 **INSTITUTIONS FOR MENTAL DISEASES RE-**
12 **QUIREMENTS AND PRACTICES UNDER MED-**
13 **ICAID.**

14 (a) IN GENERAL.—Not later than January 1, 2020,
15 the Medicaid and CHIP Payment and Access Commission
16 established under section 1900 of the Social Security Act
17 (42 U.S.C. 1396) shall conduct an exploratory study,
18 using data from a representative sample of States, and
19 submit to Congress a report on at least the following infor-
20 mation, with respect to services furnished to individuals
21 enrolled under State plans under the Medicaid program
22 under title XIX of such Act (42 U.S.C. 1396 et seq.) (or
23 waivers of such plans) who are patients in institutions for
24 mental diseases and for which payment is made through

1 fee-for-service or managed care arrangements under such
2 State plans (or waivers):

3 (1) A description of such institutions for mental
4 diseases in each such State, including at a min-
5 imum—

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

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

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

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

16 (A) such services provided at such institu-
17 tion;

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

21 (C) the discharge process used by such in-
22 stitution, including any care continuum of rel-
23 evant services or facilities provided or used in
24 such process.

25 (3) A description of—

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

4 (B) any other Medicaid funding sources
5 used by each such State for funding such insti-
6 tutions, such as supplemental payments.

7 (4) A summary of State requirements (such as
8 certification, licensure, and accreditation) applied by
9 each such State to such institutions in order for
10 such institutions to receive payment under the State
11 plan (or waiver) and how each such State deter-
12 mines if such requirements have been met.

13 (5) A summary of State standards (such as
14 quality standards, clinical standards, and facility
15 standards) that such institutions must meet to re-
16 ceive payment under such State plans (or waivers)
17 and how each such State determines if such stand-
18 ards have been met.

19 (6) Recommendations for actions by Congress
20 and the Centers for Medicare & Medicaid Services.
21 such as how State Medicaid programs may improve
22 care and improve standards and including a rec-
23 ommendation for how the Centers for Medicare &
24 Medicaid Services can improve data collection from
25 such programs to address any gaps in information.

1 (b) STAKEHOLDER INPUT.—In carrying out sub-
2 section (a), the Medicaid and CHIP Payment and Access
3 Commission shall seek input from State Medicaid direc-
4 tors and stakeholders, including at a minimum the Sub-
5 stance Abuse and Mental Health Services Administration,
6 Centers for Medicare & Medicaid Services, State Medicaid
7 officials, State mental health authorities, Medicaid bene-
8 ficiary advocates, health care providers, and Medicaid
9 managed care organizations.

10 (c) DEFINITIONS.—In this section:

11 (1) REPRESENTATIVE SAMPLE OF STATES.—
12 The term “representative sample of States” means
13 a non-probability sample in which at least two
14 States are selected based on the knowledge and pro-
15 fessional judgment of the selector.

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

19 (3) INSTITUTION FOR MENTAL DISEASES.—The
20 term “institution for mental diseases” has the mean-
21 ing given such term in section 435.1009 of title 42,
22 Code of Federal Regulations, or any successor regu-
23 lation.

1 **Subtitle C—CHIP Mental Health**
2 **Parity**

3 **SEC. 5021. SHORT TITLE.**

4 This subtitle may be cited as the “CHIP Mental
5 Health Parity Act”.

6 **SEC. 5022. ENSURING ACCESS TO MENTAL HEALTH AND**
7 **SUBSTANCE USE DISORDER SERVICES FOR**
8 **CHILDREN AND PREGNANT WOMEN UNDER**
9 **THE CHILDREN’S HEALTH INSURANCE PRO-**
10 **GRAM.**

11 (a) **IN GENERAL.**—Section 2103(c)(1) of the Social
12 Security Act (42 U.S.C. 1397cc(e)(1)) is amended by add-
13 ing at the end the following new subparagraph:

14 “(E) Mental health and substance use dis-
15 order services (as defined in paragraph (5)).”.

16 (b) **MENTAL HEALTH AND SUBSTANCE USE DIS-**
17 **ORDER SERVICES.**—

18 (1) **IN GENERAL.**—Section 2103(c) of the So-
19 cial Security Act (42 U.S.C. 1397cc(e)) is amend-
20 ed—

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

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

1 “(5) MENTAL HEALTH AND SUBSTANCE USE
2 DISORDER SERVICES.—Regardless of the type of cov-
3 erage elected by a State under subsection (a), child
4 health assistance provided under such coverage for
5 targeted low-income children and, in the case that
6 the State elects to provide pregnancy-related assist-
7 ance under such coverage pursuant to section 2112,
8 such pregnancy-related assistance for targeted low-
9 income women (as defined in section 2112(d))
10 shall—

11 “(A) include coverage of mental health
12 services (including behavioral health treatment)
13 necessary to prevent, diagnose, and treat a
14 broad range of mental health symptoms and
15 disorders, including substance use disorders;
16 and

17 “(B) be delivered in a culturally and lin-
18 guistically appropriate manner.”.

19 (2) CONFORMING AMENDMENTS.—

20 (A) Section 2103(a) of the Social Security
21 Act (42 U.S.C. 1397cc(a)) is amended, in the
22 matter before paragraph (1), by striking “para-
23 graphs (5), (6), and (7)” and inserting “para-
24 graphs (5), (6), (7), and (8)”.

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

3 (i) in paragraph (18), by striking
4 “substance abuse” each place it appears
5 and inserting “substance use”; and

6 (ii) in paragraph (19), by striking
7 “substance abuse” and inserting “sub-
8 stance use”.

9 (C) Section 2110(b)(5)(A)(i) of the Social
10 Security Act (42 U.S.C. 1397jj(b)(5)(A)(i)) is
11 amended by striking “subsection (c)(5)” and in-
12 serting “subsection (c)(6)”.

13 (c) ASSURING ACCESS TO CARE.—Section
14 2102(a)(7)(B) of the Social Security Act (42 U.S.C.
15 1397bb(c)(2)) is amended by striking “section
16 2103(c)(5)” and inserting “paragraphs (5) and (6) of sec-
17 tion 2103(c)”.

18 (d) MENTAL HEALTH SERVICES PARITY.—Subpara-
19 graph (A) of paragraph (7) of section 2103(c) of the So-
20 cial Security Act (42 U.S.C. 1397cc(e)) (as redesignated
21 by subsection (b)(1)) is amended to read as follows:

22 “(A) IN GENERAL.—A State child health
23 plan shall ensure that the financial require-
24 ments and treatment limitations applicable to
25 mental health and substance use disorder serv-

1 ices (as described in paragraph (5)) provided
2 under such plan comply with the requirements
3 of section 2726(a) of the Public Health Service
4 Act in the same manner as such requirements
5 or limitations apply to a group health plan
6 under such section.”.

7 (e) EFFECTIVE DATE.—

8 (1) IN GENERAL.—Subject to paragraph (2),
9 the amendments made by this section shall take ef-
10 fect with respect to child health assistance provided
11 on or after the date that is 1 year after the date of
12 the enactment of this Act.

13 (2) EXCEPTION FOR STATE LEGISLATION.—In
14 the case of a State child health plan under title XXI
15 of the Social Security Act (or a waiver of such plan),
16 which the Secretary of Health and Human Services
17 determines requires State legislation in order for the
18 respective plan (or waiver) to meet any requirement
19 imposed by the amendments made by this section,
20 the respective plan (or waiver) shall not be regarded
21 as failing to comply with the requirements of such
22 title solely on the basis of its failure to meet such
23 an additional requirement before the first day of the
24 first calendar quarter beginning after the close of
25 the first regular session of the State legislature that

1 begins after the date of enactment of this section.
2 For purposes of the previous sentence, in the case
3 of a State that has a 2-year legislative session, each
4 year of the session shall be considered to be a separate
5 regular session of the State legislature.

6 **Subtitle D—Medicaid Reentry**

7 **SEC. 5031. SHORT TITLE.**

8 This subtitle may be cited as the “Medicaid Reentry
9 Act”.

10 **SEC. 5032. PROMOTING STATE INNOVATIONS TO EASE** 11 **TRANSITIONS INTEGRATION TO THE COMMU-** 12 **NITY FOR CERTAIN INDIVIDUALS.**

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

15 (1) **STAKEHOLDER GROUP BEST PRACTICES.—**

16 Not later than 6 months after the date of the enact-
17 ment of this Act, the Secretary of Health and
18 Human Services shall convene a stakeholder group
19 of representatives of managed care organizations,
20 Medicaid beneficiaries, health care providers, the
21 National Association of Medicaid Directors, and
22 other relevant representatives from local, State, and
23 Federal jail and prison systems to develop best prac-
24 tices (and submit to the Secretary and Congress a
25 report on such best practices) for States—

1 (A) to ease the health care-related transi-
2 tion of an individual who is an inmate of a pub-
3 lic institution from the public institution to the
4 community, including best practices for ensur-
5 ing continuity of health insurance coverage or
6 coverage under the State Medicaid plan under
7 title XIX of the Social Security Act, as applica-
8 ble, and relevant social services; and

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

13 (2) STATE MEDICAID PROGRAM INNOVATION.—

14 The Secretary of Health and Human Services shall
15 work with States on innovative strategies to help in-
16 dividuals who are inmates of public institutions and
17 otherwise eligible for medical assistance under the
18 Medicaid program under title XIX of the Social Se-
19 curity Act transition, with respect to enrollment for
20 medical assistance under such program, seamlessly
21 to the community.

22 (b) GUIDANCE ON INNOVATIVE SERVICE DELIVERY
23 SYSTEMS DEMONSTRATION PROJECT OPPORTUNITIES.—

24 Not later than 1 year after the date of the enactment of
25 this Act, the Secretary of Health and Human Services,

1 through the Administrator of the Centers for Medicare &
2 Medicaid Services, shall issue a State Medicaid Director
3 letter, based on best practices developed under subsection
4 (a)(1), regarding opportunities to design demonstration
5 projects under section 1115 of the Social Security Act (42
6 U.S.C. 1315) to improve care transitions for certain indi-
7 viduals who are soon-to-be former inmates of a public in-
8 stitution and who are otherwise eligible to receive medical
9 assistance under title XIX of such Act, including systems
10 for, with respect to a period (not to exceed 30 days) imme-
11 diately prior to the day on which such individuals are ex-
12 pected to be released from such institution—

13 (1) providing assistance and education for en-
14 rollment under a State plan under the Medicaid pro-
15 gram under title XIX of such Act for such individ-
16 uals during such period; and

17 (2) providing health care services for such indi-
18 viduals during such period.

19 (c) **RULE OF CONSTRUCTION.**—Nothing under title
20 XIX of the Social Security Act or any other provision of
21 law precludes a State from reclassifying or suspending
22 (rather than terminating) eligibility of an individual for
23 medical assistance under title XIX of the Social Security
24 Act while such individual is an inmate of a public institu-
25 tion.

1 **Subtitle E—Medicaid Partnership**

2 **SEC. 5041. SHORT TITLE.**

3 This subtitle may be cited as the “Medicaid Providers
4 Are Required To Note Experiences in Record Systems to
5 Help In-need Patients Act” or the “Medicaid PARTNER-
6 SHIP Act”.

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

10 (a) REQUIREMENTS UNDER THE MEDICAID PRO-
11 GRAM RELATING TO QUALIFIED PRESCRIPTION DRUG
12 MONITORING PROGRAMS AND PRESCRIBING CERTAIN
13 CONTROLLED SUBSTANCES.—Title XIX of the Social Se-
14 curity Act (42 U.S.C. 1396 et seq.) is amended by insert-
15 ing after section 1943 the following new section:

16 **“SEC. 1944. REQUIREMENTS RELATING TO QUALIFIED PRE-**
17 **SCRIPTION DRUG MONITORING PROGRAMS**
18 **AND PRESCRIBING CERTAIN CONTROLLED**
19 **SUBSTANCES.**

20 “(a) IN GENERAL.—Beginning October 1, 2021, a
21 State shall, subject to subsection (d), require each covered
22 provider to check, in accordance with such timing, man-
23 ner, and form as specified by the State, the prescription
24 drug history of a covered individual being treated by the
25 covered provider through a qualified prescription drug

1 monitoring program described in subsection (b) before
2 prescribing to such individual a controlled substance.

3 “(b) QUALIFIED PRESCRIPTION DRUG MONITORING
4 PROGRAM DESCRIBED.—A qualified prescription drug
5 monitoring program described in this subsection is, with
6 respect to a State, a prescription drug monitoring pro-
7 gram administered by the State that, at a minimum, satis-
8 fies each of the following criteria:

9 “(1) The program facilitates access by a cov-
10 ered provider to, at a minimum, the following infor-
11 mation with respect to a covered individual, in as
12 close to real-time as possible:

13 “(A) Information regarding the prescrip-
14 tion drug history of a covered individual with
15 respect to controlled substances.

16 “(B) The number and type of controlled
17 substances prescribed to and filled for the cov-
18 ered individual during at least the most recent
19 12-month period.

20 “(C) The name, location, and contact in-
21 formation (or other identifying number selected
22 by the State, such as a national provider identi-
23 fier issued by the National Plan and Provider
24 Enumeration System of the Centers for Medi-
25 care & Medicaid Services) of each covered pro-

1 vider who prescribed a controlled substance to
2 the covered individual during at least the most
3 recent 12-month period.

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

9 A qualified prescription drug monitoring program de-
10 scribed in this subsection, with respect to a State, may
11 have in place, in accordance with applicable State and
12 Federal law, a data sharing agreement with the State
13 Medicaid program that allows the medical director and
14 pharmacy director of such program (and any designee of
15 such a director who reports directly to such director) to
16 access the information described in paragraph (1) in an
17 electronic format. The State Medicaid program under this
18 title may facilitate reasonable and limited access, as deter-
19 mined by the State and ensuring documented beneficiary
20 protections regarding the use of such data, to such quali-
21 fied prescription drug monitoring program for the medical
22 director or pharmacy director of any managed care entity
23 (as defined under section 1932(a)(1)(B)) that has a con-
24 tract with the State under section 1903(m) or under sec-
25 tion 1905(t)(3), or the medical director or pharmacy direc-

1 tor of any entity has a contract to manage the pharma-
2 ceutical benefit with respect to individuals enrolled in the
3 State plan (or waiver of the State plan). All applicable
4 State and Federal security and privacy laws shall apply
5 to the directors or designees of such directors of any State
6 Medicaid program or entity accessing a qualified prescrip-
7 tion drug monitoring program under this section.

8 “(c) APPLICATION OF PRIVACY RULES CLARIFICA-
9 TION.—The Secretary shall clarify privacy requirements,
10 including requirements under the regulations promulgated
11 pursuant to section 264(c) of the Health Insurance Port-
12 ability and Accountability Act of 1996 (42 U.S.C. 1320d-
13 2 note), related to the sharing of data under subsection
14 (b) in the same manner as the Secretary is required under
15 subparagraph (J) of section 1860D-4(c)(5) to clarify pri-
16 vacy requirements related to the sharing of data described
17 in such subparagraph.

18 “(d) ENSURING ACCESS.—In order to ensure reason-
19 able access to health care, the Secretary shall waive the
20 application of the requirement under subsection (a), with
21 respect to a State, in the case of natural disasters and
22 similar situations, and in the case of the provision of emer-
23 gency services (as defined for purposes of section 1860D-
24 4(c)(5)(D)(ii)(II)).

25 “(e) REPORTS.—

1 “(1) STATE REPORTS.—Each State shall in-
2 clude in the annual report submitted to the Sec-
3 retary under section 1927(g)(3)(D), beginning with
4 such reports submitted for 2023, information includ-
5 ing, at a minimum, the following information for the
6 most recent 12-month period:

7 “(A) The percentage of covered providers
8 (as determined pursuant to a process estab-
9 lished by the State) who checked the prescrip-
10 tion drug history of a covered individual
11 through a qualified prescription drug moni-
12 toring program described in subsection (b) be-
13 fore prescribing to such individual a controlled
14 substance.

15 “(B) Aggregate trends with respect to pre-
16 scribing controlled substances such as—

17 “(i) the quantity of daily morphine
18 milligram equivalents prescribed for con-
19 trolled substances;

20 “(ii) the number and quantity of daily
21 morphine milligram equivalents prescribed
22 for controlled substances per covered indi-
23 vidual; and

24 “(iii) the types of controlled sub-
25 stances prescribed, including the dates of

1 such prescriptions, the supplies authorized
2 (including the duration of such supplies),
3 and the period of validity of such prescrip-
4 tions, in different populations (such as in-
5 dividuals who are elderly, individuals with
6 disabilities, and individuals who are en-
7 rolled under both this title and title
8 XVIII).

9 “(C) Whether or not the State requires
10 (and a detailed explanation as to why the State
11 does or does not require) pharmacists to check
12 the prescription drug history of a covered indi-
13 vidual through a qualified drug management
14 program before dispensing a controlled sub-
15 stance to such individual.

16 “(2) REPORT BY CMS.—Not later than October
17 1, 2023, the Administrator of the Centers for Medi-
18 care & Medicaid Services shall publish on the pub-
19 licly available website of the Centers for Medicare &
20 Medicaid Services a report including the following
21 information:

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

1 “(B) Best practices for how States and
2 covered providers should use such qualified pre-
3 scription drug monitoring programs to reduce
4 the occurrence of abuse of controlled sub-
5 stances.

6 “(f) INCREASE TO FEDERAL MATCHING RATE FOR
7 CERTAIN EXPENDITURES RELATING TO QUALIFIED PRE-
8 SCRIPTION DRUG MANAGEMENT PROGRAMS.—The Sec-
9 retary shall increase the Federal medical assistance per-
10 centage or Federal matching rate that would otherwise
11 apply to a State under section 1903(a) for a calendar
12 quarter occurring during the period beginning October 1,
13 2018, and ending September 30, 2021, for expenditures
14 by the State for activities under the State plan (or waiver
15 of the State plan) to implement a prescription drug man-
16 agement program that satisfies the criteria described in
17 paragraphs (1) and (2) of subsection (b) if the State (in
18 this subsection referred to as the ‘administering State’)
19 has in place agreements with all States that are contig-
20 uous to such administering State that, when combined, en-
21 able covered providers in all such contiguous States to ac-
22 cess, through the prescription drug management program,
23 the information that is described in subsection (b)(1) of
24 covered individuals of such administering State and that
25 covered providers in such administering State are able to

1 access through such program. In no case shall an increase
2 under this subsection result in a Federal medical assist-
3 ance percentage or Federal matching rate that exceeds
4 100 percent.

5 “(g) RULE OF CONSTRUCTION.—Nothing in this sec-
6 tion prevents a State from requiring pharmacists to check
7 the prescription drug history of covered individuals
8 through a qualified drug management program before dis-
9 pensing controlled substances to such individuals.

10 “(h) DEFINITIONS.—In this section:

11 “(1) CONTROLLED SUBSTANCE.—The term
12 ‘controlled substance’ means a drug that is included
13 in schedule II of section 202(c) of the Controlled
14 Substances Act and, at the option of the State in-
15 volved, a drug included in schedule III or IV of such
16 section.

17 “(2) COVERED INDIVIDUAL.—The term ‘cov-
18 ered individual’ means, with respect to a State, an
19 individual who is enrolled in the State plan (or
20 under a waiver of such plan). Such term does not in-
21 clude an individual who—

22 “(A) is receiving—

23 “(i) hospice or palliative care; or

24 “(ii) treatment for cancer;

1 “(B) is a resident of a long-term care facil-
2 ity, of a facility described in section 1905(d), or
3 of another facility for which frequently abused
4 drugs are dispensed for residents through a
5 contract with a single pharmacy; or

6 “(C) the State elects to treat as exempted
7 from such term.

8 “(3) COVERED PROVIDER.—

9 “(A) IN GENERAL.—The term ‘covered
10 provider’ means, subject to subparagraph (B),
11 with respect to a State, a health care provider
12 who is participating under the State plan (or
13 waiver of the State plan) and licensed, reg-
14 istered, or otherwise permitted by the State to
15 prescribe a controlled substance (or the des-
16 ignee of such provider).

17 “(B) EXCEPTIONS.—

18 “(i) IN GENERAL.—Beginning Octo-
19 ber 1, 2021, for purposes of this section,
20 such term does not include a health care
21 provider included in any type of health
22 care provider determined by the Secretary
23 to be exempt from application of this sec-
24 tion under clause (ii).

1 “(ii) EXCEPTIONS PROCESS.—Not
2 later than October 1, 2020, the Secretary,
3 after consultation with the National Asso-
4 ciation of Medicaid Directors, national
5 health care provider associations, Medicaid
6 beneficiary advocates, and advocates for in-
7 dividuals with rare diseases, shall deter-
8 mine, based on such consultations, the
9 types of health care providers (if any) that
10 should be exempted from the definition of
11 the term ‘covered provider’ for purposes of
12 this section.”.

13 (b) GUIDANCE.—Not later than October 1, 2019, the
14 Administrator of the Centers for Medicare & Medicaid
15 Services, in consultation with the Director of the Centers
16 for Disease Control and Prevention, shall issue guidance
17 on best practices on the uses of prescription drug moni-
18 toring programs required of prescribers and on protecting
19 the privacy of Medicaid beneficiary information main-
20 tained in and accessed through prescription drug moni-
21 toring programs.

22 (c) DEVELOPMENT OF MODEL STATE PRACTICES.—

23 (1) IN GENERAL.—Not later than October 1,
24 2020, the Secretary of Health and Human Services
25 shall develop and publish model practices to assist

1 State Medicaid program operations in identifying
2 and implementing strategies to utilize data sharing
3 agreements described in the matter following para-
4 graph (2) of section 1944(b) of the Social Security
5 Act, as added by subsection (a), for the following
6 purposes:

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

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

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

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

17 (iii) pay for prescription drugs with
18 cash.

19 (C) Any other purposes specified by the
20 Secretary.

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

23 (A) shall include strategies for assisting
24 States in allowing the medical director or phar-
25 macy director (or designees of such a director)

1 of managed care organizations or pharma-
2 ceutical benefit managers to access information
3 with respect to all covered individuals served by
4 such managed care organizations or pharma-
5 ceutical benefit managers to access as a single
6 data set, in an electronic format; and

7 (B) shall include any appropriate bene-
8 ficiary protections and privacy guidelines.

9 (3) CONSULTATION.—In developing model prac-
10 tices under this subsection, the Secretary shall con-
11 sult with the National Association of Medicaid Di-
12 rectors, managed care entities (as defined in section
13 1932(a)(1)(B) of the Social Security Act) with con-
14 tracts with States pursuant to section 1903(m) of
15 such Act, pharmaceutical benefit managers, physi-
16 cians and other health care providers, beneficiary
17 advocates, and individuals with expertise in health
18 care technology related to prescription drug moni-
19 toring programs and electronic health records.

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

1 **TITLE VI—OTHER MEDICARE**
2 **PROVISIONS**

3 **Subtitle A—Testing of Incentive**
4 **Payments for Behavioral Health**
5 **Providers for Adoption and Use**
6 **of Certified Electronic Health**
7 **Record Technology**

8 **SEC. 6001. TESTING OF INCENTIVE PAYMENTS FOR BEHAV-**
9 **IORAL HEALTH PROVIDERS FOR ADOPTION**
10 **AND USE OF CERTIFIED ELECTRONIC**
11 **HEALTH RECORD TECHNOLOGY.**

12 Section 1115A(b)(2)(B) of the Social Security Act
13 (42 U.S.C. 1315a(b)(2)(B)) is amended by adding at the
14 end the following new clause:

15 “(xxv) Providing, for the adoption and
16 use of certified EHR technology (as de-
17 fined in section 1848(o)(4)) to improve the
18 quality and coordination of care through
19 the electronic documentation and exchange
20 of health information, incentive payments
21 to behavioral health providers (such as
22 psychiatric hospitals (as defined in section
23 1861(f)), community mental health centers
24 (as defined in section 1861(ff)(3)(B)), hos-
25 pitals that participate in a State plan

1 under title XIX or a waiver of such plan,
 2 treatment facilities that participate in such
 3 a State plan or such a waiver, mental
 4 health or substance use disorder providers
 5 that participate in such a State plan or
 6 such a waiver, clinical psychologists (as de-
 7 fined in section 1861(ii)), nurse practi-
 8 tioners (as defined in section 1861(aa)(5))
 9 with respect to the provision of psychiatric
 10 services, and clinical social workers (as de-
 11 fined in section 1861(hh)(1)).”.

12 **Subtitle B—Abuse Deterrent Access**

13 **SEC. 6011. SHORT TITLE.**

14 This subtitle may be cited at the “Abuse Deterrent
 15 Access Act of 2018”.

16 **SEC. 6012. STUDY ON ABUSE-DETERRENT OPIOID FORMU- 17 LATIONS ACCESS BARRIERS UNDER MEDI- 18 CARE.**

19 (a) IN GENERAL.—Not later than 1 year after the
 20 date of the enactment of this Act, the Secretary of Health
 21 and Human Services shall conduct a study and submit to
 22 Congress a report on the adequacy of access to abuse-de-
 23 terrent opioid formulations for individuals with chronic
 24 pain enrolled in an MA–PD plan under part C of title
 25 XVIII of the Social Security Act or a prescription drug

1 plan under part D of such title of such Act, taking into
 2 account any barriers preventing such individuals from ac-
 3 ccessing such formulations under such MA–PD or part D
 4 plans, such as cost-sharing tiers, fail-first requirements,
 5 the price of such formulations, and prior authorization re-
 6 quirements.

7 (b) DEFINITION OF ABUSE-DETERRENT OPIOID FOR-
 8 MULATION.—In this section, the term “abuse-deterrent
 9 opioid formulation” means an opioid that is a prodrug or
 10 that has certain abuse-deterrent properties, such as phys-
 11 ical or chemical barriers, agonist or antagonist combina-
 12 tions, aversion properties, delivery system mechanisms, or
 13 other features designed to prevent abuse of such opioid.

14 **Subtitle C—Medicare Opioid Safety**
 15 **Education**

16 **SEC. 6021. SHORT TITLE.**

17 This subtitle may be cited as the “Medicare Opioid
 18 Safety Education Act of 2018”.

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

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

1 “(d) The notice provided under subsection (a) shall
2 include—

3 “(1) educational resources, compiled by the Sec-
4 retary, regarding opioid use and pain management;
5 and

6 “(2) a description of alternative, non-opioid
7 pain management treatments covered under this
8 title.”.

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

13 **Subtitle D—Opioid Addiction** 14 **Action Plan**

15 **SEC. 6031. SHORT TITLE.**

16 This subtitle may be cited as the “Opioid Addiction
17 Action Plan Act”.

18 **SEC. 6032. ACTION PLAN ON RECOMMENDATIONS FOR** 19 **CHANGES UNDER MEDICARE AND MEDICAID** 20 **TO PREVENT OPIOIDS ADDICTIONS AND EN-** 21 **HANCE ACCESS TO MEDICATION-ASSISTED** 22 **TREATMENT.**

23 (a) IN GENERAL.—Not later than January 1, 2019,
24 the Secretary of Health and Human Services (in this sec-
25 tion referred to as the “Secretary”), in collaboration with

1 the Pain Management Best Practices Inter-Agency Task
2 Force convened under section 101(b) of the Comprehen-
3 sive Addiction and Recovery Act of 2016 (Public Law
4 114–198), shall develop an action plan that provides rec-
5 ommendations described in subsection (b).

6 (b) ACTION PLAN COMPONENTS.—Recommendations
7 described in this subsection are, based on an examination
8 by the Secretary of potential obstacles to an effective re-
9 sponse to the opioid crisis, recommendations, as deter-
10 mined appropriate by the Secretary, on the following:

11 (1) Recommendations on changes to the Medi-
12 care program under title XVIII of the Social Secu-
13 rity Act and the Medicaid program under title XIX
14 of such Act that would enhance coverage and pay-
15 ment under such programs of all medication-assisted
16 treatment approved by the Food and Drug Adminis-
17 tration for the treatment of opioid addiction and
18 other therapies that manage chronic and acute pain
19 and treat and minimize risk of opioid addiction, in-
20 cluding recommendations on changes to the Medi-
21 care prospective payment system for hospital inpa-
22 tient department services under section 1886(d) of
23 such Act (42 U.S.C. 1395ww(d)) and the Medicare
24 prospective payment system for hospital outpatient
25 department services under section 1833(t) of such

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

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

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

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

1 and other therapies that manage chronic and acute
2 pain and treatment and minimize risk of opioid ad-
3 diction.

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

13 (c) STAKEHOLDER MEETINGS.—

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

20 (2) PARTICIPANTS.—Participants of meetings
21 described in paragraph (1) shall include representa-
22 tives from the Food and Drug Administration and
23 National Institutes of Health, biopharmaceutical in-
24 dustry members, medical researchers, health care
25 providers, the medical device industry, the Medicare

1 program, the Medicaid program, and patient advo-
2 cates.

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

10 (e) REPORT TO CONGRESS.—Not later than June 1,
11 2019, the Secretary shall submit to Congress, and make
12 public, a report that includes—

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

15 (2) the Secretary’s planned next steps with re-
16 spect to the action plan; and

17 (3) an evaluation of price trends for drugs used
18 to reverse opioid overdoses (such as naloxone), in-
19 cluding recommendations on ways to lower such
20 prices for consumers.

21 (f) DEFINITION OF MEDICATION-ASSISTED TREAT-
22 MENT.—In this section, the term “medication-assisted
23 treatment” includes opioid treatment programs, behav-
24 ioral therapy, and medications to treat substance abuse
25 disorder.

1 **Subtitle E—Advancing High Qual-**
2 **ity Treatment for Opioid Use**
3 **Disorders in Medicare**

4 **SEC. 6041. SHORT TITLE.**

5 This subtitle may be cited as the “Advancing High
6 Quality Treatment for Opioid Use Disorders in Medicare
7 Act”.

8 **SEC. 6042. OPIOID USE DISORDER TREATMENT DEM-**
9 **ONSTRATION PROGRAM.**

10 Title XVIII of the Social Security Act (42 U.S.C.
11 1395 et seq.) is amended by inserting after section 1866E
12 (42 U.S.C. 1395cc–5) the following new section:

13 **“SEC. 1866F. OPIOID USE DISORDER TREATMENT DEM-**
14 **ONSTRATION PROGRAM.**

15 “(a) IMPLEMENTATION OF 4-YEAR DEMONSTRATION
16 PROGRAM.—

17 “(1) IN GENERAL.—Not later than January 1,
18 2021, the Secretary shall implement a 4-year dem-
19 onstration program under this title (in this section
20 referred to as the ‘Program’) to increase access of
21 applicable beneficiaries to opioid use disorder treat-
22 ment services, improve physical and mental health
23 outcomes for such beneficiaries, and to the extent
24 possible, reduce expenditures under this title. Under
25 the Program, the Secretary shall make payments

1 under subsection (e) to participants (as defined in
2 subsection (c)(1)(A)) for furnishing opioid use dis-
3 order treatment services delivered through opioid use
4 disorder care teams, or arranging for such services
5 to be furnished, to applicable beneficiaries partici-
6 pating in the Program.

7 “(2) OPIOID USE DISORDER TREATMENT SERV-
8 ICES.—For purposes of this section, the term ‘opioid
9 use disorder treatment services’—

10 “(A) means, with respect to an applicable
11 beneficiary, services that are furnished for the
12 treatment of opioid use disorders and that uti-
13 lize drugs approved under section 505 of the
14 Federal Food, Drug, and Cosmetic Act for the
15 treatment of opioid use disorders in an out-
16 patient setting; and

17 “(B) includes—

18 “(i) medication assisted treatment;

19 “(ii) treatment planning;

20 “(iii) psychiatric, psychological, or
21 counseling services (or any combination of
22 such services), as appropriate;

23 “(iv) social support services, as appro-
24 priate; and

1 “(v) care management and care co-
2 ordination services, including coordination
3 with other providers of services and sup-
4 pliers not on an opioid use disorder care
5 team.

6 “(b) PROGRAM DESIGN.—

7 “(1) IN GENERAL.—The Secretary shall design
8 the Program in such a manner to allow for the eval-
9 uation of the extent to which the Program accom-
10 plishes the following purposes:

11 “(A) Reduces hospitalizations and emer-
12 gency department visits.

13 “(B) Increases use of medication-assisted
14 treatment for opioid use disorders.

15 “(C) Improves health outcomes of individ-
16 uals with opioid use disorders, including by re-
17 ducing the incidence of infectious diseases (such
18 as hepatitis C and HIV).

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

21 “(E) Reduces deaths from opioid overdose.

22 “(F) Reduces the utilization of inpatient
23 residential treatment.

24 “(2) CONSULTATION.—In designing the Pro-
25 gram, including the criteria under subsection

1 (e)(2)(A), the Secretary shall, not later than 3
2 months after the date of the enactment of this sec-
3 tion, consult with specialists in the field of addiction,
4 clinicians in the primary care community, and bene-
5 ficiary groups.

6 “(c) PARTICIPANTS; OPIOID USE DISORDER CARE
7 TEAMS.—

8 “(1) PARTICIPANTS.—

9 “(A) DEFINITION.—In this section, the
10 term ‘participant’ means an entity or indi-
11 vidual—

12 “(i) that is otherwise enrolled under
13 this title and that is—

14 “(I) a physician (as defined in
15 section 1861(r)(1));

16 “(II) a group practice comprised
17 of at least one physician described in
18 subclause (I);

19 “(III) a hospital outpatient de-
20 partment;

21 “(IV) a federally qualified health
22 center (as defined in section
23 1861(aa)(4));

24 “(V) a rural health clinic (as de-
25 fined in section 1861(aa)(2));

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

4 “(VII) a clinic certified as a cer-
5 tified community behavioral health
6 clinic pursuant to section 223 of the
7 Protecting Access to Medicare Act of
8 2014; or

9 “(VIII) any other individual or
10 entity specified by the Secretary;

11 “(ii) that applied for and was selected
12 to participate in the Program pursuant to
13 an application and selection process estab-
14 lished by the Secretary; and

15 “(iii) that establishes an opioid use
16 disorder care team (as defined in para-
17 graph (2)) through employing or con-
18 tracting with health care practitioners de-
19 scribed in paragraph (2)(A), and uses such
20 team to furnish or arrange for opioid use
21 disorder treatment services in the out-
22 patient setting under the Program.

23 “(B) PREFERENCE.—In selecting partici-
24 pants for the Program, the Secretary shall give
25 preference to individuals and entities that are

1 located in areas with a prevalence of opioid use
2 disorders that is higher than the national aver-
3 age prevalence.

4 “(2) OPIOID USE DISORDER CARE TEAMS.—

5 “(A) IN GENERAL.—For purposes of this
6 section, the term ‘opioid use disorder care team’
7 means a team of health care practitioners es-
8 tablished by a participant described in para-
9 graph (1)(A) that—

10 “(i) shall include—

11 “(I) at least one physician (as
12 defined in section 1861(r)(1)) fur-
13 nishing primary care services or ad-
14 diction treatment services to an appli-
15 cable beneficiary; and

16 “(II) at least one eligible practi-
17 tioner (as defined in paragraph
18 (3)(A)), who may be a physician who
19 meets the criterion in subclause (I);
20 and

21 “(ii) may include other practitioners
22 licensed under State law to furnish psy-
23 chiatric, psychological, counseling, and so-
24 cial services to applicable beneficiaries.

1 “(B) REQUIREMENTS FOR RECEIPT OF
2 PAYMENT UNDER PROGRAM.—In order to re-
3 ceive payments under subsection (e), each par-
4 ticipant in the Program shall—

5 “(i) furnish opioid use disorder treat-
6 ment services through opioid use disorder
7 care teams to applicable beneficiaries who
8 agree to receive the services;

9 “(ii) meet minimum criteria, as estab-
10 lished by the Secretary; and

11 “(iii) submit to the Secretary, in such
12 form, manner, and frequency as specified
13 by the Secretary, with respect to each ap-
14 plicable beneficiary for whom opioid use
15 disorder treatment services are furnished
16 by the opioid use disorder care team, data
17 and such other information as the Sec-
18 retary determines appropriate to—

19 “(I) monitor and evaluate the
20 Program;

21 “(II) determine if minimum cri-
22 teria are met under clause (ii); and

23 “(III) determine the incentive
24 payment under subsection (e).

1 “(3) ELIGIBLE PRACTITIONERS; OTHER PRO-
2 VIDER-RELATED DEFINITIONS AND APPLICATION
3 PROVISIONS.—

4 “(A) ELIGIBLE PRACTITIONERS.—For pur-
5 poses of this section, the term ‘eligible practi-
6 tioner’ means a physician or other health care
7 practitioner, such as a nurse practitioner,
8 that—

9 “(i) is enrolled under section
10 1866(j)(1);

11 “(ii) is authorized to prescribe or dis-
12 pense narcotic drugs to individuals for
13 maintenance treatment or detoxification
14 treatment; and

15 “(iii) has in effect a waiver in accord-
16 ance with section 303(g) of the Controlled
17 Substances Act for such purpose and is
18 otherwise in compliance with regulations
19 promulgated by the Substance Abuse and
20 Mental Health Services Administration to
21 carry out such section.

22 “(B) ADDICTION SPECIALISTS.—For pur-
23 poses of subsection (e)(1)(B)(iv), the term ‘ad-
24 diction specialist’ means a physician that pos-
25 sesses expert knowledge and skills in addiction

1 medicine, as evidenced by appropriate certifi-
2 cation from a specialty body, a certificate of ad-
3 vanced qualification in addiction medicine, or
4 completion of an accredited residency or fellow-
5 ship in addiction medicine or addiction psychi-
6 atry, as determined by the Secretary.

7 “(d) PARTICIPATION OF APPLICABLE BENE-
8 FICIARIES.—

9 “(1) APPLICABLE BENEFICIARY DEFINED.—In
10 this section, the term ‘applicable beneficiary’ means
11 an individual who—

12 “(A) is entitled to, or enrolled for, benefits
13 under part A and enrolled for benefits under
14 part B;

15 “(B) is not enrolled in a Medicare Advan-
16 tage plan under part C;

17 “(C) has a current diagnosis for an opioid
18 use disorder; and

19 “(D) meets such other criteria as the Sec-
20 retary determines appropriate.

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

1 “(2) VOLUNTARY BENEFICIARY PARTICIPATION;
2 LIMITATION ON NUMBER OF BENEFICIARIES.—An
3 applicable beneficiary may participate in the Pro-
4 gram on a voluntary basis and may terminate par-
5 ticipation in the Program at any time. Not more
6 than 20,000 applicable beneficiaries may participate
7 in the Program at any time.

8 “(3) SERVICES.—In order to participate in the
9 Program, an applicable beneficiary shall agree to re-
10 ceive opioid use disorder treatment services from a
11 participant. Participation under the Program shall
12 not affect coverage of or payment for any other item
13 or service under this title for the applicable bene-
14 ficiary.

15 “(4) BENEFICIARY ACCESS TO SERVICES.—
16 Nothing in this section shall be construed as encour-
17 aging providers to limit applicable beneficiary access
18 to services covered under this title and applicable
19 beneficiaries shall not be required to relinquish ac-
20 cess to any benefit under this title as a condition of
21 receiving services from a participant in the Program.

22 “(e) PAYMENTS.—

23 “(1) PER APPLICABLE BENEFICIARY PER
24 MONTH CARE MANAGEMENT FEE.—

1 “(A) IN GENERAL.—The Secretary shall
2 establish a schedule of per applicable bene-
3 ficiary per month care management fees. Such
4 a per applicable beneficiary per month care
5 management fee shall be paid to a participant
6 in addition to any other amount otherwise pay-
7 able under this title to the health care practi-
8 tioners in the participant’s opioid use disorder
9 care team or, if applicable, to the participant.
10 A participant may use such per applicable bene-
11 ficiary per month care management fee to de-
12 liver additional services to applicable bene-
13 ficiaries, including services not otherwise eligi-
14 ble for payment under this title.

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

17 “(i) consider payments otherwise pay-
18 able under this title for opioid use disorder
19 treatment services and the needs of appli-
20 cable beneficiaries;

21 “(ii) pay a higher per applicable bene-
22 ficiary per month care management fee for
23 an applicable beneficiary who receives more
24 intensive treatment services from a partici-
25 pant and for whom those services are ap-

1 appropriate based on clinical guidelines for
2 opioid use disorder care;

3 “(iii) pay a higher per applicable ben-
4 eficiary per month care management fee
5 for the month in which the applicable ben-
6 eficiary begins treatment with a partici-
7 pant than in subsequent months, to reflect
8 the greater time and costs required for the
9 planning and initiation of treatment, as
10 compared to maintenance of treatment;

11 “(iv) pay higher per applicable bene-
12 ficiary per month care management fees
13 for participants that have established
14 opioid use disorder care teams that include
15 an addiction specialist (as defined in sub-
16 section (c)(3)(B)); and

17 “(v) take into account whether a par-
18 ticipant’s opioid use disorder care team re-
19 fers applicable beneficiaries to other sup-
20 pliers or providers for any opioid use dis-
21 order treatment services.

22 “(C) NO DUPLICATE PAYMENT.—The Sec-
23 retary shall make payments under this para-
24 graph to only one participant for services fur-

1 nished to an applicable beneficiary during a cal-
2 endar month.

3 “(2) INCENTIVE PAYMENTS.—

4 “(A) IN GENERAL.—Under the Program,
5 the Secretary shall establish a performance-
6 based incentive payment, which shall be paid
7 (using a methodology established and at a time
8 determined appropriate by the Secretary) to
9 participants based on the performance of par-
10 ticipants with respect to criteria, as determined
11 appropriate by the Secretary, in accordance
12 with subparagraph (B).

13 “(B) CRITERIA.—

14 “(i) IN GENERAL.—Criteria described
15 in subparagraph (A) may include consider-
16 ation of the following:

17 “(I) Patient engagement and re-
18 tention in treatment.

19 “(II) Evidence-based medication-
20 assisted treatment.

21 “(III) Other criteria established
22 by the Secretary.

23 “(ii) REQUIRED CONSULTATION AND
24 CONSIDERATION.—In determining criteria

1 described in subparagraph (A), the Sec-
2 retary shall—

3 “(I) consult with stakeholders,
4 including clinicians in the primary
5 care community and in the field of ad-
6 diction medicine; and

7 “(II) consider existing clinical
8 guidelines for the treatment of opioid
9 use disorders.

10 “(C) NO DUPLICATE PAYMENT.—The Sec-
11 retary shall ensure that no duplicate payments
12 under this paragraph are made with respect to
13 an applicable beneficiary.

14 “(f) MULTIPAYER STRATEGY.—In carrying out the
15 Program, the Secretary shall encourage other payers to
16 provide similar payments and to use similar criteria as ap-
17 plied under the Program under subsection (e)(2)(C). The
18 Secretary may enter into a memorandum of understanding
19 with other payers to align the methodology for payment
20 provided by such a payer related to opioid use disorder
21 treatment services with such methodology for payment
22 under the Program.

23 “(g) EVALUATION.—

24 “(1) IN GENERAL.—The Secretary shall con-
25 duct an intermediate and final evaluation of the pro-

1 gram. Each such evaluation shall determine the ex-
2 tent to which each of the purposes described in sub-
3 section (b) have been accomplished under the Pro-
4 gram.

5 “(2) REPORTS.—The Secretary shall submit to
6 the Secretary and Congress—

7 “(A) a report with respect to the inter-
8 mediate evaluation under paragraph (1) not
9 later than 3 years after the date of the imple-
10 mentation of the Program; and

11 “(B) a report with respect to the final
12 evaluation under paragraph (1) not later than
13 6 years after such date.

14 “(h) FUNDING.—

15 “(1) ADMINISTRATIVE FUNDING.—For the pur-
16 poses of implementing, administering, and carrying
17 out the Program (other than for purposes described
18 in paragraph (2)), \$5,000,000 shall be available
19 from the Federal Supplementary Medical Insurance
20 Trust Fund under section 1841.

21 “(2) CARE MANAGEMENT FEES AND INCEN-
22 TIVES.—For the purposes of making payments
23 under subsection (e), \$10,000,000 shall be available
24 from the Federal Supplementary Medical Insurance

1 Trust Fund under section 1841 for each of fiscal
2 years 2021 through 2024.

3 “(3) AVAILABILITY.—Amounts transferred
4 under this subsection for a fiscal year shall be avail-
5 able until expended.

6 “(i) WAIVERS.—The Secretary may waive any provi-
7 sion of this title as may be necessary to carry out the Pro-
8 gram under this section.”.

9 **Subtitle F—Responsible Education**
10 **Achieves Care and Healthy Out-**
11 **comes for Users’ Treatment**

12 **SEC. 6051. SHORT TITLE.**

13 This subtitle may be cited as the “Responsible Edu-
14 cation Achieves Care and Healthy Outcomes for Users’
15 Treatment Act of 2018” or the “REACH OUT Act of
16 2018”.

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

19 (a) GRANTS AUTHORIZED.—The Secretary of Health
20 and Human Services (in this section referred to as the
21 “Secretary”) shall, through the Centers for Medicare &
22 Medicaid Services, award grants, contracts, or cooperative
23 agreements to eligible entities for the purposes described
24 in subsection (b).

1 (b) USE OF FUNDS.—Grants, contracts, and coopera-
2 tive agreements awarded under subsection (a) shall be
3 used to support eligible entities through technical assist-
4 ance—

5 (1) to educate and provide outreach to outlier
6 prescribers of opioids about best practices for pre-
7 scribing opioids;

8 (2) to educate and provide outreach to outlier
9 prescribers of opioids about non-opioid pain manage-
10 ment therapies; and

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

13 (c) APPLICATION.—Each eligible entity seeking to re-
14 ceive a grant, contract, or cooperative agreement under
15 subsection (a) shall submit to the Secretary an applica-
16 tion, at such time, in such manner, and containing such
17 information as the Secretary may require.

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

22 (e) DEFINITIONS.—In this section:

23 (1) ELIGIBLE ENTITY.—The term “eligible enti-
24 ty” means—

25 (A) an organization—

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

5 (ii) that has at least—

6 (I) one individual who is a rep-
7 resentative of consumers on its gov-
8 erning body; and

9 (II) one individual who is a rep-
10 resentative of health care providers on
11 its governing body; or

12 (B) an entity that is a quality improve-
13 ment entity with a contract under part B of
14 title XI of the Social Security Act (42 U.S.C.
15 1320c et seq.).

16 (2) OUTLIER PRESCRIBER OF OPIOIDS.—The
17 term “outlier prescriber of opioids” means a pre-
18 scriber, identified by the Secretary of Health and
19 Human Services (through use of prescriber informa-
20 tion provided by prescriber National Provider Identifi-
21 fiers included pursuant to section 1860D–4(c)(4)(A)
22 of the Social Security Act (42 U.S.C. 1395w–
23 104(c)(4)(A)) on claims for covered part D drugs for
24 part D eligible individuals enrolled in prescription
25 drug plans under part D of title XVIII of such Act

1 (42 U.S.C. 1395w–101 et seq.) and MA–PD plans
2 under part C of such title (42 U.S.C. 1395w–21 et
3 seq.)) as prescribing, as compared to other pre-
4 scribers in the specialty of the prescriber and geo-
5 graphic area, amounts of opioids in excess of a
6 threshold (and other criteria) specified by the Sec-
7 retary, after consultation with stakeholders.

8 (3) PRESCRIBERS.—The term “prescriber”
9 means any health care professional, including a
10 nurse practitioner or physician assistant, who is li-
11 censed to prescribe opioids by the State or territory
12 in which such professional practices.

13 (f) FUNDING.—For purposes of implementing this
14 section, \$75,000,000 shall be available from the Federal
15 Supplementary Medical Insurance Trust Fund under sec-
16 tion 1841 of the Social Security Act (42 U.S.C. 1395t),
17 to remain available until expended.

18 **Subtitle G—Preventing Addiction** 19 **for Susceptible Seniors**

20 **SEC. 6061. SHORT TITLE.**

21 This subtitle may be cited as the “Preventing Addic-
22 tion for Susceptible Seniors Act of 2018” or the “PASS
23 Act of 2018”.

1 **SEC. 6062. ELECTRONIC PRIOR AUTHORIZATION FOR COV-**
2 **ERED PART D DRUGS.**

3 (a) INCLUSION IN ELECTRONIC PRESCRIPTION PRO-
4 GRAM.—Section 1860D–4(e)(2) of the Social Security Act
5 (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the
6 end the following new subparagraph:

7 “(E) ELECTRONIC PRIOR AUTHORIZA-
8 TION.—

9 “(i) IN GENERAL.—Not later than
10 January 1, 2021, the program shall pro-
11 vide for the secure electronic transmission
12 of—

13 “(I) a prior authorization request
14 from the prescribing health care pro-
15 fessional for coverage of a covered
16 part D drug for a part D eligible indi-
17 vidual enrolled in a part D plan (as
18 defined in section 1860D–23(a)(5)) to
19 the PDP sponsor or Medicare Advan-
20 tage organization offering such plan;
21 and

22 “(II) a response, in accordance
23 with this subparagraph, from such
24 PDP sponsor or Medicare Advantage
25 organization, respectively, to such pro-
26 fessional.

1 “(ii) ELECTRONIC TRANSMISSION.—

2 “(I) EXCLUSIONS.—For purposes
3 of this subparagraph, a facsimile, a
4 proprietary payer portal that does not
5 meet standards specified by the Sec-
6 retary, or an electronic form shall not
7 be treated as an electronic trans-
8 mission described in clause (i).

9 “(II) STANDARDS.—In order to
10 be treated, for purposes of this sub-
11 paragraph, as an electronic trans-
12 mission described in clause (i), such
13 transmission shall comply with tech-
14 nical standards adopted by the Sec-
15 retary in consultation with the Na-
16 tional Council for Prescription Drug
17 Programs, other standard setting or-
18 ganizations determined appropriate by
19 the Secretary, and stakeholders in-
20 cluding PDP sponsors, Medicare Ad-
21 vantage organizations, health care
22 professionals, and health information
23 technology software vendors.

24 “(III) APPLICATION.—Notwith-
25 standing any other provision of law,

1 for purposes of this subparagraph, the
2 Secretary may require the use of such
3 standards adopted under subclause
4 (II) in lieu of any other applicable
5 standards for an electronic trans-
6 mission described in clause (i) for a
7 covered part D drug for a part D eli-
8 gible individual.”.

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

12 (1) there should be increased use of electronic
13 prior authorizations for coverage of covered part D
14 drugs for part D eligible individuals enrolled in pre-
15 scription drug plans under part D of title XVIII of
16 the Social Security Act and MA–PD plans under
17 part C of such title to reduce access delays by re-
18 solving coverage issues before prescriptions for such
19 drugs are transmitted; and

20 (2) greater priority should be placed on increas-
21 ing the adoption of use of such electronic prior au-
22 thorizations among prescribers of such drugs, phar-
23 macies, PDP sponsors, and Medicare Advantage or-
24 ganizations.

1 **SEC. 6063. PROGRAM INTEGRITY TRANSPARENCY MEAS-**
2 **URES UNDER MEDICARE PARTS C AND D.**

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

6 “(i) PROGRAM INTEGRITY TRANSPARENCY MEAS-
7 URES.—

8 “(1) PROGRAM INTEGRITY PORTAL.—

9 “(A) IN GENERAL.—Not later than 2 years
10 after the date of the enactment of this sub-
11 section, the Secretary shall, after consultation
12 with stakeholders, establish a secure Internet
13 website portal (or other successor technology)
14 that would allow a secure path for communica-
15 tion between the Secretary, MA plans under
16 this part, prescription drug plans under part D,
17 and an eligible entity with a contract under sec-
18 tion 1893 (such as a Medicare drug integrity
19 contractor or an entity responsible for carrying
20 out program integrity activities under this part
21 and part D) for the purpose of enabling
22 through such portal (or other successor tech-
23 nology)—

24 “(i) the referral by such plans of sub-
25 stantiated fraud, waste, and abuse for ini-

1 tiating or assisting investigations con-
2 ducted by the eligible entity; and

3 “(ii) data sharing among such MA
4 plans, prescription drug plans, and the
5 Secretary.

6 “(B) REQUIRED USES OF PORTAL.—The
7 Secretary shall disseminate the following infor-
8 mation to MA plans under this part and pre-
9 scription drug plans under part D through the
10 secure Internet website portal (or other suc-
11 cessor technology) established under subpara-
12 graph (A):

13 “(i) Providers of services and sup-
14 pliers that have been referred pursuant to
15 subparagraph (A)(i) during the previous
16 12-month period.

17 “(ii) Providers of services and sup-
18 pliers who are the subject of an active ex-
19 clusion under section 1128 or who are sub-
20 ject to a suspension of payment under this
21 title pursuant to section 1862(o) or other-
22 wise.

23 “(iii) Providers of services and sup-
24 pliers who are the subject of an active rev-
25 ocation of participation under this title, in-

1 cluding for not satisfying conditions of par-
2 ticipation.

3 “(iv) In the case of such a plan that
4 makes a referral under subparagraph
5 (A)(i) through the portal (or other suc-
6 cessor technology) with respect to activities
7 of substantiated fraud, waste, or abuse of
8 a provider of services or supplier, if such
9 provider or supplier has been the subject of
10 an administrative action under this title or
11 title XI with respect to similar activities, a
12 notification to such plan of such action so
13 taken.

14 “(C) RULEMAKING.—For purposes of this
15 paragraph, the Secretary shall, through rule-
16 making, specify what constitutes substantiated
17 fraud, waste, and abuse, using guidance such as
18 what is provided in the Medicare Program In-
19 tegrity Manual 4.7.1. In carrying out this sub-
20 section, a fraud hotline tip (as defined by the
21 Secretary) without further evidence shall not be
22 treated as sufficient evidence for substantiated
23 fraud, waste, or abuse.

24 “(D) HIPAA COMPLIANT INFORMATION
25 ONLY.—For purposes of this subsection, com-

1 communications may only occur if the communica-
2 tions are permitted under the Federal regula-
3 tions (concerning the privacy of individually
4 identifiable health information) promulgated
5 under section 264(e) of the Health Insurance
6 Portability and Accountability Act of 1996.

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

19 “(A) include administrative actions, perti-
20 nent information related to opioid overpre-
21 scribing, and other data determined appropriate
22 by the Secretary in consultation with stake-
23 holders; and

1 “(B) be anonymized information submitted
2 by plans without identifying the source of such
3 information.

4 “(3) CLARIFICATION.—Nothing in this sub-
5 section shall be construed as precluding or otherwise
6 affecting referrals described in subparagraph (A)
7 that may otherwise be made to law enforcement en-
8 tities or to the Secretary.”.

9 (b) CONTRACT REQUIREMENT TO COMMUNICATE
10 PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRE-
11 SCRIBERS.—Section 1857(e) of the Social Security Act
12 (42 U.S.C. 1395w–27(e)) is amended by adding at the end
13 the following new paragraph:

14 “(5) COMMUNICATING PLAN CORRECTIVE AC-
15 TIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

16 “(A) IN GENERAL.—Beginning with plan
17 years beginning on or after January 1, 2021, a
18 contract under this section with an MA organi-
19 zation shall require the organization to submit
20 to the Secretary, through the process estab-
21 lished under subparagraph (B), information on
22 the investigations and other actions taken by
23 such plans related to providers of services who
24 prescribe a high volume of opioids.

1 “(B) PROCESS.—Not later than January
2 1, 2021, the Secretary shall, in consultation
3 with stakeholders, establish a process under
4 which MA plans and prescription drug plans
5 shall submit to the Secretary information de-
6 scribed in subparagraph (A).

7 “(C) REGULATIONS.—For purposes of this
8 paragraph, including as applied under section
9 1860D–12(b)(3)(D), the Secretary shall, pursu-
10 ant to rulemaking—

11 “(i) specify a definition for the term
12 ‘high volume of opioids’ and a method for
13 determining if a provider of services pre-
14 scribes such a high volume; and

15 “(ii) establish the process described in
16 subparagraph (B) and the types of infor-
17 mation that shall be submitted through
18 such process.”.

19 (c) REFERENCE UNDER PART D TO PROGRAM IN-
20 TEGRITY TRANSPARENCY MEASURES.—Section 1860D–4
21 of the Social Security Act (42 U.S.C. 1395w–104) is
22 amended by adding at the end the following new sub-
23 section:

24 “(m) PROGRAM INTEGRITY TRANSPARENCY MEAS-
25 URES.—For program integrity transparency measures ap-

1 plied with respect to prescription drug plan and MA plans,
2 see section 1859(i).”.

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

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

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

11 (2) by striking “are part D eligible individuals
12 who—” and inserting “are the following:

13 “(I) Part D eligible individuals
14 who—”; and

15 (3) by adding at the end the following new sub-
16 clause:

17 “(II) Beginning January 1,
18 2021, at-risk beneficiaries for pre-
19 scription drug abuse (as defined in
20 paragraph (5)(C)).”.

21 **SEC. 6065. MEDICARE NOTIFICATIONS TO OUTLIER PRE-**
22 **SCRIBERS OF OPIOIDS.**

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

1 “(D) OUTLIER PRESCRIBER NOTIFICA-
2 TION.—

3 “(i) NOTIFICATION.—Beginning not
4 later than 2 years after the date of the en-
5 actment of this subparagraph, the Sec-
6 retary shall, in the case of a prescriber
7 identified by the Secretary under clause
8 (ii) to be an outlier prescriber of opioids,
9 provide, subject to clause (iv), an annual
10 notification to such prescriber that such
11 prescriber has been so identified and that
12 includes resources on proper prescribing
13 methods and other information specified in
14 accordance with clause (iii).

15 “(ii) IDENTIFICATION OF OUTLIER
16 PRESCRIBERS OF OPIOIDS.—

17 “(I) IN GENERAL.—The Sec-
18 retary shall, subject to subclause (III),
19 using the valid prescriber National
20 Provider Identifiers included pursuant
21 to subparagraph (A) on claims for
22 covered part D drugs for part D eligi-
23 ble individuals enrolled in prescription
24 drug plans under this part or MA-PD
25 plans under part C and based on the

1 threshold established under subclause
2 (II), conduct an analysis to identify
3 prescribers that are outlier opioid pre-
4 scribers for a period specified by the
5 Secretary.

6 “(II) ESTABLISHMENT OF
7 THRESHOLD.—For purposes of sub-
8 clause (I) and subject to subclause
9 (III), the Secretary shall, after con-
10 sultation with stakeholders, establish
11 a threshold, based on prescriber spe-
12 cialty and geographic area, for identi-
13 fying whether a prescriber in a spe-
14 cialty and geographic area is an
15 outlier prescriber of opioids as com-
16 pared to other prescribers of opioids
17 within such specialty and area.

18 “(III) EXCLUSIONS.—The Sec-
19 retary may exclude the following indi-
20 viduals and prescribers from the anal-
21 ysis under this clause:

22 “(aa) Individuals receiving
23 hospice services.

24 “(bb) Individuals with a
25 cancer diagnosis.

1 “(cc) Prescribers who are
2 the subject of an investigation by
3 the Centers for Medicare & Med-
4 icaid Services or the Office of In-
5 spector General of the Depart-
6 ment of Health and Human
7 Services.

8 “(iii) CONTENTS OF NOTIFICATION.—
9 The Secretary shall, based on input from
10 stakeholders, specify the resources and
11 other information to be included in notifi-
12 cations provided under clause (i).

13 “(iv) MODIFICATIONS AND EXPAN-
14 SIONS.—

15 “(I) FREQUENCY.—Beginning 5
16 years after the date of the enactment
17 of this subparagraph, the Secretary
18 may change the frequency of the noti-
19 fications described in clause (i) based
20 on stakeholder input.

21 “(II) EXPANSION TO OTHER
22 PRESCRIPTIONS.—The Secretary may
23 expand notifications under this sub-
24 paragraph to include identifications
25 and notifications with respect to con-

1 current prescriptions of covered Part
2 D drugs used in combination with
3 opioids that are considered to have
4 adverse side effects when so used in
5 such combination, as determined by
6 the Secretary.

7 “(v) OPIOIDS DEFINED.—For pur-
8 poses of this subparagraph, the term
9 ‘opioids’ has such meaning as specified by
10 the Secretary through program instruction
11 or otherwise.”.

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

13 No additional funds are authorized to be appro-
14 priated to carry out the requirements of this subtitle and
15 the amendments made by this subtitle. Such requirements
16 shall be carried out using amounts otherwise authorized
17 to be appropriated.

18 **Subtitle H—Expanding Oversight**
19 **of Opioid Prescribing and Payment**

20 **SEC. 6071. SHORT TITLE.**

21 This subtitle may be cited as the “Expanding Over-
22 sight of Opioid Prescribing and Payment Act of 2018”.

1 **SEC. 6072. MEDICARE PAYMENT ADVISORY COMMISSION**
2 **REPORT ON OPIOID PAYMENT, ADVERSE IN-**
3 **CENTIVES, AND DATA UNDER THE MEDICARE**
4 **PROGRAM.**

5 Not later than March 15, 2019, the Medicare Pay-
6 ment Advisory Commission shall submit to Congress a re-
7 port on, with respect to the Medicare program under title
8 XVIII of the Social Security Act, the following:

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

13 (2) The identification of incentives under the
14 hospital inpatient prospective payment system under
15 section 1886 of the Social Security Act (42 U.S.C.
16 1395ww) and incentives under the hospital out-
17 patient prospective payment system under section
18 1833(t) of such Act (42 U.S.C. 1395l(t)) for pre-
19 scribing opioids and incentives under each such sys-
20 tem for prescribing non-opioid treatments, and rec-
21 ommendations as the Commission deems appropriate
22 for addressing any of such incentives that are ad-
23 verse incentives.

24 (3) A description of how opioid use is tracked
25 and monitored through Medicare claims data and
26 other mechanisms and the identification of any areas

1 in which further data and methods are needed for
2 improving data and understanding of opioid use.

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

4 No additional funds are authorized to be appro-
5 priated to carry out the requirements of this subtitle. Such
6 requirements shall be carried out using amounts otherwise
7 authorized to be appropriated.

8 **Subtitle I—Dr. Todd Graham Pain**
9 **Management, Treatment, and**
10 **Recovery**

11 **SEC. 6081. SHORT TITLE.**

12 This subtitle may be cited as the “Dr. Todd Graham
13 Pain Management, Treatment, and Recovery Act of
14 2018”.

15 **SEC. 6082. REVIEW AND ADJUSTMENT OF PAYMENTS**
16 **UNDER THE MEDICARE OUTPATIENT PRO-**
17 **SPECTIVE PAYMENT SYSTEM TO AVOID FI-**
18 **NANCIAL INCENTIVES TO USE OPIOIDS IN-**
19 **STEAD OF NON-OPIOID ALTERNATIVE TREAT-**
20 **MENTS.**

21 (a) OUTPATIENT PROSPECTIVE PAYMENT SYS-
22 TEM.—Section 1833(t) of the Social Security Act (42
23 U.S.C. 1395l(t)) is amended by adding at the end the fol-
24 lowing new paragraph:

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

3 “(A) IN GENERAL.—With respect to pay-
4 ments made under this subsection for covered
5 OPD services (or groups of services), including
6 covered OPD services assigned to a comprehen-
7 sive ambulatory payment classification, the Sec-
8 retary—

9 “(i) shall, as soon as practicable, con-
10 duct a review (part of which may include
11 a request for information) of payments for
12 opioids and evidence-based non-opioid al-
13 ternatives for pain management (including
14 drugs and devices, nerve blocks, surgical
15 injections, and neuromodulation) with a
16 goal of ensuring that there are not finan-
17 cial incentives to use opioids instead of
18 non-opioid alternatives;

19 “(ii) may, as the Secretary determines
20 appropriate, conduct subsequent reviews of
21 such payments; and

22 “(iii) shall consider the extent to
23 which revisions under this subsection to
24 such payments (such as the creation of ad-
25 ditional groups of covered OPD services to

1 classify separately those procedures that
2 utilize opioids and non-opioid alternatives
3 for pain management) would reduce pay-
4 ment incentives to use opioids instead of
5 non-opioid alternatives for pain manage-
6 ment.

7 “(B) PRIORITY.—In conducting the review
8 under clause (i) of subparagraph (A) and con-
9 sidering revisions under clause (iii) of such sub-
10 paragraph, the Secretary shall focus on covered
11 OPD services (or groups of services) assigned
12 to a comprehensive ambulatory payment classi-
13 fication, ambulatory payment classifications
14 that primarily include surgical services, and
15 other services determined by the Secretary
16 which generally involve treatment for pain man-
17 agement.

18 “(C) REVISIONS.—If the Secretary identi-
19 fies revisions to payments pursuant to subpara-
20 graph (A)(iii), the Secretary shall, as deter-
21 mined appropriate, begin making such revisions
22 for services furnished on or after January 1,
23 2020. Revisions under the previous sentence
24 shall be treated as adjustments for purposes of
25 application of paragraph (9)(B).

1 “(D) RULES OF CONSTRUCTION.—Nothing
2 in this paragraph shall be construed to preclude
3 the Secretary—

4 “(i) from conducting a demonstration
5 before making the revisions described in
6 subparagraph (C); or

7 “(ii) prior to implementation of this
8 paragraph, from changing payments under
9 this subsection for covered OPD services
10 (or groups of services) which include
11 opioids or non-opioid alternatives for pain
12 management.”.

13 (b) AMBULATORY SURGICAL CENTERS.—Section
14 1833(i) of the Social Security Act (42 U.S.C. 1395l(i))
15 is amended by adding at the end the following new para-
16 graph:

17 “(8) The Secretary shall conduct a similar type of
18 review as required under paragraph (22) of section
19 1833(t)), including the second sentence of subparagraph
20 (C) of such paragraph, to payment for services under this
21 subsection, and make such revisions under this paragraph,
22 in an appropriate manner (as determined by the Sec-
23 retary).”.

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

5 (a) **FEDERALLY QUALIFIED HEALTH CENTERS.**—
6 Section 1834(o) of the Social Security Act (42 U.S.C.
7 1395m(o)) is amended by adding at the end the following
8 new paragraph:

9 “(3) **ADDITIONAL PAYMENTS FOR CERTAIN**
10 **FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS**
11 **RECEIVING DATA 2000 WAIVERS.**—

12 “(A) **IN GENERAL.**—In the case of a Fed-
13 erally qualified health center with respect to
14 which, beginning on or after January 1, 2019,
15 Federally-qualified health center services (as de-
16 fined in section 1861(aa)(3)) are furnished for
17 the treatment of opioid use disorder by a physi-
18 cian or practitioner who meets the requirements
19 described in subparagraph (C) the Secretary
20 shall, subject to availability of funds under sub-
21 paragraph (D), make a payment (at such time
22 and in such manner as specified by the Sec-
23 retary) to such Federally qualified health center
24 after receiving and approving an application
25 submitted by such Federally qualified health
26 center under subparagraph (B). Such a pay-

1 ment shall be in an amount determined by the
2 Secretary, based on an estimate of the average
3 costs of training for purposes of receiving a
4 waiver described in subparagraph (C)(ii). Such
5 a payment may be made only one time with re-
6 spect to each such physician or practitioner.

7 “(B) APPLICATION.—In order to receive a
8 payment described in subparagraph (A), a Fed-
9 erally-qualified health center shall submit to the
10 Secretary an application for such a payment at
11 such time, in such manner, and containing such
12 information as specified by the Secretary. A
13 Federally-qualified health center may apply for
14 such a payment for each physician or practi-
15 tioner described in subparagraph (A) furnishing
16 services described in such subparagraph at such
17 center.

18 “(C) REQUIREMENTS.—For purposes of
19 subparagraph (A), the requirements described
20 in this subparagraph, with respect to a physi-
21 cian or practitioner, are the following:

22 “(i) The physician or practitioner is
23 employed by or working under contract
24 with a Federally qualified health center de-

1 scribed in subparagraph (A) that submits
2 an application under subparagraph (B).

3 “(ii) The physician or practitioner
4 first receives a waiver under section 303(g)
5 of the Controlled Substances Act on or
6 after January 1, 2019.

7 “(D) FUNDING.—For purposes of making
8 payments under this paragraph, there are ap-
9 propriated, out of amounts in the Treasury not
10 otherwise appropriated, \$6,000,000, which shall
11 remain available until expended.”.

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

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

17 (2) by adding at the end the following new sub-
18 section:

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

22 “(1) IN GENERAL.—In the case of a rural
23 health clinic with respect to which, beginning on or
24 after January 1, 2019, rural health clinic services
25 (as defined in section 1861(aa)(1)) are furnished for

1 the treatment of opioid use disorder by a physician
2 or practitioner who meets the requirements de-
3 scribed in paragraph (3), the Secretary shall, subject
4 to availability of funds under paragraph (4), make
5 a payment (at such time and in such manner as
6 specified by the Secretary) to such rural health clinic
7 after receiving and approving an application de-
8 scribed in paragraph (2). Such payment shall be in
9 an amount determined by the Secretary, based on an
10 estimate of the average costs of training for pur-
11 poses of receiving a waiver described in paragraph
12 (3)(B). Such payment may be made only one time
13 with respect to each such physician or practitioner.

14 “(2) APPLICATION.—In order to receive a pay-
15 ment described in paragraph (1), a rural health clin-
16 ic shall submit to the Secretary an application for
17 such a payment at such time, in such manner, and
18 containing such information as specified by the Sec-
19 retary. A rural health clinic may apply for such a
20 payment for each physician or practitioner described
21 in paragraph (1) furnishing services described in
22 such paragraph at such clinic.

23 “(3) REQUIREMENTS.—For purposes of para-
24 graph (1), the requirements described in this para-

1 graph, with respect to a physician or practitioner,
2 are the following:

3 “(A) The physician or practitioner is em-
4 ployed by or working under contract with a
5 rural health clinic described in paragraph (1)
6 that submits an application under paragraph
7 (2).

8 “(B) The physician or practitioner first re-
9 ceives a waiver under section 303(g) of the
10 Controlled Substances Act or after January
11 1, 2019.

12 “(4) FUNDING.—For purposes of making pay-
13 ments under this subsection, there are appropriated,
14 out of amounts in the Treasury not otherwise appro-
15 priated, \$2,000,000, which shall remain available
16 until expended.”.

17 **SEC. 6084. STUDYING THE AVAILABILITY OF SUPPLE-**
18 **MENTAL BENEFITS DESIGNED TO TREAT OR**
19 **PREVENT SUBSTANCE USE DISORDERS**
20 **UNDER MEDICARE ADVANTAGE PLANS.**

21 (a) IN GENERAL.—Not later than 2 years after the
22 date of the enactment of this Act, the Secretary of Health
23 and Human Services (in this section referred to as the
24 “Secretary”) shall submit to Congress a report on the
25 availability of supplemental health care benefits (as de-

1 scribed in section 1852(a)(3)(A) of the Social Security Act
2 (42 U.S.C. 1395w-22(a)(3)(A))) designed to treat or pre-
3 vent substance use disorders under Medicare Advantage
4 plans offered under part C of title XVIII of such Act. Such
5 report shall include the analysis described in subsection
6 (c) and any differences in the availability of such benefits
7 under specialized MA plans for special needs individuals
8 (as defined in section 1859(b)(6) of such Act (42 U.S.C.
9 1395w-28(b)(6))) offered to individuals entitled to med-
10 ical assistance under title XIX of such Act and other such
11 Medicare Advantage plans.

12 (b) CONSULTATION.—The Secretary shall develop the
13 report described in subsection (a) in consultation with rel-
14 evant stakeholders, including—

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

18 (2) entities who advocate on behalf of such indi-
19 viduals;

20 (3) Medicare Advantage organizations;

21 (4) pharmacy benefit managers; and

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

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

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

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

12 (B) non-opioid alternatives for the treat-
13 ment of pain.

14 (2) Challenges associated with such plans offer-
15 ing supplemental health care benefits relating to cov-
16 erage of items and services described in subpara-
17 graph (A) or (B) of paragraph (1).

18 (3) The impact, if any, of increasing the appli-
19 cable rebate percentage determined under section
20 1854(b)(1)(C) of the Social Security Act (42 U.S.C.
21 1395w–24(b)(1)(C)) for plans offering such benefits
22 relating to such coverage would have on the avail-
23 ability of such benefits relating to such coverage of-
24 fered under Medicare Advantage plans.

1 (4) Potential ways to improve upon such cov-
2 erage or to incentivize such plans to offer additional
3 supplemental health care benefits relating to such
4 coverage.

5 **SEC. 6085. CLINICAL PSYCHOLOGIST SERVICES MODELS**
6 **UNDER THE CENTER FOR MEDICARE AND**
7 **MEDICAID INNOVATION; GAO STUDY AND RE-**
8 **PORT.**

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

12 “(xxv) Supporting ways to familiarize
13 individuals with the availability of coverage
14 under part B of title XVIII for qualified
15 psychologist services (as defined in section
16 1861(ii)).

17 “(xxvi) Exploring ways to avoid un-
18 necessary hospitalizations or emergency de-
19 partment visits for mental and behavioral
20 health services (such as for treating de-
21 pression) through use of a 24-hour, 7-day
22 a week help line that may inform individ-
23 uals about the availability of treatment op-
24 tions, including the availability of qualified

1 psychologist services (as defined in section
2 1861(ii)).”.

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

10 (1) Information about services furnished by
11 psychiatrists, clinical psychologists, and other profes-
12 sionals.

13 (2) Information about ways that Medicare bene-
14 ficiaries familiarize themselves about the availability
15 of Medicare payment for qualified psychologist serv-
16 ices (as defined in section 1861(ii) of the Social Se-
17 curity Act (42 U.S.C. 1395x(ii)) and ways that the
18 provision of such information could be improved.

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

20 (a) IN GENERAL.—Not later than 1 year after the
21 date of enactment of this Act, the Secretary of Health and
22 Human Services (referred to in this section as the “Sec-
23 retary”) shall conduct a study analyzing best practices as
24 well as payment and coverage for pain management serv-
25 ices under title XVIII of the Social Security Act and sub-

1 mit to the Committee on Ways and Means and the Com-
2 mittee on Energy and Commerce of the House of Rep-
3 resentatives and the Committee on Finance of the Senate
4 a report containing options for revising payment to pro-
5 viders and suppliers of services and coverage related to
6 the use of multi-disciplinary, evidence-based, non-opioid
7 treatments for acute and chronic pain management for in-
8 dividuals entitled to benefits under part A or enrolled
9 under part B of title XVIII of the Social Security Act.
10 The Secretary shall make such report available on the
11 public website of the Centers for Medicare & Medicaid
12 Services.

13 (b) CONSULTATION.—In developing the report de-
14 scribed in subsection (a), the Secretary shall consult
15 with—

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

18 (2) licensed and practicing osteopathic and
19 allopathic physicians, behavioral health practitioners,
20 physician assistants, nurse practitioners, dentists,
21 pharmacists, and other providers of health services;

22 (3) providers and suppliers of services (as such
23 terms are defined in section 1861 of the Social Secu-
24 rity Act (42 U.S.C. 1395x));

1 (4) substance abuse and mental health profes-
2 sional organizations;

3 (5) pain management professional organizations
4 and advocacy entities, including individuals who per-
5 sonally suffer chronic pain;

6 (6) medical professional organizations and med-
7 ical specialty organizations;

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

10 (8) organizations with expertise in the develop-
11 ment of innovative medical technologies for pain
12 management;

13 (9) beneficiary advocacy organizations; and

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

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

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

22 (A) Evidence-based treatments and tech-
23 nologies for chronic or acute pain, including
24 such treatments that are covered, not covered,
25 or have limited coverage under such title.

1 (B) Evidence-based treatments and tech-
2 nologies that monitor substance use withdrawal
3 and prevent overdoses of opioids.

4 (C) Evidence-based treatments and tech-
5 nologies that treat substance use disorders.

6 (D) Items and services furnished by practi-
7 tioners through a multi-disciplinary treatment
8 model for pain management, including the pa-
9 tient-centered medical home.

10 (E) Medical devices, non-opioid based
11 drugs, and other therapies (including inter-
12 ventional and integrative pain therapies) ap-
13 proved or cleared by the Food and Drug Ad-
14 ministration for the treatment of pain.

15 (F) Items and services furnished to bene-
16 ficiaries with psychiatric disorders, substance
17 use disorders, or who are at risk of suicide, or
18 have comorbidities and require consultation or
19 management of pain with one or more special-
20 ists in pain management, mental health, or ad-
21 diction treatment.

22 (2) An evaluation of the following:

23 (A) Barriers inhibiting individuals entitled
24 to benefits under part A or enrolled under part
25 B of such title from accessing treatments and

1 technologies described in subparagraphs (A)
2 through (F) of paragraph (1).

3 (B) Costs and benefits associated with po-
4 tential expansion of coverage under such title to
5 include items and services not covered under
6 such title that may be used for the treatment
7 of pain, such as acupuncture, therapeutic mas-
8 sage, and items and services furnished by inte-
9 grated pain management programs.

10 (C) Pain management guidance published
11 by the Federal Government that may be rel-
12 evant to coverage determinations or other cov-
13 erage requirements under title XVIII of the So-
14 cial Security Act.

15 (3) An assessment of all guidance published by
16 the Department of Health and Human Services on
17 or after January 1, 2016, relating to the prescribing
18 of opioids. Such assessment shall consider incor-
19 porating into such guidance relevant elements of the
20 “Va/DoD Clinical Practice Guideline for Opioid
21 Therapy for Chronic Pain” published in February
22 2017 by the Department of Veterans Affairs and
23 Department of Defense, including adoption of ele-
24 ments of the Department of Defense and Depart-
25 ment of Veterans Affairs pain rating scale.

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

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

4 (d) OPTIONS.—The options described in this sub-
5 section are, with respect to individuals entitled to benefits
6 under part A or enrolled under part B of title XVIII of
7 the Social Security Act, legislative and administrative op-
8 tions for accomplishing the following:

9 (1) Improving coverage of and payment for pain
10 management therapies without the use of opioids, in-
11 cluding interventional pain therapies, and options to
12 augment opioid therapy with other clinical and com-
13plementary, integrative health services to minimize
14 the risk of substance use disorder, including in a
15 hospital setting.

16 (2) Improving coverage of and payment for
17 medical devices and non-opioid based pharma-
18cological and non-pharmacological therapies ap-
19proved or cleared by the Food and Drug Administra-
20tion for the treatment of pain as an alternative or
21augment to opioid therapy.

22 (3) Improving and disseminating treatment
23 strategies for beneficiaries with psychiatric dis-
24orders, substance use disorders, or who are at risk
25 of suicide, and treatment strategies to address

1 health disparities related to opioid use and opioid
2 abuse treatment.

3 (4) Improving and disseminating treatment
4 strategies for beneficiaries with comorbidities who
5 require a consultation or comanagement of pain with
6 one or more specialists in pain management, mental
7 health, or addiction treatment, including in a hos-
8 pital setting.

9 (5) Educating providers on risks of coadminis-
10 tration of opioids and other drugs, particularly
11 benzodiazepines.

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

17 (7) Expanding outreach activities designed to
18 educate providers of services and suppliers under the
19 Medicare program and individuals entitled to bene-
20 fits under part A or under part B of such title on
21 alternative, non-opioid therapies to manage and
22 treat acute and chronic pain.

23 (8) Creating a beneficiary education tool on al-
24 ternatives to opioids for chronic pain management.

1 (e) IMPACT ANALYSIS.—The impact analysis de-
 2 scribed in this subsection consists of an analysis of any
 3 potential effects implementing the options described in
 4 subsection (d) would have—

5 (1) on expenditures under the Medicare pro-
 6 gram; and

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

10 **Subtitle J—Combating Opioid** 11 **Abuse for Care in Hospitals**

12 **SEC. 6091. SHORT TITLE.**

13 This subtitle may be cited as the “Combating Opioid
 14 Abuse for Care in Hospitals Act of 2018” or the “COACH
 15 Act of 2018”.

16 **SEC. 6092. DEVELOPING GUIDANCE ON PAIN MANAGEMENT** 17 **AND OPIOID USE DISORDER PREVENTION** 18 **FOR HOSPITALS RECEIVING PAYMENT** 19 **UNDER PART A OF THE MEDICARE PROGRAM.**

20 (a) IN GENERAL.—Not later than January 1, 2019,
 21 the Secretary of Health and Human Services (in this sec-
 22 tion referred to as the “Secretary”) shall develop and pub-
 23 lish on the public website of the Centers for Medicare &
 24 Medicaid Services guidance for hospitals receiving pay-
 25 ment under part A of title XVIII of the Social Security

1 Act (42 U.S.C. 1395c et seq.) on pain management strate-
2 gies and opioid use disorder prevention strategies with re-
3 spect to individuals entitled to benefits under such part.

4 (b) CONSULTATION.—In developing the guidance de-
5 scribed in subsection (a), the Secretary shall consult with
6 relevant stakeholders, including—

7 (1) medical professional organizations;

8 (2) providers and suppliers of services (as such
9 terms are defined in section 1861 of the Social Secu-
10 rity Act (42 U.S.C. 1395x));

11 (3) health care consumers or groups rep-
12 resenting such consumers; and

13 (4) other entities determined appropriate by the
14 Secretary.

15 (c) CONTENTS.—The guidance described in sub-
16 section (a) shall include, with respect to hospitals and indi-
17 viduals described in such subsection, the following:

18 (1) Best practices regarding evidence-based
19 screening and practitioner education initiatives relat-
20 ing to screening and treatment protocols for opioid
21 use disorder, including—

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

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

3 (C) resources available to such individuals,
4 such as opioid treatment programs, peer sup-
5 port groups, and other recovery programs.

6 (2) Best practices for such hospitals to educate
7 practitioners furnishing items and services at such
8 hospital with respect to pain management and sub-
9 stance use disorders, including education on—

10 (A) the adverse effects of prolonged opioid
11 use;

12 (B) non-opioid, evidence-based, non-phar-
13 macological pain management treatments;

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

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

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

22 (4) A notification template developed by the
23 Secretary, for use as appropriate, for such individ-
24 uals who are prescribed an opioid that—

1 (A) explains the risks and side effects asso-
2 ciated with opioid use (including the risks of
3 addiction and overdose) and the importance of
4 adhering to the prescribed treatment regimen,
5 avoiding medications that may have an adverse
6 interaction with such opioid, and storing such
7 opioid safely and securely;

8 (B) highlights multimodal and evidence-
9 based non-opioid alternatives for pain manage-
10 ment;

11 (C) encourages such individuals to talk to
12 their health care providers about such alter-
13 natives;

14 (D) provides for a method (through signa-
15 ture or otherwise) for such an individual, or
16 person acting on such individual's behalf, to ac-
17 knowledge receipt of such notification template;

18 (E) is worded in an easily understandable
19 manner and made available in multiple lan-
20 guages determined appropriate by the Sec-
21 retary; and

22 (F) includes any other information deter-
23 mined appropriate by the Secretary.

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

4 (A) ways for such hospital to establish tar-
5 get levels, taking into account the specialties of
6 such practitioners and the geographic area in
7 which such hospital is located, with respect to
8 opioids prescribed by such practitioners;

9 (B) guidance on checking the medical
10 records of such individuals against information
11 included in prescription drug monitoring pro-
12 grams;

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

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

17 (6) Other information the Secretary determines
18 appropriate, including any such information from
19 the Opioid Safety Initiative established by the De-
20 partment of Veterans Affairs or the Opioid Overdose
21 Prevention Toolkit published by the Substance
22 Abuse and Mental Health Services Administration.

1 **SEC. 6093. REQUIRING THE REVIEW OF QUALITY MEAS-**
2 **URES RELATING TO OPIOIDS AND OPIOID**
3 **USE DISORDER TREATMENTS FURNISHED**
4 **UNDER THE MEDICARE PROGRAM AND**
5 **OTHER FEDERAL HEALTH CARE PROGRAMS.**

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

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

11 “(1) IN GENERAL.—Not later than 180 days
12 after the date of the enactment of this subsection,
13 the Secretary shall establish a technical expert panel
14 for purposes of reviewing quality measures relating
15 to opioids and opioid use disorders, including care,
16 prevention, diagnosis, health outcomes, and treat-
17 ment furnished to individuals with opioid use dis-
18 orders. The Secretary may use the entity with a con-
19 tract under section 1890(a) and amend such con-
20 tract as necessary to provide for the establishment
21 of such technical expert panel.

22 “(2) REVIEW AND ASSESSMENT.—Not later
23 than 1 year after the date the technical expert panel
24 described in paragraph (1) is established (and peri-
25 odically thereafter as the Secretary determines ap-
26 propriate), the technical expert panel shall—

1 “(A) review quality measures that relate to
2 opioids and opioid use disorders, including ex-
3 isting measures and those under development;

4 “(B) identify gaps in areas of quality
5 measurement that relate to opioids and opioid
6 use disorders, and identify measure develop-
7 ment priorities for such measure gaps; and

8 “(C) make recommendations to the Sec-
9 retary on quality measures with respect to
10 opioids and opioid use disorders for purposes of
11 improving care, prevention, diagnosis, health
12 outcomes, and treatment, including rec-
13 ommendations for revisions of such measures,
14 need for development of new measures, and rec-
15 ommendations for including such measures in
16 the Merit-Based Incentive Payment System
17 under section 1848(q), the alternative payment
18 models under section 1833(z)(3)(C), the shared
19 savings program under section 1899, the qual-
20 ity reporting requirements for inpatient hos-
21 pitals under section 1886(b)(3)(B)(viii), and
22 the hospital value-based purchasing program
23 under section 1886(o).

24 “(3) CONSIDERATION OF MEASURES BY SEC-
25 RETARY.—The Secretary shall consider—

1 “(A) using opioid and opioid use disorder
2 measures (including measures used under the
3 Merit-Based Incentive Payment System under
4 section 1848(q), measures recommended under
5 paragraph (2)(C), and other such measures
6 identified by the Secretary) in alternative pay-
7 ment models under section 1833(z)(3)(C) and
8 in the shared savings program under section
9 1899; and

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

16 “(4) PRIORITIZATION OF MEASURE DEVELOP-
17 MENT.—The Secretary shall prioritize for measure
18 development the gaps in quality measures identified
19 under paragraph (2)(B).”.

20 (b) EXPEDITED ENDORSEMENT PROCESS FOR
21 OPIOID MEASURES.—Section 1890(b)(2) of the Social Se-
22 curity Act (42 U.S.C. 1395aaa(b)(2)) is amended by add-
23 ing at the end the following new flush sentence:

24 “Such endorsement process shall, as determined
25 practicable by the entity, provide for an expedited

1 process with respect to the endorsement of such
2 measures relating to opioids and opioid use dis-
3 orders.”.

4 **SEC. 6094. TECHNICAL EXPERT PANEL ON REDUCING SUR-**
5 **GICAL SETTING OPIOID USE; DATA COLLEC-**
6 **TION ON PERIOPERATIVE OPIOID USE.**

7 (a) TECHNICAL EXPERT PANEL ON REDUCING SUR-
8 GICAL SETTING OPIOID USE.—

9 (1) IN GENERAL.—Not later than 6 months
10 after the date of the enactment of this Act, the Sec-
11 retary of Health and Human Services shall convene
12 a technical expert panel, including medical and sur-
13 gical specialty societies and hospital organizations,
14 to provide recommendations on reducing opioid use
15 in the inpatient and outpatient surgical settings and
16 on best practices for pain management, including
17 with respect to the following:

18 (A) Approaches that limit patient exposure
19 to opioids during the perioperative period, in-
20 cluding pre-surgical and post-surgical injec-
21 tions, and that identify such patients at risk of
22 opioid use disorder pre-operation.

23 (B) Shared decision making with patients
24 and families on pain management, including
25 recommendations for the development of an

1 evaluation and management code for purposes
2 of payment under the Medicare program under
3 title XVIII of the Social Security Act that
4 would account for time spent on shared decision
5 making.

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

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

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

14 (2) REPORT.—Not later than 1 year after the
15 date of the enactment of this Act, the Secretary
16 shall submit to Congress and make public a report
17 containing the recommendations developed under
18 paragraph (1) and an action plan for broader imple-
19 mentation of pain management protocols that limit
20 the use of opioids in the perioperative setting and
21 upon discharge from such setting.

22 (b) DATA COLLECTION ON PERIOPERATIVE OPIOID
23 USE.—Not later than 1 year after the date of the enact-
24 ment of this Act, the Secretary of Health and Human

1 Services shall submit to Congress a report that contains
2 the following:

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

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

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

13 (B) opioid consumption, including—

14 (i) perioperative days of therapy;

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

18 (iii) post-discharge prescriptions and
19 other combination drugs that are used be-
20 fore intervention and after intervention;

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

23 (v) quantity consumed and number of
24 refills;

1 (C) regional anesthesia and analgesia prac-
2 tices, including pre-surgical and post-surgical
3 injections;

4 (D) naloxone reversal;

5 (E) post-operative respiratory failure;

6 (F) information about storage and dis-
7 posal; and

8 (G) such other information as the Sec-
9 retary may specify.

10 (3) Recommendations for improving data collec-
11 tion on perioperative opioid use, including an anal-
12 ysis to identify and reduce barriers to collecting, re-
13 porting, and analyzing the data described in para-
14 graph (2), including barriers related to technological
15 availability.

16 **SEC. 6095. REQUIRING THE POSTING AND PERIODIC UP-**
17 **DATE OF OPIOID PRESCRIBING GUIDANCE**
18 **FOR MEDICARE BENEFICIARIES.**

19 (a) IN GENERAL.—Not later than 180 days after the
20 date of the enactment of this Act, the Secretary of Health
21 and Human Services (in this section referred to as the
22 “Secretary”) shall post on the public website of the Cen-
23 ters for Medicare & Medicaid Services all guidance pub-
24 lished by the Department of Health and Human Services
25 on or after January 1, 2016, relating to the prescribing

1 of opioids and applicable to opioid prescriptions for indi-
2 viduals entitled to benefits under part A of title XVIII
3 of the Social Security Act (42 U.S.C. 1395e et seq.) or
4 enrolled under part B of such title of such Act (42 U.S.C.
5 1395j et seq.).

6 (b) UPDATE OF GUIDANCE.—

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

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

15 (A) Medical professional organizations.

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

19 (C) Health care consumers or groups rep-
20 resenting such consumers.

21 (D) Other entities determined appropriate
22 by the Secretary.

1 **Subtitle K—Stop Excessive Nar-**
2 **cotics in Our Retirement Com-**
3 **munities Protection**

4 **SEC. 6101. SHORT TITLE.**

5 This subtitle may be cited as the “Stop Excessive
6 Narcotics in our Retirement Communities Protection Act
7 of 2018” or the “SENIOR Communities Protection Act
8 of 2018”.

9 **SEC. 6102. SUSPENSION OF PAYMENTS BY MEDICARE PRE-**
10 **SCRIPTION DRUG PLANS AND MA-PD PLANS**
11 **PENDING INVESTIGATIONS OF CREDIBLE AL-**
12 **LEGATIONS OF FRAUD BY PHARMACIES.**

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

16 “(7) SUSPENSION OF PAYMENTS PENDING IN-
17 VESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD
18 BY PHARMACIES.—

19 “(A) IN GENERAL.—The provisions of sec-
20 tion 1862(o) shall apply with respect to a PDP
21 sponsor with a contract under this part, a phar-
22 macy, and payments to such pharmacy under
23 this part in the same manner as such provisions
24 apply with respect to the Secretary, a provider

1 of services or supplier, and payments to such
2 provider of services or supplier under this title.

3 “(B) RULE OF CONSTRUCTION.—Nothing
4 in this paragraph shall be construed as limiting
5 the authority of a PDP sponsor to conduct
6 postpayment review.”.

7 (b) APPLICATION TO MA–PD PLANS.—Section
8 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–
9 27(f)(3)) is amended by adding at the end the following
10 new subparagraph:

11 “(D) SUSPENSION OF PAYMENTS PENDING
12 INVESTIGATION OF CREDIBLE ALLEGATIONS OF
13 FRAUD BY PHARMACIES.—Section 1860D–
14 12(b)(7).”.

15 (c) CONFORMING AMENDMENT.—Section 1862(o)(3)
16 of the Social Security Act (42 U.S.C. 1395y(o)(3)) is
17 amended by inserting “, section 1860D–12(b)(7) (includ-
18 ing as applied pursuant to section 1857(f)(3)(D)),” after
19 “this subsection”.

20 (d) CLARIFICATION RELATING TO CREDIBLE ALLE-
21 GATION OF FRAUD.—Section 1862(o) of the Social Secu-
22 rity Act (42 U.S.C. 1395y(o)) is amended by adding at
23 the end the following new paragraph:

24 “(4) CREDIBLE ALLEGATION OF FRAUD.—In
25 carrying out this subsection, section 1860D–

1 12(b)(7) (including as applied pursuant to section
2 1857(f)(3)(D)), and section 1903(i)(2)(C), a fraud
3 hotline tip (as defined by the Secretary) without fur-
4 ther evidence shall not be treated as sufficient evi-
5 dence for a credible allegation of fraud.”.

6 (e) EFFECTIVE DATE.—The amendments made by
7 this section shall apply with respect to plan years begin-
8 ning on or after January 1, 2020.

9 **Subtitle L—Providing Reliable Op-**
10 **tions for Patients and Edu-**
11 **catinal Resources**

12 **SEC. 6111. SHORT TITLE.**

13 This subtitle may be cited as the “Providing Reliable
14 Options for Patients and Educational Resources Act of
15 2018” or the “PROPER Act of 2018”.

16 **SEC. 6112. REQUIRING MEDICARE ADVANTAGE PLANS AND**
17 **PART D PRESCRIPTION DRUG PLANS TO IN-**
18 **CLUDE INFORMATION ON RISKS ASSOCIATED**
19 **WITH OPIOIDS AND COVERAGE OF NON-**
20 **PHARMACOLOGICAL THERAPIES AND**
21 **NONOPIOID MEDICATIONS OR DEVICES USED**
22 **TO TREAT PAIN.**

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

1 (1) in subparagraph (A), by inserting “, subject
2 to subparagraph (C),” before “including”;

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

5 “(vi) For plan year 2021 and each
6 subsequent plan year, subject to subpara-
7 graph (C), with respect to the treatment of
8 pain—

9 “(I) the risks associated with
10 prolonged opioid use; and

11 “(II) coverage of nonpharma-
12 cological therapies, devices, and
13 nonopioid medications—

14 “(aa) in the case of an MA-
15 PD plan under part C, under
16 such plan; and

17 “(bb) in the case of a pre-
18 scription drug plan, under such
19 plan and under parts A and B.”;
20 and

21 (3) by adding at the end the following new sub-
22 paragraph:

23 “(C) TARGETED PROVISION OF INFORMA-
24 TION.—A PDP sponsor of a prescription drug
25 plan may, in lieu of disclosing the information

1 described in subparagraph (B)(vi) to each en-
2 rollee under the plan, disclose such information
3 through mail or electronic communications to a
4 subset of enrollees under the plan, such as en-
5 rollees who have been prescribed an opioid in
6 the previous 2-year period.”.

7 **SEC. 6113. REQUIRING MEDICARE ADVANTAGE PLANS AND**
8 **PRESCRIPTION DRUG PLANS TO PROVIDE IN-**
9 **FORMATION ON THE SAFE DISPOSAL OF PRE-**
10 **SCRIPTION DRUGS.**

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

14 “(n) **PROVISION OF INFORMATION RELATING TO THE**
15 **SAFE DISPOSAL OF CERTAIN PRESCRIPTION DRUGS.**—

16 “(1) **IN GENERAL.**—In the case of an individual
17 enrolled under an MA or MA-PD plan who is fur-
18 nished an in-home health risk assessment on or after
19 January 1, 2021, such plan shall ensure that such
20 assessment includes information on the safe disposal
21 of prescription drugs that are controlled substances
22 that meets the criteria established under paragraph
23 (2). Such information shall include information on
24 drug takeback programs that meet such require-

1 ments determined appropriate by the Secretary and
2 information on in-home disposal.

3 “(2) CRITERIA.—The Secretary shall, through
4 rulemaking, establish criteria the Secretary deter-
5 mines appropriate with respect to information pro-
6 vided to an individual to ensure that such informa-
7 tion sufficiently educates such individual on the safe
8 disposal of prescription drugs that are controlled
9 substances.”.

10 (b) PRESCRIPTION DRUG PLANS.—Section 1860D-
11 4(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w-
12 104(c)(2)(B)) is amended—

13 (1) by striking “may include elements that pro-
14 mote”;

15 (2) by redesignating clauses (i) through (iii) as
16 subclauses (I) through (III) and adjusting the mar-
17 gins accordingly;

18 (3) by inserting before subclause (I), as so re-
19 designated, the following new clause:

20 “(i) may include elements that pro-
21 mote—”;

22 (4) in subclause (III), as so redesignated, by
23 striking the period at the end and inserting “; and”;
24 and

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

3 “(ii) with respect to plan years begin-
4 ning on or after January 1, 2021, shall
5 provide for—

6 “(I) the provision of information
7 to the enrollee on the safe disposal of
8 prescription drugs that are controlled
9 substances that meets the criteria es-
10 tablished under section 1852(n)(2),
11 including information on drug
12 takeback programs that meet such re-
13 quirements determined appropriate by
14 the Secretary and information on in-
15 home disposal; and

16 “(II) cost-effective means by
17 which an enrollee may so safely dis-
18 pose of such drugs.”.

19 **SEC. 6114. REVISING MEASURES USED UNDER THE HOS-**
20 **PITAL CONSUMER ASSESSMENT OF**
21 **HEALTHCARE PROVIDERS AND SYSTEMS**
22 **SURVEY RELATING TO PAIN MANAGEMENT.**

23 (a) RESTRICTION ON THE USE OF PAIN QUESTIONS
24 IN HCAHPS.—Section 1886(b)(3)(B)(viii) of the Social

1 Security Act (42 U.S.C. 1395ww(b)(3)(B)(viii)) is amend-
2 ed by adding at the end the following new subclause:

3 “(XII)(aa) With respect to a Hospital Consumer As-
4 sessment of Healthcare Providers and Systems survey (or
5 a successor survey) conducted on or after January 1,
6 2019, such survey may not include questions about com-
7 munication by hospital staff with an individual about such
8 individual’s pain unless such questions take into account,
9 as applicable, whether an individual experiencing pain was
10 informed about risks associated with the use of opioids
11 and about non-opioid alternatives for the treatment of
12 pain.

13 “(bb) The Secretary shall not include on the Hospital
14 Compare Internet website any measures based on the
15 questions appearing on the Hospital Consumer Assess-
16 ment of Healthcare Providers and Systems survey in 2018
17 about communication by hospital staff with an individual
18 about such individual’s pain.”.

19 (b) RESTRICTION ON USE OF 2018 PAIN QUESTIONS
20 IN THE HOSPITAL VALUE-BASED PURCHASING PRO-
21 GRAM.—Section 1886(o)(2)(B) of the Social Security Act
22 (42 U.S.C. 1395ww(o)(2)(B)) is amended by adding at the
23 end the following new clause:

24 “(iii) HCAHPS PAIN QUESTIONS.—
25 The Secretary may not include under sub-

1 paragraph (A) a measure that is based on
2 the questions appearing on the Hospital
3 Consumer Assessment of Healthcare Pro-
4 viders and Systems survey in 2018 about
5 communication by hospital staff with an
6 individual about the individual’s pain.”.

7 **TITLE VII—OTHER HEALTH** 8 **PROVISIONS**

9 **Subtitle A—Synthetic Drug** 10 **Awareness**

11 **SEC. 7001. SHORT TITLE.**

12 This subtitle may be cited as the “Synthetic Drug
13 Awareness Act of 2018”.

14 **SEC. 7002. REPORT ON EFFECTS ON PUBLIC HEALTH OF** 15 **SYNTHETIC DRUG USE.**

16 (a) **IN GENERAL.**—Not later than 3 years after the
17 date of the enactment of this Act, the Surgeon General
18 of the Public Health Service shall submit to Congress a
19 report on the health effects of new psychoactive substances
20 (including synthetic drugs) used since January 2010 by
21 persons who are at least 12 years of age but no more than
22 18 years of age.

23 (b) **NEW PSYCHOACTIVE SUBSTANCE DEFINED.**—
24 For purposes of subsection (a), the term “new
25 psychoactive substance” means a controlled substance

1 analogue (as defined in section 102(32) of the Controlled
2 Substances Act (21 U.S.C. 802(32)).

3 **Subtitle B—Empowering Phar-**
4 **macists in the Fight Against**
5 **Opioid Abuse**

6 **SEC. 7011. SHORT TITLE.**

7 This subtitle may be cited as the “Empowering Phar-
8 macists in the Fight Against Opioid Abuse Act”.

9 **SEC. 7012. PROGRAMS AND MATERIALS FOR TRAINING ON**
10 **CERTAIN CIRCUMSTANCES UNDER WHICH A**
11 **PHARMACIST MAY DECLINE TO FILL A PRE-**
12 **SCRIPTION.**

13 (a) IN GENERAL.—Not later than 1 year after the
14 date of enactment of this Act, the Secretary of Health and
15 Human Services, in consultation with the Administrator
16 of the Drug Enforcement Administration, the Commis-
17 sioner of Food and Drugs, the Director of the Centers for
18 Disease Control and Prevention, and the Assistant Sec-
19 retary for Mental Health and Substance Use, shall develop
20 and disseminate programs and materials for training
21 pharmacists, health care providers, and patients on—

22 (1) circumstances under which a pharmacist
23 may, consistent with section 201 of the Controlled
24 Substances Act (21 U.S.C. 811) and regulations
25 thereunder, including section 1306.04 of title 21,

1 Code of Federal Regulations, decline to fill a pre-
2 scription for a controlled substance because the
3 pharmacist suspects the prescription is fraudulent,
4 forged, or otherwise indicative of abuse or diversion;
5 and

6 (2) any Federal requirements pertaining to de-
7 clining to fill a prescription under such circum-
8 stances.

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

12 (1) pharmacists on how to decline to fill a pre-
13 scription and actions to take after declining to fill a
14 prescription; and

15 (2) other health care practitioners and the pub-
16 lic on a pharmacist's responsibility to decline to fill
17 prescriptions in certain circumstances.

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

1 **Subtitle C—Indexing Narcotics,**
2 **Fentanyl, and Opioids**

3 **SEC. 7021. SHORT TITLE.**

4 This subtitle may be cited as the “Indexing Nar-
5 cotics, Fentanyl, and Opioids Act of 2018” or the “INFO
6 Act”.

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

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

12 **“SEC. 1711. ESTABLISHMENT OF SUBSTANCE USE DIS-**
13 **ORDER INFORMATION DASHBOARD.**

14 “(a) IN GENERAL.—Not later than 6 months after
15 the date of the enactment of this section, the Secretary
16 of Health and Human Services shall, in consultation with
17 the Director of National Drug Control Policy, establish
18 and periodically update a public information dashboard
19 that—

20 “(1) coordinates information on programs with-
21 in the Department of Health and Human Services
22 related to the reduction of opioid abuse and other
23 substance use disorders;

24 “(2) provides access to publicly available data
25 from other Federal agencies; State, local, and Tribal

1 governments; nonprofit organizations; law enforce-
2 ment; medical experts; public health educators; and
3 research institutions regarding prevention, treat-
4 ment, recovery, and other services for opioid use dis-
5 order and other substance use disorders;

6 “(3) provides comparable data on substance use
7 disorder prevention and treatment strategies in dif-
8 ferent regions and population of the United States;

9 “(4) provides recommendations for health care
10 providers on alternatives to controlled substances for
11 pain management, including approaches studied by
12 the National Institutes of Health Pain Consortium
13 and the National Center for Complimentary and In-
14 tegrative Health; and

15 “(5) provides guidelines and best practices for
16 health care providers regarding treatment of sub-
17 stance use disorders.

18 “(b) CONTROLLED SUBSTANCE DEFINED.—In this
19 section, the term ‘controlled substance’ has the meaning
20 given that term in section 102 of the Controlled Sub-
21 stances Act (21 U.S.C. 802).”.

22 **SEC. 7023. INTERAGENCY SUBSTANCE USE DISORDER CO-**
23 **ORDINATING COMMITTEE.**

24 (a) ESTABLISHMENT.—Not later than 3 months after
25 the date of the enactment of this Act, the Secretary of

1 Health and Human Services (in this section referred to
2 as the “Secretary”) shall, in consultation with the Direc-
3 tor of National Drug Control Policy, establish a com-
4 mittee, to be known as the Interagency Substance Use
5 Disorder Coordinating Committee (in this section referred
6 to as the “Committee”), to coordinate all efforts within
7 the Department of Health and Human Services con-
8 cerning substance use disorder.

9 (b) MEMBERSHIP.—

10 (1) FEDERAL MEMBERS.—The following indi-
11 viduals shall be the Federal members of the Com-
12 mittee:

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

15 (B) The Attorney General of the United
16 States.

17 (C) The Secretary of Labor.

18 (D) The Secretary of Housing and Urban
19 Development.

20 (E) The Secretary of Education.

21 (F) The Secretary of Veterans Affairs.

22 (G) The Commissioner of Social Security.

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

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

3 (J) The Director of the National Institutes
4 of Health and the Directors of such national re-
5 search institutes of the National Institutes of
6 Health as the Secretary determines appropriate.

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

9 (L) The Director of National Drug Control
10 Policy.

11 (M) Representatives of other Federal agen-
12 cies that serve individuals with substance use
13 disorder.

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

17 (A) at least two such members shall be an
18 individual who has received treatment for a di-
19 agnosis of an opioid use disorder;

20 (B) at least two such members shall be an
21 individual who has received treatment for a di-
22 agnosis of a substance use disorder other than
23 an opioid use disorder;

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

1 (D) at least two such members shall be a
2 representative of a leading research, advocacy,
3 or service organization for adults with sub-
4 stance use disorder;

5 (E) at least two such members shall—

6 (i) be a physician, licensed mental
7 health professional, advance practice reg-
8 istered nurse, or physician assistant; and

9 (ii) have experience in treating indi-
10 viduals with opioid use disorder or other
11 substance use disorders;

12 (F) at least one such member shall be a
13 substance use disorder treatment professional
14 who is employed with an opioid treatment pro-
15 gram;

16 (G) at least one such member shall be a
17 substance use disorder treatment professional
18 who has research or clinical experience in work-
19 ing with racial and ethnic minority populations;

20 (H) at least one such member shall be a
21 substance use disorder treatment professional
22 who has research or clinical mental health expe-
23 rience in working with medically underserved
24 populations;

1 (I) at least one such member shall be a
2 State-certified substance use disorder peer sup-
3 port specialist;

4 (J) at least one such member shall be a
5 drug court judge or a judge with experience in
6 adjudicating cases related to substance use dis-
7 order;

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

12 (L) at least one such member shall be an
13 individual with experience providing services for
14 homeless individuals and working with adults
15 with a substance use disorder.

16 (c) TERMS.—

17 (1) IN GENERAL.—A member of the Committee
18 appointed under subsection (b)(2) shall be appointed
19 for a term of 3 years and may be reappointed for
20 one or more 3-year terms.

21 (2) VACANCIES.—A vacancy on the Committee
22 shall be filled in the same manner in which the origi-
23 nal appointment was made. Any individual appointed
24 to fill a vacancy for an unexpired term shall be ap-
25 pointed for the remainder of such term and may

1 serve after the expiration of such term until a suc-
2 cessor has been appointed.

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

5 (e) DUTIES.—The Committee shall—

6 (1) monitor opioid use disorder and other sub-
7 stance use disorder research, services, and support
8 and prevention activities across all relevant Federal
9 agencies, including coordination of Federal activities
10 with respect to opioid use disorder and other sub-
11 stance use disorders;

12 (2) identify and provide to the Secretary rec-
13 ommendations for improving Federal grants and
14 programs for the prevention and treatment of, and
15 recovery from, opioid use disorder and other sub-
16 stance use disorders;

17 (3) review substance use disorder prevention
18 and treatment strategies in different regions and
19 populations in the United States and evaluate the
20 extent to which Federal substance use disorder pre-
21 vention and treatment strategies are aligned with
22 State and local substance use disorder prevention
23 and treatment strategies;

24 (4) make recommendations to the Secretary re-
25 garding any appropriate changes with respect to the

1 activities and strategies described in paragraphs (1)
2 through (3);

3 (5) make recommendations to the Secretary re-
4 garding public participation in decisions relating to
5 opioid use disorder and other substance use dis-
6 orders and the process by which public feedback can
7 be better integrated into such decisions; and

8 (6) make recommendations to ensure that
9 opioid use disorder and other substance use disorder
10 research, services, and support and prevention activi-
11 ties of the Department of Health and Human Serv-
12 ices and other Federal agencies are not unneces-
13 sarily duplicative.

14 (f) ANNUAL REPORT.—

15 (1) IN GENERAL.—Not later than 1 year after
16 the date of the enactment of this Act, and annually
17 thereafter for the life of the Committee, the Com-
18 mittee shall publish on the public information dash-
19 board established under section 7022(a) a report
20 summarizing the activities carried out by the Com-
21 mittee pursuant to subsection (e), including any
22 findings resulting from such activities.

23 (2) RECOMMENDATION FOR COMMITTEE EX-
24 TENSION.—After the publication of the second re-
25 port of the Committee under paragraph (1), the Sec-

1 retary shall submit to Congress a recommendation
2 on whether or not the operations of the Committee
3 should continue after the termination date described
4 in subsection (i).

5 (g) WORKING GROUPS.—The Committee may estab-
6 lish working groups for purposes of carrying out the duties
7 described in subsection (e). Any such working group shall
8 be composed of members of the Committee (or the des-
9 ignees of such members) and may hold such meetings as
10 are necessary to enable the working group to carry out
11 the duties delegated to the working group.

12 (h) FEDERAL ADVISORY COMMITTEE ACT.—The
13 Federal Advisory Committee Act (5 U.S.C. App.) shall
14 apply to the Committee only to the extent that the provi-
15 sions of such Act do not conflict with the requirements
16 of this section.

17 (i) SUNSET.—The Committee shall terminate on the
18 date that is 6 years after the date on which the Committee
19 is established under subsection (a).

20 **Subtitle D—Ensuring Access to**
21 **Quality Sober Living**

22 **SEC. 7031. SHORT TITLE.**

23 This subtitle may be cited as the “Ensuring Access
24 to Quality Sober Living Act of 2018”.

1 **SEC. 7032. NATIONAL RECOVERY HOUSING BEST PRAC-**
2 **TICES.**

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

5 **“SEC. 399V-7. NATIONAL RECOVERY HOUSING BEST PRAC-**
6 **TICES.**

7 “(a) BEST PRACTICES.—The Secretary of Health
8 and Human Services, in consultation with the Secretary
9 for Housing and Urban Development, patients with a his-
10 tory of opioid use disorder, and other stakeholders, which
11 may include State accrediting entities and reputable pro-
12 viders, analysts, and stakeholders of recovery housing
13 services, such as the National Alliance for Recovery Resi-
14 dences, shall identify or facilitate the development of best
15 practices, which may include model laws for implementing
16 suggested minimum standards, for operating recovery
17 housing.

18 “(b) DISSEMINATION.—The Secretary shall dissemi-
19 nate the best practices identified or developed under sub-
20 section (a) to—

21 “(1) State agencies, which may include the pro-
22 vision of technical assistance to State agencies seek-
23 ing to adopt or implement such best practices;

24 “(2) recovery housing entities; and

25 “(3) the public, as appropriate.

26 “(c) DEFINITIONS.—In this section:

1 “(1) The term ‘recovery housing’ means a
2 shared living environment free from alcohol and il-
3 licit drug use and centered on peer support and con-
4 nection to services, including medication-assisted
5 treatment services, that promote sustained recovery
6 from substance use disorders.

7 “(2) The term ‘State’ includes any of the sev-
8 eral States, the District of Columbia, each Indian
9 tribe or tribal organization (as those terms are de-
10 fined in section 4 of the Indian Self-Determination
11 and Education Assistance Act), and any territory or
12 possession of the United States.

13 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
14 carry out this section, there is authorized to be appro-
15 priated \$3,000,000 for the period of fiscal years 2019
16 through 2021.”.

17 **Subtitle E—Advancing Cutting** 18 **Edge Research**

19 **SEC. 7041. SHORT TITLE.**

20 This subtitle may be cited as the “Advancing Cutting
21 Edge Research Act” or the “ACE Research Act”.

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

23 Section 402(n)(1) of the Public Health Service Act
24 (42 U.S.C. 282(n)(1)) is amended—

25 (1) in subparagraph (A), by striking “or”;

1 (2) in subparagraph (B), by striking the period
2 and inserting “; or”; and

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

4 “(C) high impact cutting-edge research
5 that fosters scientific creativity and increases
6 fundamental biological understanding leading to
7 the prevention, diagnosis, or treatment of dis-
8 eases and disorders, or research urgently re-
9 quired to respond to a public health threat.”.

10 **Subtitle F—Jessie’s Law**

11 **SEC. 7051. SHORT TITLE.**

12 This subtitle may be cited as “Jessie’s Law”.

13 **SEC. 7052. INCLUSION OF OPIOID ADDICTION HISTORY IN** 14 **PATIENT RECORDS.**

15 (a) BEST PRACTICES.—

16 (1) IN GENERAL.—Not later than 1 year after
17 the date of enactment of this Act, the Secretary of
18 Health and Human Services, in consultation with
19 appropriate stakeholders, including a patient with a
20 history of opioid use disorder, an expert in electronic
21 health records, an expert in the confidentiality of pa-
22 tient health information and records, and a health
23 care provider, shall identify or facilitate the develop-
24 ment of best practices regarding—

1 (A) the circumstances under which infor-
2 mation that a patient has provided to a health
3 care provider regarding such patient's history of
4 opioid use disorder should, only at the patient's
5 request, be prominently displayed in the med-
6 ical records (including electronic health records)
7 of such patient;

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

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

13 (2) DISSEMINATION.—The Secretary shall dis-
14 seminate the best practices developed under para-
15 graph (1) to health care providers and State agen-
16 cies.

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

21 (1) The potential for addiction relapse or over-
22 dose, including overdose death, when opioid medica-
23 tions are prescribed to a patient recovering from
24 opioid use disorder.

1 (2) The benefits of displaying information
2 about a patient’s opioid use disorder history in a
3 manner similar to other potentially lethal medical
4 concerns, including drug allergies and contraindica-
5 tions.

6 (3) The importance of prominently displaying
7 information about a patient’s opioid use disorder
8 when a physician or medical professional is pre-
9 scribing medication, including methods for avoiding
10 alert fatigue in providers.

11 (4) The importance of a variety of appropriate
12 medical professionals, including physicians, nurses,
13 and pharmacists, to have access to information de-
14 scribed in this section when prescribing or dis-
15 pensing opioid medication, consistent with Federal
16 and State laws and regulations.

17 (5) The importance of protecting patient pri-
18 vacy, including the requirements related to consent
19 for disclosure of substance use disorder information
20 under all applicable laws and regulations.

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

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

3 (a) **PROMOTING AWARENESS OF AUTHORIZED DIS-**
4 **CLOSURES DURING EMERGENCIES.**—The Secretary of
5 Health and Human Services, acting through the Adminis-
6 trator of the Centers for Medicare & Medicaid Services
7 and the Administrator of the Health Resources and Serv-
8 ices Administration, shall annually develop and dissemi-
9 nate written materials (electronically or by other means)
10 to health care providers regarding permitted disclosures
11 under Federal health care privacy law during emergencies,
12 including overdoses, of certain health information to fami-
13 lies, caregivers, and health care providers.

14 (b) **USE OF MATERIAL.**—For the purposes of car-
15 rying out subsection (a), the Secretary of Health and
16 Human Services may use material produced under section
17 11004 of the 21st Century Cures Act (42 U.S.C. 1320d–
18 2 note).

19 **Subtitle G—Safe Disposal of**
20 **Unused Medication**

21 **SEC. 7061. SHORT TITLE.**

22 This subtitle may be cited as the “Safe Disposal of
23 Unused Medication Act”.

1 **SEC. 7062. DISPOSAL OF CONTROLLED SUBSTANCES OF A**
2 **DECEASED HOSPICE PATIENT BY EMPLOY-**
3 **EES OF A QUALIFIED HOSPICE PROGRAM.**

4 Subsection (g) of section 302 of the Controlled Sub-
5 stances Act (21 U.S.C. 822) is amended by adding at the
6 end the following:

7 “(5)(A) In the case of a person receiving hospice care,
8 an employee of a qualified hospice program, acting within
9 the scope of employment, may handle, without being reg-
10 istered under this section, any controlled substance that
11 was lawfully dispensed to the person receiving hospice
12 care, for the purpose of disposal of the controlled sub-
13 stance after the death of such person, so long as such dis-
14 posal occurs onsite in accordance with all applicable Fed-
15 eral, State, Tribal, and local law.

16 “(B) For the purposes of this paragraph:

17 “(i) The terms ‘hospice care’ and ‘hospice pro-
18 gram’ have the meanings given to those terms in
19 section 1861(dd) of the Social Security Act.

20 “(ii) The term ‘employee of a qualified hospice
21 program’ means a physician, nurse, or other person
22 who—

23 “(I) is employed by, or pursuant to ar-
24 rangements made by, a qualified hospice pro-
25 gram;

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

4 “(bb) is acting within the scope of such
5 employment in accordance with applicable State
6 law; and

7 “(III) has completed training through the
8 qualified hospice program regarding the dis-
9 posal of controlled substances in a secure and
10 responsible manner so as to discourage abuse,
11 misuse, or diversion.

12 “(iii) The term ‘qualified hospice program’
13 means a hospice program that—

14 “(I) has written policies and procedures for
15 assisting in the disposal of the controlled sub-
16 stances of a person receiving hospice care after
17 the person’s death;

18 “(II) at the time when the controlled sub-
19 stances are first ordered—

20 “(aa) provides a copy of the written
21 policies and procedures to the patient or
22 patient representative and family;

23 “(bb) discusses the policies and proce-
24 dures with the patient or representative
25 and the family in a language and manner

1 that they understand to ensure that these
 2 parties are educated regarding the safe
 3 disposal of controlled substances; and

4 “(cc) documents in the patient’s clin-
 5 ical record that the written policies and
 6 procedures were provided and discussed;
 7 and

8 “(III) at the time following the disposal of
 9 the controlled substances—

10 “(aa) documents in the patient’s clin-
 11 ical record the type of controlled sub-
 12 stance, dosage, route of administration,
 13 and quantity so disposed; and

14 “(bb) the time, date, and manner in
 15 which that disposal occurred.”.

16 **Subtitle H—Substance Use Dis-**
 17 **order Workforce Loan Repay-**
 18 **ment**

19 **SEC. 7071. SHORT TITLE.**

20 This subtitle may be cited as the “Substance Use
 21 Disorder Workforce Loan Repayment Act of 2018”.

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

24 Title VII of the Public Health Service Act is amend-
 25 ed—

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

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

4 **“PART F—SUBSTANCE USE DISORDER**

5 **TREATMENT EMPLOYEES**

6 **“SEC. 781. LOAN REPAYMENT PROGRAM FOR SUBSTANCE**

7 **USE DISORDER TREATMENT EMPLOYEES.**

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

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

15 “(2) the individuals each agree to complete a
16 period of service in a substance use disorder treat-
17 ment job, as described in subsection (d).

18 “(b) PAYMENTS.—For each year of obligated service
19 by an individual pursuant to an agreement under sub-
20 section (a), the Secretary shall make a payment to such
21 individual as follows:

22 “(1) SERVICE IN A SHORTAGE AREA.—The Sec-
23 retary shall pay—

24 “(A) for each year of obligated service by
25 an individual pursuant to an agreement under

1 subsection (a), $\frac{1}{6}$ of the principal of and inter-
2 est on each eligible loan of the individual which
3 is outstanding on the date the individual began
4 service pursuant to the agreement; and

5 “(B) for completion of the sixth and final
6 year of such service, the remainder of such
7 principal and interest.

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

11 “(c) ELIGIBLE LOANS.—The loans eligible for repay-
12 ment under this section are each of the following:

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

15 “(2) Any loan under part E of title VIII (relat-
16 ing to nursing student loans).

17 “(3) Any Federal Direct Stafford Loan, Fed-
18 eral Direct PLUS Loan, or Federal Direct Unsub-
19 sidized Stafford Loan, or Federal Direct Consolida-
20 tion Loan (as such terms are used in section 455 of
21 the Higher Education Act of 1965).

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

24 “(5) Any other Federal loan as determined ap-
25 propriate by the Secretary.

1 “(d) PERIOD OF SERVICE.—The period of service re-
2 quired by an agreement under subsection (a) shall consist
3 of up to 6 years of full-time employment, with no more
4 than 1 year passing between any 2 years of covered em-
5 ployment, in a substance use disorder treatment job in the
6 United States in—

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

9 “(2) a county (or a municipality, if not con-
10 tained within any county) where the mean drug
11 overdose death rate per 100,000 people over the past
12 3 years for which official data is available from the
13 State, is higher than the most recent available na-
14 tional average overdose death rate per 100,000 peo-
15 ple, as reported by the Centers for Disease Control
16 and Prevention.

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

20 “(1) this subsection; and

21 “(2) any Federally supported loan forgiveness
22 program, including under section 338B, 338I, or
23 846 of this Act, or section 428J, 428L, 455(m), or
24 460 of the Higher Education Act of 1965.

25 “(f) BREACH.—

1 “(1) LIQUIDATED DAMAGES FORMULA.—The
2 Secretary may establish a liquidated damages for-
3 mula to be used in the event of a breach of an
4 agreement entered into under subsection (a).

5 “(2) LIMITATION.—The failure by an individual
6 to complete the full period of service obligated pur-
7 suant to such an agreement, taken alone, shall not
8 constitute a breach of the agreement, so long as the
9 individual completed in good faith the years of serv-
10 ice for which payments were made to the individual
11 under this section.

12 “(g) ADDITIONAL CRITERIA.—The Secretary—

13 “(1) may establish such criteria and rules to
14 carry out this section as the Secretary determines
15 are needed and in addition to the criteria and rules
16 specified in this section; and

17 “(2) shall give notice to the committees speci-
18 fied in subsection (h) of any criteria and rules so es-
19 tablished.

20 “(h) REPORT TO CONGRESS.—Not later than 5 years
21 after the date of enactment of the Substance Use Disorder
22 Workforce Loan Repayment Act of 2018, and every other
23 year thereafter, the Secretary shall prepare and submit
24 to the Committee on Energy and Commerce of the House

1 of Representatives and the Committee on Health, Edu-
2 cation, Labor, and Pensions of the Senate a report on—

3 “(1) the number and location of borrowers who
4 have qualified for loan repayments under this sec-
5 tion; and

6 “(2) the impact of this section on the avail-
7 ability of substance use disorder treatment employ-
8 ees nationally and in shortage areas and counties de-
9 scribed in subsection (d).

10 “(i) DEFINITION.—In this section:

11 “(1) The term ‘municipality’ means a city,
12 town, or other public body created by or pursuant to
13 State law, or an Indian Tribe.

14 “(2) The term ‘substance use disorder treat-
15 ment job’ means a full-time job (including a fellow-
16 ship)—

17 “(A) where the primary intent and func-
18 tion of the job is the direct treatment or recov-
19 ery support of patients with or in recovery from
20 a substance use disorder, such as a physician,
21 physician assistant, registered nurse, nurse
22 practitioner, advanced practice registered nurse,
23 social worker, recovery coach, mental health
24 counselor, addictions counselor, psychologist or
25 other behavioral health professional, or any

1 other relevant professional as determine by the
2 Secretary; and

3 “(B) which is located at a substance use
4 disorder treatment program, private physician
5 practice, hospital or health system-affiliated in-
6 patient treatment center or outpatient clinic
7 (including an academic medical center-affiliated
8 treatment program), correctional facility or pro-
9 gram, youth detention center or program, inpa-
10 tient psychiatric facility, crisis stabilization
11 unit, community health center, community men-
12 tal health or other specialty community behav-
13 ioral health center, recovery center, school, com-
14 munity-based organization, telehealth platform,
15 migrant health center, health program or facil-
16 ity operated by a tribe or tribal organization,
17 Federal medical facility, or any other facility as
18 determined appropriate for purposes of this sec-
19 tion by the Secretary.

20 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
21 are authorized to be appropriated to carry out this section
22 \$25,000,000 for each of fiscal years 2019 through 2028.”.

1 **Subtitle I—Preventing Overdoses**
2 **While in Emergency Rooms**

3 **SEC. 7081. SHORT TITLE.**

4 This subtitle may be cited as the “Preventing
5 Overdoses While in Emergency Rooms Act of 2018”.

6 **SEC. 7082. PROGRAM TO SUPPORT EMERGENCY ROOM DIS-**
7 **CHARGE AND CARE COORDINATION FOR**
8 **DRUG OVERDOSE PATIENTS.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services shall establish a program (in this subtitle
11 referred to as the “Program”) to develop protocols for dis-
12 charging patients who have presented with a drug over-
13 dose and enhance the integration and coordination of care
14 and treatment options for individuals with substance use
15 disorder after discharge.

16 (b) GRANT ESTABLISHMENT AND PARTICIPATION.—

17 (1) IN GENERAL.—In carrying out the Pro-
18 gram, the Secretary shall award grants on a com-
19 petitive basis to not more than 20 eligible entities
20 described in paragraph (2).

21 (2) ELIGIBILITY.—

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

1 (i) a health care site described in sub-
2 paragraph (B); or

3 (ii) a health care site coordinator de-
4 scribed in subparagraph (C).

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

8 (i) submit an application to the Sec-
9 retary at such time, in such manner, and
10 containing such information as specified by
11 the Secretary;

12 (ii) have an emergency department;

13 (iii)(I) have a licensed health care pro-
14 fessional onsite who has a waiver under
15 section 303(g) of the Controlled Sub-
16 stances Act (21 U.S.C. 823(g)) to dispense
17 or prescribe covered drugs; or

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

23 (iv) have in place an agreement with
24 a sufficient number and range of entities
25 certified under applicable State and Fed-

1 eral law, such as pursuant to registration
2 or a waiver under section 303(g) of the
3 Controlled Substances Act (21 U.S.C.
4 823(g)) or certification as described in sec-
5 tion 8.2 of title 42 of the Code of Federal
6 Regulations, to provide treatment for sub-
7 stance use disorder such that the entity or
8 the resulting network of entities with an
9 agreement with the hospital cumulatively
10 are capable of providing all evidence-based
11 services for the treatment of substance use
12 disorder, as medically appropriate for the
13 individual involved, including—

14 (I) medication-assisted treat-
15 ment;

16 (II) withdrawal and detoxifica-
17 tion services that include patient eval-
18 uation, stabilization, and readiness for
19 and entry into treatment; and

20 (III) counseling;

21 (v) deploy onsite peer recovery special-
22 ists to help connect patients with treat-
23 ment and recovery support services; and

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

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

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

12 (ii) submit an application to the Sec-
13 retary at such time, in such manner, and
14 containing such information as specified by
15 the Secretary; and

16 (iii) have an agreement with multiple
17 eligible health care sites described in sub-
18 paragraph (B).

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

23 (A) The eligible health care site is, or the
24 eligible health care site coordinator has an
25 agreement described in paragraph (2)(C)(iii)

1 with a site that is, a critical access hospital (as
2 defined in section 1861(mm)(1) of the Social
3 Security Act (42 U.S.C. 1395x(mm)(1))), a
4 low-volume hospital (as defined in section
5 1886(d)(12)(C)(i) of such Act (42 U.S.C.
6 1395ww(d)(12)(C)(i))), or a sole community
7 hospital (as defined in section
8 1886(d)(5)(D)(iii) of such Act (42 U.S.C.
9 1395ww(d)(5)(D)(iii))).

10 (B) The eligible health care site or the eli-
11 gible health care site coordinator is located in
12 a geographic area with a drug overdose rate
13 that is higher than the national rate, or in a ge-
14 ographic area with a rate of emergency depart-
15 ment visits for overdoses that is higher than the
16 national rate, as determined by the Secretary
17 based on the most recent data from the Centers
18 for Disease Control and Prevention.

19 (4) MEDICATION-ASSISTED TREATMENT DE-
20 FINED.—For purposes of this section, the term
21 “medication-assisted treatment” means the use of a
22 drug approved under section 505 of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
24 a biological product licensed under section 351 of
25 the Public Health Service Act (42 U.S.C. 262), in

1 combination with behavioral health services, to pro-
2 vide an individualized approach to the treatment of
3 substance use disorders, including opioid use dis-
4 orders.

5 (c) PERIOD OF GRANT.—A grant awarded to an eligi-
6 ble entity under this section shall be for a period of at
7 least 2 years.

8 (d) GRANT USES.—

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

12 (A) To establish policies and procedures
13 that address the provision of overdose reversal
14 medication, prescription and dispensing of
15 medication-assisted treatment to an emergency
16 department patient who has had a non-fatal
17 overdose or who is at risk of a drug overdose,
18 and the subsequent referral to evidence-based
19 treatment upon discharge for patients who have
20 experienced a non-fatal drug overdose or who
21 are at risk of a drug overdose.

22 (B) To develop best practices for treating
23 non-fatal drug overdoses, including with respect
24 to care coordination and integrated care models
25 for long term treatment and recovery options

1 for individuals who have experienced a non-fatal
2 drug overdose.

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

6 (A) To hire emergency department peer re-
7 covery specialists; counselors; therapists; social
8 workers; or other licensed medical professionals
9 specializing in the treatment of substance use
10 disorder.

11 (B) To establish integrated models of care
12 for individuals who have experienced a non-fatal
13 drug overdose which may include patient as-
14 sessment, follow up, and transportation to
15 treatment facilities.

16 (C) To provide for options for increasing
17 the availability and access of medication-as-
18 sisted treatment and other evidence-based treat-
19 ment for individuals with substance use dis-
20 orders.

21 (D) To offer consultation with and referral
22 to other supportive services that help in treat-
23 ment and recovery.

24 (e) **REPORTING REQUIREMENTS.**—

1 (1) REPORTS BY GRANTEES.—Each eligible en-
2 tity awarded a grant under this section shall submit
3 to the Secretary an annual report for each year for
4 which the entity has received such grant that in-
5 cludes information on—

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

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

15 (C) the number of individuals referred by
16 such site or sites to other treatment facilities
17 after a non-fatal overdose, the types of such
18 other facilities, and the number of such individ-
19 uals admitted to such other facilities pursuant
20 to such referrals;

21 (D) the frequency and number of patient
22 readmissions for non-fatal overdoses and sub-
23 stance use disorder;

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

1 (F) the effectiveness of, and any other rel-
2 evant additional data regarding, having an on-
3 site health care professional to administer and
4 begin medication-assisted treatment for sub-
5 stance use disorders.

6 (2) REPORT BY SECRETARY.—Not less than 1
7 year after the conclusion of the Program, the Sec-
8 retary shall submit to Congress a report that in-
9 cludes—

10 (A) findings of the Program;

11 (B) overall patient outcomes under the
12 Program, such as with respect to hospital read-
13 mission;

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

18 (D) an evaluation determining the effec-
19 tiveness of having a practitioner onsite to ad-
20 minister and begin medication-assisted treat-
21 ment for substance use disorder; and

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

1 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
2 authorized to be appropriated to carry out this subtitle
3 \$50,000,000 for the period of fiscal years 2019 through
4 2023.

5 **Subtitle J—Alternatives to Opioids**
6 **in the Emergency Department**

7 **SEC. 7091. SHORT TITLE.**

8 This subtitle may be cited as the “Alternatives to
9 Opioids in the Emergency Department Act” or the
10 “ALTO Act”.

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

13 (a) DEMONSTRATION PROGRAM GRANTS.—The Sec-
14 retary of Health and Human Services (in this section re-
15 ferred to as the “Secretary”) shall carry out a demonstra-
16 tion program under which the Secretary shall award
17 grants to hospitals and emergency departments, including
18 freestanding emergency departments, to develop, imple-
19 ment, enhance, or study alternative pain management pro-
20 tocols and treatments that limit the use and prescription
21 of opioids in emergency departments.

22 (b) ELIGIBILITY.—To be eligible to receive a grant
23 under subsection (a), a hospital or emergency department
24 shall submit an application to the Secretary at such time,

1 in such manner, and containing such information as the
2 Secretary may require.

3 (c) GEOGRAPHIC DIVERSITY.—In awarding grants
4 under this section, the Secretary shall seek to ensure geo-
5 graphical diversity among grant recipients.

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

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

11 (2) train providers and other hospital personnel
12 on protocols and the use of treatments that limit the
13 use and prescription of opioids in the emergency de-
14 partment; and

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

19 (e) CONSULTATION.—The Secretary shall implement
20 a process for recipients of grants under subsection (a) to
21 consult (in a manner that allows for sharing of evidence-
22 based best practices) with each other and with persons
23 having robust knowledge, including emergency depart-
24 ments and physicians that have successfully deployed al-
25 ternative pain management protocols, such as non-drug

1 approaches studied through the National Center for Com-
2 plimentary and Integrative Health including acupuncture
3 that limit the use of opioids. The Secretary shall offer to
4 each recipient of a grant under subsection (a) technical
5 support as necessary.

6 (f) REPORT TO THE SECRETARY.—Each recipient of
7 a grant under this section shall submit to the Secretary
8 (during the period of such grant) annual reports on the
9 progress of the program funded through the grant. These
10 reports shall include, in accordance with State and Fed-
11 eral statutes and regulations regarding disclosure of pa-
12 tient information—

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

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

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

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

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

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

3 (4) data on the opioid prescriptions written, in-
4 cluding—

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

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

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

11 (5) the demographic characteristics of patients
12 who were treated with an alternative pain manage-
13 ment protocol, including age, sex, race, ethnicity,
14 and insurance status and type;

15 (6) data on patients who were eventually pre-
16 scribed opioids after alternative pain management
17 protocols and treatments were employed; and

18 (7) any other information the Secretary deems
19 necessary.

20 (g) REPORT TO CONGRESS.—Not later than 1 year
21 after completion of the demonstration program under this
22 section, the Secretary shall submit a report to the Con-
23 gress on the results of the demonstration program and in-
24 clude in the report—

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

3 (2) a summary of the reports described in sub-
4 section (f), including standardized data; and

5 (3) recommendations for broader implementa-
6 tion of pain management protocols that limit the use
7 and prescription of opioids in emergency depart-
8 ments or other areas of the health care delivery sys-
9 tem.

10 (h) AUTHORIZATION OF APPROPRIATIONS.—To carry
11 out this section, there is authorized to be appropriated
12 \$10,000,000 for each of fiscal years 2019 through 2021.

13 **Subtitle K—Stop Counterfeit Drugs**
14 **by Regulating and Enhancing**
15 **Enforcement Now**

16 **SEC. 7101. SHORT TITLE.**

17 This subtitle may be cited as the “Stop Counterfeit
18 Drugs by Regulating and Enhancing Enforcement Now
19 Act” or the “SCREEN Act”.

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

22 (a) INCREASING THE MAXIMUM DOLLAR AMOUNT OF
23 DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence
24 in section 801(a) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 381(a)) is amended by striking “ex-

1 cept that the Secretary” and all that follows through the
2 two periods at the end and inserting “except that the Sec-
3 retary of Health and Human Services may destroy, with-
4 out the opportunity for export, any drug refused admission
5 under this section, if such drug is declared to be valued
6 at an amount that is \$2,500 or less (or such higher
7 amount as the Secretary of the Treasury may set by regu-
8 lation pursuant to section 498(a)(1) of the Tariff Act of
9 1930 or such higher amount as the Commissioner of Food
10 and Drugs may set based on a finding by the Commis-
11 sioner that the higher amount is in the interest of public
12 health), or if such drug is entering the United States by
13 mail, and was not brought into compliance as described
14 under subsection (b).”.

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

23 (c) TECHNICAL AMENDMENTS.—The seventh, eighth,
24 and ninth sentences of section 801(a) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amend-
2 ed—

3 (1) by striking “a drug” each place it appears
4 and inserting “an article”; and

5 (2) by striking “the drug” each place it appears
6 and inserting “the article”.

7 (d) **RULE OF CONSTRUCTION.**—The last sentence in
8 section 801(a) of the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 381(a)) is amended to read as follows:
10 “Clauses (2), (5), and (6) of the third sentence of this
11 subsection shall not be construed to prohibit the admission
12 of narcotic or nonnarcotic drugs or other substances, the
13 importation of which is permitted under the Controlled
14 Substances Import and Export Act.”.

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

18 (a) **PROHIBITED ACTS.**—Section 301 of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amend-
20 ed by adding at the end the following:

21 “(eee) The failure to comply with any order issued
22 under section 569D.”.

23 (b) **NOTIFICATION, NONDISTRIBUTION, AND RECALL**
24 **OF ADULTERATED OR MISBRANDED DRUGS.**—Subchapter
25 E of chapter V of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 360bbb et seq.) is amended by adding at
2 the end the following:

3 **“SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RE-**
4 **CALL OF ADULTERATED OR MISBRANDED**
5 **DRUGS.**

6 “(a) ORDER TO CEASE DISTRIBUTION AND RE-
7 CALL.—

8 “(1) IN GENERAL.—Upon a determination that
9 the use or consumption of, or exposure to, a drug
10 may present an imminent or substantial hazard to
11 the public health, the Secretary shall issue an order
12 requiring any person who distributes the drug to im-
13 mediately cease distribution of the drug.

14 “(2) HEARING.—An order under paragraph (1)
15 shall provide the person subject to the order with an
16 opportunity for an informal hearing, to be held not
17 later than 10 days after the date of issuance of the
18 order, on—

19 “(A) the actions required by the order; and

20 “(B) whether the order should be amended
21 to require a recall of the drug.

22 “(3) INADEQUATE GROUNDS.—If, after pro-
23 viding an opportunity for a hearing under paragraph
24 (2), the Secretary determines that inadequate

1 grounds exist to support the actions required by the
2 order, the Secretary shall vacate the order.

3 “(4) AMENDMENT TO ORDER TO REQUIRE RE-
4 CALL.—If, after providing an opportunity for an in-
5 formal hearing under paragraph (2), the Secretary
6 determines that the order should be amended to in-
7 clude a recall of the drug with respect to which the
8 order was issued, the Secretary shall—

9 “(A) amend the order to require a recall;

10 and

11 “(B) after consultation with the drug
12 sponsor, specify a timetable in which the recall
13 will occur.

14 “(5) NOTICE TO PERSONS AFFECTED.—An
15 order under this subsection shall require any person
16 who distributes the drug to provide for notice, in-
17 cluding to individuals as appropriate, to persons who
18 may be affected by the order to cease distribution of
19 or recall the drug, as applicable.

20 “(6) ACTION FOLLOWING ORDER.—Any person
21 who is subject to an order under paragraph (1) or
22 (4) shall immediately cease distribution of or recall,
23 as applicable, the drug and provide notification as
24 required by such order.

1 “(b) NOTICE TO CONSUMERS AND HEALTH OFFI-
2 CIALS.—The Secretary shall, as the Secretary determines
3 to be necessary, provide notice of a recall order under this
4 section to—

5 “(1) consumers to whom the drug was, or may
6 have been, distributed; and

7 “(2) appropriate State and local health officials.

8 “(c) ORDER TO RECALL.—

9 “(1) CONTENTS.—An order to recall a drug
10 under subsection (a) shall—

11 “(A) require periodic reports to the Sec-
12 retary describing the progress of the recall; and

13 “(B) provide for notice, including to indi-
14 viduals as appropriate, to persons who may be
15 affected by the recall.

16 “(2) ASSISTANCE ALLOWED.—In providing for
17 notice under paragraph (1)(B), the Secretary may
18 allow for the assistance of health professionals, State
19 or local officials, or other individuals designated by
20 the Secretary.

21 “(3) NONDELEGATION.—An order under this
22 section shall be ordered by the Secretary or an offi-
23 cial designated by the Secretary. An official may not
24 be so designated under this section unless the offi-
25 cial is the Director of the Center for Drug Evalua-

1 tion and Research, is an official senior to such Di-
2 rector, or is so designated by such Director.

3 “(d) SAVINGS CLAUSE.—Nothing contained in this
4 section shall be construed as limiting—

5 “(1) the authority of the Secretary to issue an
6 order to cease distribution of, or to recall, an drug
7 under any other provision of this Act or the Public
8 Health Service Act; or

9 “(2) the ability of the Secretary to request any
10 person to perform a voluntary activity related to any
11 drug subject to this Act or the Public Health Service
12 Act.”.

13 (c) DRUGS SUBJECT TO REFUSAL.—The third sen-
14 tence of subsection (a) of section 801 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
16 inserting “or (5) in the case of a drug, such drug is sub-
17 ject to an order under section 568 to cease distribution
18 of or recall the drug,” before “then such article shall be
19 refused admission”.

20 (d) APPLICATION.—Sections 301(eee) and 569D of
21 the Federal Food, Drug, and Cosmetic Act, as added by
22 subsections (a) and (b), shall apply with respect to a drug
23 as of such date, not later than 1 year after the date of
24 the enactment of this Act, as the Secretary of Health and
25 Human Services shall specify.

1 **SEC. 7104. SINGLE SOURCE PATTERN OF SHIPMENTS OF**
2 **ADULTERATED OR MISBRANDED DRUGS.**

3 Section 801 of the Federal Food, Drug, and Cosmetic
4 Act is amended by adding at the end the following:

5 “(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF
6 ADULTERATED OR MISBRANDED DRUGS.—If the Sec-
7 retary identifies a pattern of adulterated or misbranded
8 drugs being offered for import from the same manufac-
9 turer, distributor, or importer, the Secretary may by order
10 choose to treat all drugs being offered for import from
11 such manufacturer, distributor, or importer as adulterated
12 or misbranded unless otherwise demonstrated.”.

13 **SEC. 7105. FUND TO STRENGTHEN EFFORTS OF FDA TO**
14 **COMBAT THE OPIOID AND SUBSTANCE USE**
15 **EPIDEMIC.**

16 Chapter X of the Federal Food, Drug, and Cosmetic
17 Act (21 U.S.C. 391 et seq.) is amended by adding at the
18 end the following:

19 **“SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO**
20 **COMBAT THE OPIOID AND SUBSTANCE USE**
21 **EPIDEMIC.**

22 “(a) IN GENERAL.—The Commissioner of Food and
23 Drugs shall use any funds appropriated pursuant to the
24 authorization of appropriations under subsection (c) to
25 carry out the programs and activities described in sub-
26 section (d) to strengthen and facilitate the Food and Drug

1 Administration’s efforts to address the opioid and sub-
2 stance use epidemic. Such funds shall be in addition to
3 any funds which are otherwise available to carry out such
4 programs and activities.

5 “(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC
6 RESPONSE FUND.—

7 “(1) ESTABLISHMENT OF FUND.—There is es-
8 tablished in the Treasury a fund, to be known as the
9 FDA Opioid and Substance Use Epidemic Response
10 Fund (referred to in this subsection as the ‘Fund’),
11 for purposes of funding the programs and activities
12 described in subsection (d).

13 “(2) TRANSFER.—For the period of fiscal years
14 2019 through 2023, \$110,000,000 shall be trans-
15 ferred to the Fund from the general fund of the
16 Treasury.

17 “(3) AMOUNTS DEPOSITED.—Any amounts
18 transferred under paragraph (2) shall remain un-
19 available in the Fund until such amounts are appro-
20 priated pursuant to subsection (c).

21 “(c) APPROPRIATIONS.—

22 “(1) AUTHORIZATION OF APPROPRIATIONS.—
23 For the period of fiscal years 2019 through 2023,
24 there is authorized to be appropriated from the
25 Fund to the Food and Drug Administration, for the

1 purpose of carrying out the programs and activities
2 described in subsection (d), an amount not to exceed
3 the total amount transferred to the Fund under sub-
4 section (b)(2). Notwithstanding subsection (g), such
5 funds shall remain available until expended.

6 “(2) OFFSETTING FUTURE APPROPRIATIONS.—
7 For any of fiscal years 2019 through 2023, for any
8 discretionary appropriation out of the Fund to the
9 Food and Drug Administration pursuant to the au-
10 thorization of appropriations under paragraph (1)
11 for the purpose of carrying out the programs and
12 activities described in subsection (d), the total
13 amount of such appropriations for the applicable fis-
14 cal year (not to exceed the total amount remaining
15 in the Fund) shall be subtracted from the estimate
16 of discretionary budget authority and the resulting
17 outlays for any estimate under the Congressional
18 Budget and Impoundment Control Act of 1974 or
19 the Balanced Budget and Emergency Deficit Control
20 Act of 1985, and the amount transferred to the
21 Fund shall be reduced by the same amount.

22 “(d) FOOD AND DRUG ADMINISTRATION.—The en-
23 tirety of the funds made available pursuant to subsection
24 (c)(1) shall be for the Commissioner of Food and Drugs,
25 pursuant to applicable authorities in the Public Health

1 Service Act (42 U.S.C. 201 et seq.) or this Act and other
2 applicable Federal law, to support widespread innovation
3 in non-opioid and non-addictive medical products for pain
4 treatment, access to opioid addiction treatments, appro-
5 priate use of approved opioids, and efforts to reduce illicit
6 importation of opioids. Such support may include the fol-
7 lowing programs and activities:

8 “(1) Obligating contract funds beginning in fis-
9 cal year 2019 for an educational campaign that
10 will—

11 “(A) educate patients and their families to
12 differentiate opioid medications;

13 “(B) raise awareness about preferred stor-
14 age and disposal methods; and

15 “(C) inform patients, families, and commu-
16 nities about medication-assisted treatment op-
17 tions.

18 “(2) Building the Food and Drug Administra-
19 tion’s presence in international mail facilities, includ-
20 ing through—

21 “(A) improvements in equipment and in-
22 formation technology enhancements to identify
23 unapproved, counterfeit, or other unlawful
24 pharmaceuticals for destruction;

25 “(B) increased and improved surveillance;

1 “(C) renovations at international mail fa-
2 cility locations; and

3 “(D) the purchase of laboratory equip-
4 ment.

5 “(3) Enhancing the identification and targeting
6 of entities offering products and products being of-
7 fered by such entities for import into the United
8 States through review and analysis of Internet
9 websites, import data, and other sources of intel-
10 ligence for purposes of making the best use of the
11 Food and Drug Administration’s inspection and ana-
12 lytical resources.

13 “(4) Increasing the number of staff of the Food
14 and Drug Administration to increase the number of
15 packages being examined, ensuring the safety of the
16 staff undertaking such examinations, and ensuring
17 that packages identified as illegal, counterfeit, mis-
18 branded, or adulterated are removed from commerce
19 through available authorities, including administra-
20 tive destruction.

21 “(5) Enhancing the Food and Drug Adminis-
22 tration’s criminal investigations resources (including
23 full-time equivalent employees and equipment), im-
24 ports surveillance, and international work.

1 “(6) Obtaining for the Food and Drug Admin-
2 istration equipment and full-time equivalent employ-
3 ees needed to efficiently screen and analyze products
4 offered for import, including by building data libraries
5 of new substances and analogues to facilitate
6 identification and evaluation of pharmaceutical-
7 based agents and by purchasing screening tech-
8 nologies for use at international mail facilities.

9 “(7) Operating the Food and Drug Administra-
10 tion’s forensic laboratory facility to ensure adequate
11 laboratory space and functionality for additional
12 work and full-time equivalent employees.

13 “(e) ACCOUNTABILITY AND OVERSIGHT.—

14 “(1) WORK PLAN.—

15 “(A) IN GENERAL.—Not later than 180
16 days after the date of enactment of this Act,
17 the Commissioner of Food and Drugs shall sub-
18 mit to the Committee on Health, Education,
19 Labor and Pensions of the Senate and the
20 Committee on Energy and Commerce of the
21 House of Representatives, a work plan includ-
22 ing the proposed allocation of funds appro-
23 priated pursuant to the authorization of appro-
24 priations under subsection (c) for each of fiscal

1 years 2019 through 2023 and the contents de-
2 scribed in subparagraph (B).

3 “(B) CONTENTS.—The work plan sub-
4 mitted under subparagraph (A) shall include—

5 “(i) the amount of money to be obli-
6 gated or expended out of the Fund in each
7 fiscal year for each program and activity
8 described in subsection (d); and

9 “(ii) a description and justification of
10 each such program and activity.

11 “(2) REPORTS.—

12 “(A) ANNUAL REPORTS.—Not later than
13 October 1 of each of fiscal years 2020 through
14 2024, the Secretary of Health and Human
15 Services shall submit to the Committee on
16 Health, Education, Labor and Pensions of the
17 Senate and the Committee on Energy and Com-
18 merce of the House of Representatives a report
19 that includes—

20 “(i) the amount of money obligated or
21 expended out of the Fund in the prior fis-
22 cal year for each program and activity de-
23 scribed in subsection (d);

24 “(ii) a description of all programs and
25 activities using funds provided pursuant to

1 the authorization of appropriations under
2 subsection (c); and

3 “(iii) how the programs and activities
4 are advancing public health.

5 “(B) ADDITIONAL REPORTS.—At the re-
6 quest of the Committee on Health, Education,
7 Labor and Pensions of the Senate or the Com-
8 mittee on Energy and Commerce of the House
9 of Representatives, the Commissioner shall pro-
10 vide an update in the form of testimony and
11 any additional reports to the respective congres-
12 sional committee regarding the allocation of
13 funding under this section or the description of
14 the programs and activities undertaken with
15 such funding.

16 “(f) LIMITATIONS.—Notwithstanding any transfer
17 authority authorized by this section or any appropriations
18 Act, any funds made available pursuant to the authoriza-
19 tion of appropriations under subsection (c) may not be
20 used for any purpose other than the programs and activi-
21 ties described in subsection (d) to strengthen and facilitate
22 the Food and Drug Administration’s efforts to address the
23 opioid and substance use epidemic.

24 “(g) SUNSET.—This section shall expire on Sep-
25 tember 30, 2022, except that—

1 “(1) this subsection does not apply to reporting
2 under subsection (e)(2); and

3 “(2) this section shall remain in effect until
4 such time, and to such extent, as may be necessary
5 for the funds transferred by subsection (b)(2) to be
6 fully expended.”.

7 **SEC. 7106. CONSIDERATION OF POTENTIAL FOR MISUSE**
8 **AND ABUSE REQUIRED FOR DRUG AP-**
9 **PROVAL.**

10 (a) IN GENERAL.—Section 505(d) of the Federal
11 Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
12 amended—

13 (1) in the first sentence—

14 (A) by striking “or (7)” and inserting
15 “(7)”; and

16 (B) by inserting “or (8) if the drug is or
17 contains a controlled substance for which a list-
18 ing in any schedule is in effect under the Con-
19 trolled Substances Act or that is permanently
20 scheduled pursuant to section 201 of such Act,
21 on the basis of information submitted to him as
22 part of the application, or upon the basis of any
23 other information before him with respect to
24 such drug, the drug is unsafe for use due to the
25 risks of abuse or misuse or there is insufficient

1 information to show that the drug is safe for
2 use considering such risks;” before “he shall
3 issue an order refusing to approve the applica-
4 tion”; and

5 (2) in the second sentence, by striking “(6)”
6 and inserting “(8)”.

7 (b) WITHDRAWAL AUTHORITY.—Section 505(e) of
8 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(e)) is amended in the first sentence—

10 (1) by striking “or (5)” and inserting “(5)”;
11 and

12 (2) by inserting the following: “; or (6) that, in
13 the case of a drug that is or contains a controlled
14 substance for which a listing in any schedule is in
15 effect under the Controlled Substances Act or that
16 is permanently scheduled pursuant to section 201 of
17 such Act, on the basis of new information before him
18 with respect to such drug, evaluated together with
19 the information available to him when the applica-
20 tion was approved, that the drug is unsafe for use
21 due to the risks of abuse or misuse” after “of a ma-
22 terial fact”.

23 (c) RULE OF CONSTRUCTION.—Nothing in the
24 amendments made by this section shall be construed to
25 limit or narrow, in any manner, the meaning or applica-

1 tion of the provisions of paragraphs (1), (2), (3), (4), (5),
2 and (7) of section 505(d) of the Federal Food, Drug, and
3 Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and
4 (2) of section 505(e) of such Act (21 U.S.C. 355(e)).

5 **Subtitle L—Treatment, Education,**
6 **and Community Help to Combat**
7 **Addiction**

8 **SEC. 7111. SHORT TITLE.**

9 This subtitle may be cited as the “Treatment, Edu-
10 cation, and Community Help to Combat Addiction Act of
11 2018” or the “TEACH to Combat Addiction Act of
12 2018”.

13 **SEC. 7112. ESTABLISHMENT OF REGIONAL CENTERS OF EX-**
14 **CELLENCE IN SUBSTANCE USE DISORDER**
15 **EDUCATION.**

16 Part D of title V of the Public Health Service Act
17 is amended by inserting after section 549 (42 U.S.C.
18 290ee–4) the following new section:

19 **“SEC. 550. REGIONAL CENTERS OF EXCELLENCE IN SUB-**
20 **STANCE USE DISORDER EDUCATION.**

21 “(a) IN GENERAL.—The Secretary, in consultation
22 with such other agencies as are appropriate, shall, subject
23 to the availability of appropriations, establish a solicitation
24 process and award cooperative agreements to eligible enti-
25 ties for the designation of such entities as Regional Cen-

1 ters of Excellence in Substance Use Disorder Education
2 and support of such regional centers of excellence to en-
3 hance and improve how health professionals are educated
4 in substance use disorder prevention, treatment, and re-
5 covery through development, evaluation, and distribution
6 of evidence-based curricula for health profession schools.
7 An eligible entity designated by the Secretary as a Re-
8 gional Center of Excellence in Substance Use Disorder
9 Education shall carry out the activities described in sub-
10 section (b).

11 “(b) SELECTION OF CENTERS OF EXCELLENCE.—

12 “(1) ELIGIBLE ENTITIES.—To be eligible to re-
13 ceive a cooperative agreement under subsection (a),
14 an entity shall—

15 “(A) be an entity specified by the Sec-
16 retary that offers education to students in var-
17 ious health professions, which may include—

18 “(i) a health system;

19 “(ii) a teaching hospital;

20 “(iii) a medical school;

21 “(iv) a certified behavioral health clin-
22 ic; or

23 “(v) any other health profession
24 school, school of public health, or Coopera-
25 tive Extension Program at institutions of

1 higher education engaged in an aspect of
2 the prevention, treatment, or recovery of
3 substance use disorders;

4 “(B) be accredited by the appropriate edu-
5 cational accreditation body;

6 “(C) demonstrate an existing strategy, and
7 have in place a plan for continuing such strat-
8 egy, or a proposed strategy to implement a cur-
9 riculum based on best practices for substance
10 use disorder prevention, treatment, and recov-
11 ery;

12 “(D) demonstrate community engagement
13 and participation through community partners,
14 including other health profession schools, men-
15 tal health counselors, social workers, peer recov-
16 ery specialists, substance use treatment pro-
17 grams, community health centers, physicians’
18 offices, certified behavioral health clinics, law
19 enforcement, and the business community; and

20 “(E) provide to the Secretary such infor-
21 mation, at such time, and in such manner, as
22 the Secretary may require.

23 “(2) DIVERSITY.—In awarding cooperative
24 agreements under subsection (a), the Secretary shall
25 take into account regional differences among eligible

1 entities and shall make an effort to ensure geo-
2 graphic diversity.

3 “(c) DISSEMINATION OF INFORMATION.—

4 “(1) PUBLIC POSTING.—The Secretary shall
5 make information provided to the Secretary under
6 subsection (b)(1)(E) publically available on the
7 Internet website of the Department of Health and
8 Human Services.

9 “(2) EVALUATION.—The Secretary shall evalu-
10 ate each project carried out by a Regional Center of
11 Excellence in Substance Use Disorder Education
12 under this section and shall disseminate the findings
13 with respect to each such evaluation to appropriate
14 public and private entities.

15 “(d) FUNDING.—There is authorized to be appro-
16 priated to carry out this section, \$4,000,000 for each of
17 fiscal years 2019 through 2023.”.

18 **Subtitle M—Guidance From Na-**
19 **tional Mental Health and Sub-**
20 **stance Use Policy Laboratory**

21 **SEC. 7121. GUIDANCE FROM NATIONAL MENTAL HEALTH**
22 **AND SUBSTANCE USE POLICY LABORATORY.**

23 Section 501A(b) of the Public Health Service Act (42
24 U.S.C. 290aa–0(b)) is amended—

1 (1) in paragraph (5), by striking “and” at the
2 end;

3 (2) in paragraph (6), by striking the period at
4 the end and inserting “; and”; and

5 (3) by adding at the end the following:

6 “(7) issue and periodically update guidance for
7 entities applying for grants from the Substance
8 Abuse and Mental Health Services Administration in
9 order to—

10 “(A) encourage the funding of evidence-
11 based practices;

12 “(B) encourage the replication of prom-
13 ising or effective practices; and

14 “(C) inform applicants on how to best ar-
15 ticulate the rationale for the funding of a pro-
16 gram or activity.”.

17 **Subtitle N—Comprehensive Opioid**
18 **Recovery Centers**

19 **SEC. 7131. SHORT TITLE.**

20 This subtitle may be cited as the “Comprehensive
21 Opioid Recovery Centers Act of 2018”.

22 **SEC. 7132. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

23 (a) **IN GENERAL.**—Part D of title V of the Public
24 Health Service Act is amended by adding at the end the
25 following new section:

1 **“SEC. 550. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

2 “(a) IN GENERAL.—The Secretary shall award
3 grants on a competitive basis to eligible entities to estab-
4 lish or operate a comprehensive opioid recovery center (re-
5 ferred to in this section as a ‘Center’).

6 “(b) GRANT PERIOD.—

7 “(1) IN GENERAL.—A grant awarded under
8 subsection (a) shall be for a period not less than 3
9 years and not more than 5 years.

10 “(2) RENEWAL.—A grant awarded under sub-
11 section (a) may be renewed, on a competitive basis,
12 for additional periods of time, as determined by the
13 Secretary. In determining whether to renew a grant
14 under this paragraph, the Secretary shall consider
15 the data submitted under subsection (h).

16 “(c) MINIMUM NUMBER OF CENTERS.—The Sec-
17 retary shall allocate the amounts made available under
18 subsection (i) in such amounts that not fewer than 10
19 Centers will be established across the United States.

20 “(d) APPLICATION.—In order to be eligible for a
21 grant under subsection (a), an entity shall submit an ap-
22 plication to the Secretary at such time and in such manner
23 as the Secretary may require. Such application shall in-
24 clude—

1 “(1) evidence that such entity carries out, or is
2 capable of coordinating with other entities to carry
3 out, the activities described in subsection (g); and

4 “(2) such other information as the Secretary
5 may require.

6 “(e) PRIORITY.—In awarding grants under sub-
7 section (a), the Secretary shall give priority to eligible enti-
8 ties located in a State or Indian country (as defined in
9 section 1151 of title 18, United States Code)—

10 “(1) with a high per capita drug overdose mor-
11 tality rate, as determined by the Director of the
12 Centers for Disease Control and Prevention; or

13 “(2) based on any other criteria or need, as de-
14 termined by the Secretary.

15 “(f) USE OF GRANT FUNDS.—An eligible entity
16 awarded a grant under subsection (a) shall use the grant
17 funds to establish or operate a Center to carry out the
18 activities described in subsection (g).

19 “(g) CENTER ACTIVITIES AND SERVICES.—Each
20 Center shall, at a minimum, carry out the activities de-
21 scribed in this subsection. In the case of a Center that
22 determines that a service described in paragraph (2) can-
23 not reasonably be carried out by the Center, such Center
24 shall contract with such other entities as may be necessary

1 to ensure that patients have access to the full range of
2 services described in such paragraph.

3 “(1) COMMUNITY OUTREACH.—Each Center
4 shall carry out the following outreach activities:

5 “(A) Train and supervise outreach staff to
6 work with schools, workplaces, faith-based orga-
7 nizations, State and local health departments,
8 law enforcement, and first responders to ensure
9 that such institutions are aware of the services
10 of the Center.

11 “(B) Disseminate and make available on-
12 line evidence-based resources that educate pro-
13 fessionals and the public on opioid use disorder
14 and other substance use disorders.

15 “(2) TREATMENT AND RECOVERY SERVICES.—
16 Each Center shall provide the following treatment
17 and recovery services:

18 “(A) Ensure that intake evaluations meet
19 the clinical needs of patients.

20 “(B) Periodically conduct patient assess-
21 ments to ensure continued and meaningful re-
22 covery, as defined by the Assistant Secretary
23 for Mental Health and Substance Use.

24 “(C) Provide the full continuum of treat-
25 ment services, including—

1 “(i) all drugs approved under section
2 505 of the Federal Food, Drug, and Cos-
3 metic Act and all biological products li-
4 censed under section 351 of this Act, in-
5 cluding methadone, to treat substance use
6 disorders, including opioid use disorder
7 and alcohol use disorder;

8 “(ii) withdrawal management, which
9 shall include medically supervised detoxi-
10 fication that includes patient evaluation,
11 stabilization, and readiness for and entry
12 into treatment;

13 “(iii) counseling and case manage-
14 ment, including counseling and recovery
15 services for any possible co-occurring men-
16 tal illness;

17 “(iv) residential rehabilitation;

18 “(v) recovery housing;

19 “(vi) community-based and peer re-
20 covery support services;

21 “(vii) job training and placement as-
22 sistance to support reintegration into the
23 workforce; and

24 “(viii) other best practices, as deter-
25 mined by the Secretary.

1 “(D) Administer an onsite pharmacy and
2 provide toxicology services.

3 “(E) Establish and operate a secure and
4 confidential electronic health information sys-
5 tem.

6 “(F) Offer family support services such as
7 child care, family counseling, and parenting
8 interventions to help stabilize families impacted
9 by substance use disorder.

10 “(h) DATA REPORTING AND PROGRAM OVER-
11 SIGHT.—With respect to a grant awarded under sub-
12 section (a) to an eligible entity for a Center, not later than
13 90 days after the end of the first year of the grant period,
14 and annually thereafter for the duration of the grant pe-
15 riod (including the duration of any renewal period for such
16 grant), the entity shall submit data, as appropriate, to the
17 Secretary regarding—

18 “(1) the programs and activities funded by the
19 grant;

20 “(2) health outcomes of individuals with a sub-
21 stance use disorder who received services from the
22 Center;

23 “(3) the effectiveness of interventions designed,
24 tested, and evaluated by the Center; and

1 “(4) any other information that the Secretary
2 may require for the purpose of—

3 “(A) evaluating the effectiveness of the
4 Center; and

5 “(B) ensuring that the Center is complying
6 with all the requirements of the grant, including
7 providing the full continuum of services de-
8 scribed in subsection (g)(2)(C) and providing
9 drugs and devices for overdose reversal under
10 such subsection.

11 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is
12 authorized to be appropriated \$10,000,000 for each of fis-
13 cal years 2019 through 2023 for purposes of carrying out
14 this section.”.

15 (b) REPORTS TO CONGRESS.—

16 (1) PRELIMINARY REPORT.—Not later than 3
17 years after the date of the enactment of this Act, the
18 Secretary of Health and Human Services shall sub-
19 mit to Congress a preliminary report that analyzes
20 data submitted under section 550(h) of the Public
21 Health Service Act, as added by subsection (a).

22 (2) FINAL REPORT.—Not later than 1 year
23 after submitting the preliminary report required
24 under paragraph (1), the Secretary of Health and

1 Human Services shall submit to Congress a final re-
2 port that includes—

3 (A) an evaluation of the effectiveness of
4 comprehensive opioid recovery centers estab-
5 lished or operated pursuant to section 550 of
6 the Public Health Service Act, as added by sub-
7 section (a);

8 (B) recommendations on whether the grant
9 program established under such section 550
10 should be reauthorized and expanded; and

11 (C) standards and best practices for the
12 treatment of substance use disorders, as identi-
13 fied through such grant program.

14 **Subtitle O—Poison Center Network**
15 **Enhancement**

16 **SEC. 7141. SHORT TITLE.**

17 This subtitle may be cited as the “Poison Center Net-
18 work Enhancement Act of 2018”.

19 **SEC. 7142. REAUTHORIZATION OF POISON CONTROL CEN-**
20 **TERS NATIONAL TOLL-FREE NUMBER.**

21 Section 1271 of the Public Health Service Act (42
22 U.S.C. 300d–71) is amended to read as follows:

1 **“SEC. 1271. ESTABLISHMENT AND MAINTENANCE OF THE**
2 **NATIONAL TOLL-FREE NUMBER AND EN-**
3 **HANCED COMMUNICATIONS CAPABILITIES.**

4 “(a) IN GENERAL.—The Secretary shall provide co-
5 ordination and assistance to poison control centers for—

6 “(1) the development, establishment, implemen-
7 tation, and maintenance of a nationwide toll-free
8 phone number; and

9 “(2) the enhancement of communications capa-
10 bilities, which may include text capabilities.

11 “(b) CONSULTATION.—The Secretary may consult
12 with nationally recognized professional organizations in
13 the field of poison control to determine the best and most
14 effective means of achieving the goals described in para-
15 graphs (1) and (2) of subsection (a).

16 “(c) RULE OF CONSTRUCTION.—In assisting with
17 public health emergencies, responses, or preparedness,
18 nothing in this section shall be construed to restrict the
19 work of poison control centers or the use of their resources
20 by the Secretary or other governmental agencies.

21 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated to carry out this section
23 \$700,000 for each of fiscal years 2019 through 2023.”.

1 **SEC. 7143. REAUTHORIZATION OF NATIONWIDE PUBLIC**
2 **AWARENESS CAMPAIGN TO PROMOTE POI-**
3 **SON CONTROL CENTER UTILIZATION.**

4 Section 1272 of the Public Health Service Act (42
5 U.S.C. 300d-72) is amended to read as follows:

6 **“SEC. 1272. NATIONWIDE PUBLIC AWARENESS CAMPAIGN**
7 **TO PROMOTE POISON CONTROL CENTER UTI-**
8 **LIZATION AND THEIR PUBLIC HEALTH EMER-**
9 **GENCY RESPONSE CAPABILITIES.**

10 “(a) IN GENERAL.—The Secretary shall—

11 “(1) carry out, and expand upon, a national
12 public awareness campaign to educate the public and
13 health care providers about—

14 “(A) poisoning, toxic exposure, and drug
15 misuse prevention; and

16 “(B) the availability of poison control cen-
17 ter resources in local communities; and

18 “(2) as part of such campaign, highlight the
19 nationwide toll-free number and enhanced commu-
20 nications capabilities supported under section 1271.

21 “(b) CONSULTATION.—In carrying out and expand-
22 ing upon the national campaign under subsection (a), the
23 Secretary may consult with nationally recognized profes-
24 sional organizations in the field of poison control response
25 for the purpose of determining the best and most effective
26 methods for achieving public awareness.

1 “(c) CONTRACT WITH ENTITY.—The Secretary may
2 carry out subsection (a) by entering into contracts with
3 one or more public or private entities, including nationally
4 recognized professional organizations in the field of poison
5 control and national media firms, for the development and
6 implementation of the awareness campaign under sub-
7 section (a), which may include—

8 “(1) the development and distribution of poi-
9 soning and toxic exposure prevention, poison control
10 center, and public health emergency awareness and
11 response materials;

12 “(2) television, radio, internet, and newspaper
13 public service announcements; and

14 “(3) other means and activities to provide for
15 public and professional awareness and education.

16 “(d) EVALUATION.—The Secretary shall—

17 “(1) establish baseline measures and bench-
18 marks to quantitatively evaluate the impact of the
19 nationwide public awareness campaign carried out
20 under this section; and

21 “(2) on a biennial basis, prepare and submit to
22 the appropriate committees of Congress an evalua-
23 tion of the nationwide public awareness campaign.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated to carry out this section,
3 \$800,000 for each of fiscal years 2019 through 2023.”.

4 **SEC. 7144. REAUTHORIZATION OF THE POISON CONTROL**
5 **CENTER GRANT PROGRAM.**

6 Section 1273 of the Public Health Service Act (42
7 U.S.C. 300d–73) is amended to read as follows:

8 **“SEC. 1273. MAINTENANCE OF THE POISON CONTROL CEN-**
9 **TER GRANT PROGRAM.**

10 “(a) AUTHORIZATION OF PROGRAM.—The Secretary
11 shall award grants to poison control centers accredited
12 under subsection (c) (or granted a waiver under subsection
13 (d)) and nationally recognized professional organizations
14 in the field of poison control for the purposes of—

15 “(1) preventing, and providing treatment rec-
16 ommendations for, poisonings and toxic exposures
17 including opioid and drug misuse;

18 “(2) assisting with public health emergencies,
19 responses, and preparedness; and

20 “(3) complying with the operational require-
21 ments needed to sustain the accreditation of the cen-
22 ter under subsection (c).

23 “(b) ADDITIONAL USES OF FUNDS.—In addition to
24 the purposes described in subsection (a), a poison center
25 or professional organization awarded a grant under such

1 subsection may also use amounts received under such
2 grant—

3 “(1) to research, establish, implement, and
4 evaluate best practices in the United States for poi-
5 soning prevention, poison control center outreach,
6 opioid and drug misuse information and response,
7 and public health emergency, response, and pre-
8 paredness programs;

9 “(2) to research, develop, implement, revise,
10 and communicate standard patient management
11 guidelines for commonly encountered toxic expo-
12 sures;

13 “(3) to improve national toxic exposure and
14 opioid misuse surveillance by enhancing cooperative
15 activities between poison control centers in the
16 United States and the Centers for Disease Control
17 and Prevention and other governmental agencies;

18 “(4) to research, improve, and enhance the
19 communications and response capability and capac-
20 ity of the Nation’s network of poison control centers
21 to facilitate increased access to the centers through
22 the integration and modernization of the current
23 poison control centers communications and data sys-
24 tem, including enhancing the network’s telephony,
25 internet, data, and social networking technologies;

1 “(5) to develop, support, and enhance tech-
2 nology and capabilities of nationally recognized pro-
3 fessional organizations in the field of poison control
4 to collect national poisoning, toxic occurrence, and
5 related public health data;

6 “(6) to develop initiatives to foster the en-
7 hanced public health utilization of national poison
8 data collected by such organizations;

9 “(7) to support and expand the toxicologic ex-
10 pertise within poison control centers; and

11 “(8) to improve the capacity of poison control
12 centers to answer high volumes of contacts and
13 internet communications, and to sustain and en-
14 hance the poison control center’s network capability
15 to respond during times of national crisis or other
16 public health emergencies.

17 “(c) ACCREDITATION.—Except as provided in sub-
18 section (d), the Secretary may award a grant to a poison
19 control center under subsection (a) only if—

20 “(1) the center has been accredited by a nation-
21 ally recognized professional organization in the field
22 of poison control, and the Secretary has approved
23 the organization as having in effect standards for
24 accreditation that reasonably provide for the protec-

1 tion of the public health with respect to poisoning;
2 or

3 “(2) the center has been accredited by a State
4 government, and the Secretary has approved the
5 State government as having in effect standards for
6 accreditation that reasonably provide for the protec-
7 tion of the public health with respect to poisoning.

8 “(d) WAIVER OF ACCREDITATION REQUIREMENTS.—

9 “(1) IN GENERAL.—The Secretary may grant a
10 waiver of the accreditation requirements of sub-
11 section (c) with respect to a nonaccredited poison
12 control center that applies for a grant under this
13 section if such center can reasonably demonstrate
14 that the center will obtain such an accreditation
15 within a reasonable period of time as determined ap-
16 propriate by the Secretary.

17 “(2) RENEWAL.—The Secretary may renew a
18 waiver under paragraph (1).

19 “(3) LIMITATION.—The Secretary may not,
20 after the date of enactment of the Poison Control
21 Network Enhancement Act of 2018, grant to a poi-
22 son control center waivers or renewals that total
23 more than 5 years.

24 “(e) SUPPLEMENT NOT SUPPLANT.—Amounts made
25 available to a poison control center under this section shall

1 be used to supplement and not supplant other Federal,
2 State, or local funds provided for such center.

3 “(f) MAINTENANCE OF EFFORT.—A poison control
4 center, in utilizing the proceeds of a grant under this sec-
5 tion, shall maintain the annual recurring expenditures of
6 the center for its activities at a level that is not less than
7 80 percent of the average level of such recurring expendi-
8 tures maintained by the center for the preceding 3 fiscal
9 years for which a grant is received.

10 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section,
12 \$28,600,000 for each of fiscal years 2019 through 2023.
13 The Secretary may utilize an amount not to exceed 6 per-
14 cent of the amount appropriated pursuant to the pre-
15 ceding sentence for each fiscal year for coordination, dis-
16 semination, technical assistance, program evaluation, data
17 activities, and other program administration functions,
18 which are determined by the Secretary to be appropriate
19 for carrying out the program under this section.”.

20 **Subtitle P—Eliminating Opioid**
21 **Related Infectious Diseases**

22 **SEC. 7151. SHORT TITLE.**

23 This subtitle may be cited as the “Eliminating Opioid
24 Related Infectious Diseases Act of 2018”.

1 **SEC. 7152. REAUTHORIZATION AND EXPANSION OF PRO-**
2 **GRAM OF SURVEILLANCE AND EDUCATION**
3 **REGARDING INFECTIONS ASSOCIATED WITH**
4 **ILLICIT DRUG USE AND OTHER RISK FAC-**
5 **TORS.**

6 Section 317N of the Public Health Service Act (42
7 U.S.C. 247b–15) is amended to read as follows:

8 **“SEC. 317N. SURVEILLANCE AND EDUCATION REGARDING**
9 **INFECTIONS ASSOCIATED WITH ILLICIT**
10 **DRUG USE AND OTHER RISK FACTORS.**

11 “(a) IN GENERAL.—The Secretary may (directly and
12 through grants to public and nonprofit private entities)
13 provide for programs for the following:

14 “(1) To cooperate with the States and Indian
15 tribes in implementing or maintaining a surveillance
16 system to determine the incidence of infections com-
17 monly associated with illicit drug use, including in-
18 fections commonly associated with injection drug use
19 such as viral hepatitis, human immunodeficiency
20 virus, and infective endocarditis, and to assist the
21 States in determining the prevalence of such infec-
22 tions, which may include the reporting of cases of
23 such infections.

24 “(2) To identify, counsel, and offer testing to
25 individuals who are at risk of infections as a result

1 of injection drug use, receiving blood transfusions
2 prior to July 1992, or other risk factors.

3 “(3) To provide appropriate referrals for coun-
4 seling, testing, and medical treatment of individuals
5 identified under paragraph (2) and to ensure, to the
6 extent practicable, the provision of appropriate fol-
7 low-up services.

8 “(4) To develop and disseminate public infor-
9 mation and education programs for the detection
10 and control of infections described in paragraph (1),
11 with priority given to high-risk populations as deter-
12 mined by the Secretary.

13 “(5) To improve the education, training, and
14 skills of health professionals in the detection and
15 control of infections and the coordination of treat-
16 ment of addiction and infectious diseases described
17 in paragraph (1), with priority given to substance
18 use disorder treatment providers, pediatricians and
19 other primary care providers, obstetrician-gyne-
20 cologists, infectious diseases clinicians, and HIV cli-
21 nicians.

22 “(b) LABORATORY PROCEDURES.—The Secretary
23 may (directly or through grants to public and nonprofit
24 private entities) carry out programs to provide for im-

1 improvements in the quality of clinical-laboratory procedures
2 regarding infections described in subsection (a)(1).

3 “(c) DEFINITIONS.—In this section:

4 “(1) The term ‘Indian tribe’ has the meaning
5 given that term in section 4 of the Indian Self-De-
6 termination and Education Assistance Act.

7 “(2) The term ‘injection drug use’ means—

8 “(A) intravenous administration of a sub-
9 stance in schedule I under section 202 of the
10 Controlled Substances Act;

11 “(B) intravenous administration of a sub-
12 stance in schedule II, III, IV, or V under sec-
13 tion 202 of the Controlled Substances Act that
14 has not been approved for intravenous use
15 under—

16 “(i) section 505 of the Federal Food,
17 Drug and Cosmetic Act; or

18 “(ii) section 351 of the Public Health
19 Service Act; or

20 “(C) intravenous administration of a sub-
21 stance in schedule II, III, IV, or V under sec-
22 tion 202 of the Controlled Substances Act that
23 has not been prescribed to the person using the
24 substance.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated \$40,000,000 for each of the fiscal years
4 2019 through 2023.”.

5 **Subtitle Q—Better Pain**
6 **Management Through Better Data**

7 **SEC. 7161. SHORT TITLE.**

8 This subtitle may be cited as the “Better Pain Man-
9 agement Through Better Data Act of 2018”.

10 **SEC. 7162. GUIDANCE ADDRESSING ALTERNATIVE AP-**
11 **PROACHES TO DATA COLLECTION AND LA-**
12 **BELING CLAIMS FOR OPIOID SPARING.**

13 (a) IN GENERAL.—For purposes of assisting spon-
14 sors in collecting and incorporating opioid-sparing data in
15 product labeling, the Secretary of Health and Human
16 Services (referred to in this section as the “Secretary”)
17 shall conduct a public meeting and update or issue one
18 or more guidances in accordance with subsection (b).

19 (b) GUIDANCE.—

20 (1) IN GENERAL.—The Secretary of Health and
21 Human Services, acting through the Commissioner
22 of Food and Drugs, shall update or issue one or
23 more guidances addressing—

24 (A) alternative methods for data collection
25 on opioid sparing;

1 (B) alternative methods for inclusion of
2 such data in product labeling; and

3 (C) investigations other than clinical trials,
4 including partially controlled studies and objec-
5 tive trials without matched controls such as his-
6 torically controlled analyses, open-label studies,
7 and meta-analyses, on opioid sparing for inclu-
8 sion in product labeling.

9 (2) CONTENTS.—The guidances under para-
10 graph (1) shall address—

11 (A) innovative clinical trial designs for
12 ethically and efficiently collecting data on opioid
13 sparing for inclusion in product labeling;

14 (B) primary and secondary endpoints for
15 the reduction of opioid use while maintaining
16 adequate pain control;

17 (C) use of real world evidence, including
18 patient registries, and patient reported out-
19 comes to support inclusion of opioid-sparing
20 data in product labeling; and

21 (D) how sponsors may obtain feedback
22 from the Secretary relating to such issues prior
23 to—

24 (i) commencement of such data collec-
25 tion; or

1 (ii) the submission of resulting data to
2 the Secretary.

3 (3) PUBLIC MEETING.—Prior to updating or
4 issuing the guidances required by paragraph (1), the
5 Secretary shall consult with stakeholders, including
6 representatives of regulated industry, academia, pa-
7 tients, and provider organizations, through a public
8 meeting to be held not later than 12 months after
9 the date of enactment of this Act.

10 (4) TIMING.—The Secretary shall—

11 (A) not later than 12 months after the
12 date of the public meeting required by para-
13 graph (3), update or issue the one or more
14 draft guidances required by paragraph (1); and

15 (B) not later than 12 months after the
16 date on which the public comment period for
17 such draft guidances closes, finalize such guid-
18 ances.

19 (c) DEFINITION.—In this section:

20 (1) The terms “opioid sparing” and “opioid-
21 sparing” refer to the use of drugs or devices (as de-
22 fined in section 201 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 321)) that reduce pain
24 while enabling the reduction, replacement, or avoid-
25 ance of oral opioids.

1 (2) The term “Secretary” means the Secretary
2 of Health and Human Services.

3 **Subtitle R—Special Registration**
4 **for Telemedicine Clarification**

5 **SEC. 7171. SHORT TITLE.**

6 This subtitle may be cited as the “Special Registra-
7 tion for Telemedicine Clarification Act of 2018”.

8 **SEC. 7172. DEADLINE FOR INTERIM FINAL REGULATIONS**
9 **FOR A SPECIAL REGISTRATION TO ENGAGE**
10 **IN THE PRACTICE OF TELEMEDICINE.**

11 Section 311(h)(2) of the Controlled Substances Act
12 (21 U.S.C. 831(h)(2)) is amended by striking “The Attor-
13 ney General shall, with the concurrence of the Secretary,
14 promulgate regulations” and inserting “Not later than 1
15 year after the date of enactment of the Special Registra-
16 tion for Telemedicine Clarification Act of 2018, the Attor-
17 ney General shall, with the concurrence of the Secretary,
18 promulgate interim final regulations”.

19 **Subtitle S—Peer Support**
20 **Communities of Recovery**

21 **SEC. 7181. SHORT TITLE.**

22 This subtitle may be cited as the “Peer Support Com-
23 munities of Recovery Act”.

1 **SEC. 7182. BUILDING COMMUNITIES OF RECOVERY.**

2 Section 547 of the Public Health Service Act (42
3 U.S.C. 290ee-2) is amended—

4 (1) in subsection (a)—

5 (A) in the heading, by striking “DEFINI-
6 TION” and inserting “DEFINITIONS”;

7 (B) in the matter preceding paragraph (1),
8 by striking “In this section, the term ‘recovery
9 community organization’ means an independent
10 nonprofit organization that—” and inserting
11 “In this section:”;

12 (C) by redesignating paragraphs (1) and
13 (2) as subparagraphs (A) and (B), respectively,
14 and moving such subparagraphs (as so redesign-
15 ated) 2 ems to the right;

16 (D) by inserting before subparagraph (A)
17 (as so redesignated) the following:

18 “(1) RECOVERY COMMUNITY ORGANIZATION.—
19 The term ‘recovery community organization’ means
20 an independent nonprofit organization that—”; and

21 (E) by adding at the end the following:

22 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
23 tity’ means—

24 “(A) a national nonprofit entity focused on
25 substance use disorder with a network of local

1 affiliates and partners that are geographically
2 and organizationally diverse; or

3 “(B) a nonprofit organization—

4 “(i) focused on substance use dis-
5 order;

6 “(ii) established by individuals in per-
7 sonal or family recovery; and

8 “(iii) serving prevention, treatment,
9 recovery, payor, faith-based, and criminal
10 justice stakeholders in the implementation
11 of local addiction and recovery initiatives.”;

12 (2) in subsection (b)—

13 (A) by striking “The Secretary shall award
14 grants to recovery community organizations”
15 and inserting “The Secretary—

16 “(1) shall award grants to recovery community
17 organizations”;

18 (B) by striking “services.” and inserting
19 “services and allow such organizations to use
20 such grant funds to carry out the activities de-
21 scribed in subparagraphs (A) through (C) of
22 subsection (c)(2); and”;

23 (C) by adding at the end the following:

1 “(2) may award grants to eligible entities for
2 purposes of establishing regional technical assistance
3 centers, in accordance with subsection (c)(2)(D).”;

4 (3) by striking subsection (c);

5 (4) by redesignating subsections (d) and (e) as
6 subsections (c) and (d), respectively;

7 (5) in subsection (c) (as so redesignated)—

8 (A) in paragraph (1), by striking “shall be
9 used” and inserting “to a recovery community
10 organization shall be used”;

11 (B) in paragraph (2)—

12 (i) in subparagraph (A), in the matter
13 preceding clause (i), by inserting before
14 “build” the following: “in the case of a
15 grant awarded to a recovery community or-
16 ganization,”;

17 (ii) in subparagraph (B)—

18 (I) by inserting before “reduce”
19 the following: “in the case of a grant
20 awarded to a recovery community or-
21 ganization,”; and

22 (II) by striking “and” at the end;

23 (iii) in subparagraph (C)—

24 (I) by inserting before “conduct”
25 the following: “in the case of a grant

1 awarded to a recovery community or-
2 ganization,”; and

3 (II) by striking the period at the
4 end and inserting “; and”; and

5 (iv) by adding at the end the fol-
6 lowing:

7 “(D) in the case of a grant awarded to an
8 eligible entity, provide for the establishment of
9 regional technical assistance centers to provide
10 regional technical assistance for the following:

11 “(i) Implementation of regionally driv-
12 en, peer-delivered addiction recovery sup-
13 port services before, during, after, or in
14 conjunction with addiction treatment.

15 “(ii) Establishment of recovery com-
16 munity organizations.

17 “(iii) Establishment of recovery com-
18 munity centers.”; and

19 (6) in subsection (d) (as so redesignated), by
20 inserting before the period the following: “, and
21 \$15,000,000 for each of fiscal years 2019 through
22 2023”.

1 **Subtitle T—Stop Illicit Drug**
2 **Importation**

3 **SEC. 7191. SHORT TITLE.**

4 This short title may be cited as the “Stop Illicit Drug
5 Importation Act of 2018”.

6 **SEC. 7192. DETENTION, REFUSAL, AND DESTRUCTION OF**
7 **DRUGS OFFERED FOR IMPORTATION.**

8 (a) ARTICLES TREATED AS DRUGS FOR PURPOSES
9 OF IMPORTATION.—Section 801 of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
11 adding at the end the following:

12 “(t) ARTICLES TREATED AS DRUGS FOR PURPOSES
13 OF THIS SECTION.—

14 “(1) LABELED ARTICLES.—An article shall not
15 be treated as a drug pursuant to this subsection if—

16 “(A) an electronic import entry for such
17 article is submitted using an authorized elec-
18 tronic data interchange system; and

19 “(B) such article is designated in such sys-
20 tem as a drug, device, dietary supplement, or
21 other product that is regulated under this Act.

22 “(2) ARTICLES COVERED.—Subject to para-
23 graph (1), for purposes of this section, an article de-
24 scribed in this paragraph may be treated by the Sec-
25 retary as a drug if it—

1 “(A) is or contains an ingredient that is an
2 active ingredient that is contained within—

3 “(i) a drug that has been approved
4 under section 505 of this Act; or

5 “(ii) a biological product that has
6 been approved under section 351 of the
7 Public Health Service Act;

8 “(B) is or contains an ingredient that is an
9 active ingredient in a drug or biological product
10 if—

11 “(i) an investigational use exemption
12 has been authorized for such drug or bio-
13 logical product under section 505(i) of this
14 Act or section 351(a) of the Public Health
15 Service Act;

16 “(ii) substantial clinical investigation
17 has been instituted for such drug or bio-
18 logical product; and

19 “(iii) the existence of such clinical in-
20 vestigation has been made public; or

21 “(C) is or contains a substance that has a
22 chemical structure that is substantially similar
23 to the chemical structure of an active ingredient
24 in a drug or biological product described in sub-
25 paragraph (A) or (B).

1 “(3) EFFECT.—Except to the extent that an ar-
2 ticle may be treated as a drug pursuant to para-
3 graph (2), this subsection shall not be construed as
4 bearing on or being relevant to the question of
5 whether any article is a drug as defined in section
6 201(g).”.

7 (b) ARTICLES OF CONCERN.—

8 (1) DELIVERY BY TREASURY TO HHS.—The
9 first sentence of section 801(a) of the Federal Food,
10 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
11 amended by striking “and cosmetics” and inserting
12 “cosmetics, and potential articles of concern (as de-
13 fined in subsection (u))”.

14 (2) REFUSED ADMISSION.—The third sentence
15 of section 801(a) of the Federal Food, Drug, and
16 Cosmetic Act (21 U.S.C. 381(a)) is amended by
17 striking “then such article shall be refused admis-
18 sion” and inserting “or (5) such article is an article
19 of concern (as defined in subsection (u)), or (6) such
20 article is a drug that is being imported or offered for
21 import in violation of section 301(cc), then such ar-
22 ticle shall be refused admission”.

23 (3) DEFINITION OF ARTICLE OF CONCERN.—
24 Section 801 of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 381), as amended, is further
2 amended by adding at the end the following:

3 “(u) ARTICLE OF CONCERN DEFINED.—For pur-
4 poses of subsection (a), the term ‘article of concern’ means
5 an article that is or contains a drug or other substance—

6 “(1) for which, during the 24-month period
7 prior to the article being imported or offered for im-
8 port, the Secretary of Health and Human Services—

9 “(A) has requested that, based on a deter-
10 mination that the drug or other substance ap-
11 pears to meet the requirements for temporary
12 or permanent scheduling pursuant to section
13 201 of the Controlled Substances Act, the At-
14 torney General initiate the process to control
15 the drug or other substance in accordance with
16 such Act; or

17 “(B) has, following the publication by the
18 Attorney General of a notice in the Federal
19 Register of the intention to issue an order tem-
20 porarily scheduling such drug or substance in
21 schedule I of section 202 of the Controlled Sub-
22 stances Act pursuant to section 201(h) of such
23 Act, made a determination that such article
24 presents an imminent hazard to public safety;
25 and

1 “(2) with respect to which the Attorney General
2 has not—

3 “(A) scheduled the drug or other substance
4 under such Act; or

5 “(B) notified the Secretary of Health and
6 Human Services that the Attorney General has
7 made a determination not to schedule the drug
8 or other substance under such Act.”.

9 **SEC. 7193. SEIZURE.**

10 Section 304(b) of the Federal Food, Drug, and Cos-
11 metic Act (21 U.S.C. 334(b)) is amended by striking the
12 first sentence and inserting the following: “The article,
13 equipment, or other thing proceeded against shall be liable
14 to seizure by process pursuant to the libel, and the proce-
15 dure in cases under this section shall conform, as nearly
16 as may be, to the procedure in admiralty rather than the
17 procedure used for civil asset forfeiture proceedings set
18 forth in section 983 of title 18, United States Code. On
19 demand of either party any issue of fact joined in any such
20 a case brought under this section shall be tried by jury.
21 A seizure brought under this section is not governed by
22 Rule G of the Supplemental Rules of Admiralty or Mari-
23 time Claims and Asset Forfeiture Actions. Exigent cir-
24 cumstances shall be deemed to exist for all seizures
25 brought under this section, and in such cases, the sum-

1 mons and arrest warrant shall be issued by the clerk of
2 the court without court review.”.

3 **SEC. 7194. DEBARRING VIOLATIVE INDIVIDUALS OR COM-**
4 **PANIES.**

5 (a) PROHIBITED ACT.—Section 301(cc) of the Fed-
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc))
7 is amended—

8 (1) by inserting after “an article of food” the
9 following: “or a drug”; and

10 (2) by inserting after “a person debarred” the
11 following: “from such activity”.

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

15 (1) in paragraph (1)—

16 (A) in the matter preceding subparagraph
17 (A), by striking “paragraph (2)” and inserting
18 “paragraph (2) or (3)”;

19 (B) in subparagraph (B), by striking “or”
20 at the end;

21 (C) in subparagraph (C), by striking the
22 period at the end and inserting “, or”; and

23 (D) by adding at the end the following:

24 “(D) a person from importing or offering
25 to import into the United States—

1 “(i) a controlled substance as defined
2 in section 102(6) of the Controlled Sub-
3 stances Act; or

4 “(ii) any drug, if such drug is de-
5 clared to be valued at an amount that is
6 \$2,500 or less (or such higher amount as
7 the Secretary of the Treasury may set by
8 regulation pursuant to section 498(a)(1) of
9 the Tariff Act of 1930), or if such drug is
10 entering the United States by mail.”; and

11 (2) in paragraph (3)—

12 (A) in the paragraph heading after
13 “FOOD” by inserting “OR DRUG”;

14 (B) by redesignating subparagraphs (A)
15 and (B) as clauses (i) and (ii), respectively, and
16 moving the indentation of each such clause 2
17 ems to the right;

18 (C) after making the amendments required
19 by subparagraph (B), by striking “A person is
20 subject” and inserting the following:

21 “(A) FOOD.—A person is subject”; and

22 (D) by adding at the end the following:

23 “(B) IMPORTATION OF DRUGS.—A person
24 is subject to debarment under paragraph (1)(D)
25 if—

1 “(i) the person has been convicted of
2 a felony for conduct relating to the impor-
3 tation into the United States of any drug
4 or controlled substance (as defined in sec-
5 tion 102 of the Controlled Substances
6 Act); or

7 “(ii) the person has engaged in a pat-
8 tern of importing or offering for import ar-
9 ticles of drug that are—

10 “(I)(aa) adulterated, misbranded,
11 or in violation of section 505; and

12 “(bb) present a threat of serious
13 adverse health consequences or death
14 to humans or animals; or

15 “(II) controlled substances whose
16 importation is prohibited pursuant to
17 section 401(m) of the Tariff Act of
18 1930.

19 “(C) DEFINITION.—For purposes of sub-
20 paragraph (B), the term ‘pattern of importing
21 or offering for import articles of drug’ means
22 importing or offering for import articles of drug
23 described in subclause (I) or (II) of subpara-
24 graph (B)(ii) in an amount, frequency, or dos-

1 age that is inconsistent with personal or house-
2 hold use by the importer.”.

3 **Subtitle U—Creating Opportunities**
4 **That Necessitate New and En-**
5 **hanced Connections That Im-**
6 **prove Opioid Navigation Strate-**
7 **gies**

8 **SEC. 7201. SHORT TITLE.**

9 This subtitle may be cited as the “Creating Opportu-
10 nities that Necessitate New and Enhanced Connections
11 That Improve Opioid Navigation Strategies Act of 2018”
12 or the “CONNECTIONS Act”.

13 **SEC. 7202. PREVENTING OVERDOSES OF CONTROLLED SUB-**
14 **STANCES.**

15 Part P of title III of the Public Health Service Act
16 (42 U.S.C. 280g et seq.) is amended by adding at the end
17 the following new section:

18 **“SEC. 399V-7. PREVENTING OVERDOSES OF CONTROLLED**
19 **SUBSTANCES.**

20 “(a) EVIDENCE-BASED PREVENTION GRANTS.—

21 “(1) IN GENERAL.—The Director of the Cen-
22 ters for Disease Control and Prevention may—

23 “(A) to the extent practicable, carry out
24 any evidence-based prevention activity described
25 in paragraph (2);

1 “(B) provide training and technical assist-
2 ance to States, localities, and Indian tribes for
3 purposes of carrying out any such activity; and

4 “(C) award grants to States, localities, and
5 Indian tribes for purposes of carrying out any
6 such activity.

7 “(2) EVIDENCE-BASED PREVENTION ACTIVI-
8 TIES.—An evidence-based prevention activity de-
9 scribed in this paragraph is any of the following ac-
10 tivities:

11 “(A) With respect to a State, improving
12 the efficiency and use of the State prescription
13 drug monitoring program by—

14 “(i) encouraging all authorized users
15 (as specified by the State) to register with
16 and use the program and making the pro-
17 gram easier to use;

18 “(ii) enabling such users to access any
19 updates to information collected by the
20 program in as close to real-time as pos-
21 sible;

22 “(iii) providing for a mechanism for
23 the program to automatically flag any po-
24 tential misuse or abuse of controlled sub-
25 stances and any detection of inappropriate

1 prescribing practices relating to such sub-
2 stances;

3 “(iv) enhancing interoperability be-
4 tween the program and any electronic
5 health records system, including by inte-
6 grating the use of electronic health records
7 into the program for purposes of improving
8 clinical decisionmaking;

9 “(v) continually updating program ca-
10 pabilities to respond to technological inno-
11 vation for purposes of appropriately ad-
12 dressing a controlled substance overdose
13 epidemic as such epidemic may occur and
14 evolve;

15 “(vi) facilitating data sharing between
16 the program and the prescription drug
17 monitoring programs of neighboring
18 States; and

19 “(vii) meeting the purpose of the pro-
20 gram established under section 3990, as
21 described in section 3990(a).

22 “(B) Achieving community or health sys-
23 tem interventions through activities such as—

1 “(i) establishing or improving con-
2 trolled substances prescribing interventions
3 for insurers and health systems;

4 “(ii) enhancing the use of evidence-
5 based controlled substances prescribing
6 guidelines across sectors and health care
7 settings; and

8 “(iii) implementing strategies to align
9 the prescription of controlled substances
10 with the guidelines described in clause (ii).

11 “(C) Evaluating interventions to better un-
12 derstand what works to prevent overdoses, in-
13 cluding those involving prescription and illicit
14 controlled substances.

15 “(D) Implementing projects to advance an
16 innovative prevention approach with respect to
17 new and emerging public health crises and op-
18 portunities to address such crises, such as en-
19 hancing public education and awareness on the
20 risks associated with opioids.

21 “(b) ENHANCED SURVEILLANCE OF CONTROLLED
22 SUBSTANCE OVERDOSE GRANTS.—

23 “(1) IN GENERAL.—The Director of the Cen-
24 ters for Disease Control and Prevention may—

1 “(A) to the extent practicable, carry out
2 any controlled substance overdose surveillance
3 activity described in paragraph (2);

4 “(B) provide training and technical assist-
5 ance to States for purposes of carrying out any
6 such activity;

7 “(C) award grants to States for purposes
8 of carrying out any such activity; and

9 “(D) coordinate with the Assistant Sec-
10 retary for Mental Health and Substance Use to
11 collect data pursuant to section 505(d)(1)(A)
12 (relating to the number of individuals admitted
13 to the emergency rooms of hospitals as a result
14 of the abuse of alcohol or other drugs).

15 “(2) CONTROLLED SUBSTANCE OVERDOSE SUR-
16 VEILLANCE ACTIVITIES.—A controlled substance
17 overdose surveillance activity described in this para-
18 graph is any of the following activities:

19 “(A) Enhancing the timeliness of reporting
20 data to the public, including data on fatal and
21 nonfatal overdoses of controlled substances.

22 “(B) Enhancing comprehensiveness of data
23 on controlled substances overdoses by collecting
24 information on such overdoses from appropriate
25 sources such as toxicology reports, autopsy re-

1 ports, death scene investigations, and other risk
2 factors.

3 “(C) Using data to help identify risk fac-
4 tors associated with controlled substances
5 overdoses.

6 “(D) With respect to a State, supporting
7 entities involved in providing information to in-
8 form efforts within the State, such as by coro-
9 ners and medical examiners, to improve accu-
10 rate testing and reporting of causes and con-
11 tributing factors to controlled substances
12 overdoses.

13 “(E) Working to enable information shar-
14 ing regarding controlled substances overdoses
15 among data sources.

16 “(c) DEFINITIONS.—In this section:

17 “(1) CONTROLLED SUBSTANCE.—The term
18 ‘controlled substance’ has the meaning given that
19 term in section 102 of the Controlled Substances
20 Act.

21 “(2) INDIAN TRIBE.—The term ‘Indian tribe’
22 has the meaning given that term in section 4 of the
23 Indian Self-Determination and Education Assistance
24 Act.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—For
2 purposes of carrying out this section and section 3990,
3 there is authorized to be appropriated \$486,000,000 for
4 each of fiscal years 2019 through 2023.”.

5 **SEC. 7203. PRESCRIPTION DRUG MONITORING PROGRAM.**

6 Section 3990 of the Public Health Service Act (42
7 U.S.C. 280g–3) is amended to read as follows:

8 **“SEC. 3990. PRESCRIPTION DRUG MONITORING PROGRAM.**

9 “(a) PROGRAM.—

10 “(1) IN GENERAL.—Each fiscal year, the Sec-
11 retary, in consultation with the Director of National
12 Drug Control Policy, acting through the Director of
13 the Centers for Disease Control and Prevention, the
14 Assistant Secretary for Mental Health and Sub-
15 stance Use, and the National Coordinator for Health
16 Information Technology, shall support States for the
17 purpose of improving the efficiency and use of
18 PDMPs, including—

19 “(A) establishment and implementation of
20 a PDMP;

21 “(B) maintenance of a PDMP;

22 “(C) improvements to a PDMP by—

23 “(i) enhancing functional components
24 to work toward—

1 “(I) universal use of PDMPs
2 among providers and their delegates,
3 to the extent that State laws allow,
4 within a State;

5 “(II) more timely inclusion of
6 data within a PDMP;

7 “(III) active management of the
8 PDMP, in part by sending proactive
9 or unsolicited reports to providers to
10 inform prescribing; and

11 “(IV) ensuring the highest level
12 of ease in use and access of PDMPs
13 by providers and their delegates, to
14 the extent that State laws allow;

15 “(ii) improving the intrastate inter-
16 operability of PDMPs by—

17 “(I) making PDMPs more ac-
18 tionable by integrating PDMPs within
19 electronic health records and health
20 information technology infrastructure;
21 and

22 “(II) linking PDMP data to
23 other data systems within the State,
24 including—

1 “(aa) the data of pharmacy
2 benefit managers, medical exam-
3 iners and coroners, and the
4 State’s Medicaid program;

5 “(bb) worker’s compensation
6 data; and

7 “(cc) prescribing data of
8 providers of the Department of
9 Veterans Affairs and the Indian
10 Health Service within the State;

11 “(iii) improving the interstate inter-
12 operability of PDMPs through—

13 “(I) sharing of dispensing data in
14 near-real time across State lines; and

15 “(II) integration of automated
16 queries for multistate PDMP data
17 and analytics into clinical workflow to
18 improve the use of such data and ana-
19 lytics by practitioners and dispensers;
20 or

21 “(iv) improving the ability to include
22 treatment availability resources and refer-
23 ral capabilities within the PDMP.

24 “(2) STATE LEGISLATION.—As a condition on
25 the receipt of support under this section, the Sec-

1 retary shall require a State to demonstrate that the
2 State has enacted legislation or regulations—

3 “(A) to provide for the implementation of
4 the PDMP; and

5 “(B) to permit the imposition of appro-
6 priate penalties for the unauthorized use and
7 disclosure of information maintained by the
8 PDMP.

9 “(b) PDMP STRATEGIES.—The Secretary shall en-
10 courage a State, in establishing, improving, or maintaining
11 a PDMP, to implement strategies that improve—

12 “(1) the reporting of dispensing in the State of
13 a controlled substance to an ultimate user so the re-
14 porting occurs not later than 24 hours after the dis-
15 pensing event;

16 “(2) the consultation of the PDMP by each pre-
17 scribing practitioner, or their designee, in the State
18 before initiating treatment with a controlled sub-
19 stance, or any substance as required by the State to
20 be reported to the PDMP, and over the course of
21 ongoing treatment for each prescribing event;

22 “(3) the consultation of the PDMP before dis-
23 pensing a controlled substance, or any substance as
24 required by the State to be reported to the PDMP;

1 “(4) the proactive notification to a practitioner
2 when patterns indicative of controlled substance mis-
3 use by a patient, including opioid misuse, are de-
4 tected;

5 “(5) the availability of data in the PDMP to
6 other States, as allowable under State law; and

7 “(6) the availability of nonidentifiable informa-
8 tion to the Centers for Disease Control and Preven-
9 tion for surveillance, epidemiology, statistical re-
10 search, or educational purposes.

11 “(c) DRUG MISUSE AND ABUSE.—In consultation
12 with practitioners, dispensers, and other relevant and in-
13 terested stakeholders, a State receiving support under this
14 section—

15 “(1) shall establish a program to notify practi-
16 tioners and dispensers of information that will help
17 to identify and prevent the unlawful diversion or
18 misuse of controlled substances; and

19 “(2) may, to the extent permitted under State
20 law, notify the appropriate authorities responsible
21 for carrying out drug diversion investigations if the
22 State determines that information in the PDMP
23 maintained by the State indicates an unlawful diver-
24 sion or abuse of a controlled substance.

1 “(d) EVALUATION AND REPORTING.—As a condition
2 on receipt of support under this section, the State shall
3 report on interoperability with PDMPs of other States and
4 Federal agencies, where appropriate, intrastate interoper-
5 ability with health information technology systems such as
6 electronic health records, health information exchanges,
7 and e-prescribing, where appropriate, and whether or not
8 the State provides automatic, up-to-date, or daily informa-
9 tion about a patient when a practitioner (or the designee
10 of a practitioner, where permitted) requests information
11 about such patient.

12 “(e) EVALUATION AND REPORTING.—A State receiv-
13 ing support under this section shall provide the Secretary
14 with aggregate nonidentifiable information, as permitted
15 by State law, to enable the Secretary—

16 “(1) to evaluate the success of the State’s pro-
17 gram in achieving the purpose described in sub-
18 section (a); or

19 “(2) to prepare and submit to the Congress the
20 report required by subsection (i)(2).

21 “(f) EDUCATION AND ACCESS TO THE MONITORING
22 SYSTEM.—A State receiving support under this section
23 shall take steps to—

1 “(1) facilitate prescribers and dispensers, and
2 their delegates, as permitted by State law, to use the
3 PDMP, to the extent practicable; and

4 “(2) educate prescribers and dispensers, and
5 their delegates on the benefits of the use of PDMPs.

6 “(g) ELECTRONIC FORMAT.—The Secretary may
7 issue guidelines specifying a uniform electronic format for
8 the reporting, sharing, and disclosure of information pur-
9 suant to PDMPs.

10 “(h) RULES OF CONSTRUCTION.—

11 “(1) FUNCTIONS OTHERWISE AUTHORIZED BY
12 LAW.—Nothing in this section shall be construed to
13 restrict the ability of any authority, including any
14 local, State, or Federal law enforcement, narcotics
15 control, licensure, disciplinary, or program authority,
16 to perform functions otherwise authorized by law.

17 “(2) ADDITIONAL PRIVACY PROTECTIONS.—
18 Nothing in this section shall be construed as pre-
19 empting any State from imposing any additional pri-
20 vacy protections.

21 “(3) FEDERAL PRIVACY REQUIREMENTS.—
22 Nothing in this section shall be construed to super-
23 seede any Federal privacy or confidentiality require-
24 ment, including the regulations promulgated under
25 section 264(c) of the Health Insurance Portability

1 and Accountability Act of 1996 (Public Law 104–
2 191; 110 Stat. 2033) and section 543 of this Act.

3 “(4) NO FEDERAL PRIVATE CAUSE OF AC-
4 TION.—Nothing in this section shall be construed to
5 create a Federal private cause of action.

6 “(i) PROGRESS REPORT.—Not later than 3 years
7 after the date of enactment of the CONNECTIONS Act,
8 the Secretary shall—

9 “(1) complete a study that—

10 “(A) determines the progress of States in
11 establishing and implementing PDMPs con-
12 sistent with this section;

13 “(B) provides an analysis of the extent to
14 which the operation of PDMPs has—

15 “(i) reduced inappropriate use, abuse,
16 diversion of, and overdose with, controlled
17 substances;

18 “(ii) established or strengthened ini-
19 tiatives to ensure linkages to substance use
20 disorder treatment services; or

21 “(iii) affected patient access to appro-
22 priate care in States operating PDMPs;

23 “(C) determine the progress of States in
24 achieving interstate interoperability and intra-
25 state interoperability of PDMPs, including an

1 assessment of technical, legal, and financial
2 barriers to such progress and recommendations
3 for addressing these barriers;

4 “(D) determines the progress of States in
5 implementing near real-time electronic PDMPs;

6 “(E) provides an analysis of the privacy
7 protections in place for the information re-
8 ported to the PDMP in each State receiving
9 support under this section and any rec-
10 ommendations of the Secretary for additional
11 Federal or State requirements for protection of
12 this information;

13 “(F) determines the progress of States in
14 implementing technological alternatives to cen-
15 tralized data storage, such as peer-to-peer file
16 sharing or data pointer systems, in PDMPs and
17 the potential for such alternatives to enhance
18 the privacy and security of individually identifi-
19 able data; and

20 “(G) evaluates the penalties that States
21 have enacted for the unauthorized use and dis-
22 closure of information maintained in PDMPs,
23 and the criteria used by the Secretary to deter-
24 mine whether such penalties qualify as appro-
25 priate for purposes of subsection (a)(2); and

1 “(2) submit a report to the Congress on the re-
2 sults of the study.

3 “(j) ADVISORY COUNCIL.—

4 “(1) ESTABLISHMENT.—A State may establish
5 an advisory council to assist in the establishment,
6 improvement, or maintenance of a PDMP consistent
7 with this section.

8 “(2) LIMITATION.—A State may not use Fed-
9 eral funds for the operations of an advisory council
10 to assist in the establishment, improvement, or
11 maintenance of a PDMP.

12 “(3) SENSE OF CONGRESS.—It is the sense of
13 the Congress that, in establishing an advisory coun-
14 cil to assist in the establishment, improvement, or
15 maintenance of a PDMP, a State should consult
16 with appropriate professional boards and other inter-
17 ested parties.

18 “(k) DEFINITIONS.—For purposes of this section:

19 “(1) The term ‘controlled substance’ means a
20 controlled substance (as defined in section 102 of
21 the Controlled Substances Act) in schedule II, III,
22 or IV of section 202 of such Act.

23 “(2) The term ‘dispense’ means to deliver a
24 controlled substance to an ultimate user by, or pur-
25 suant to the lawful order of, a practitioner, irrespec-

1 tive of whether the dispenser uses the internet or
2 other means to effect such delivery.

3 “(3) The term ‘dispenser’ means a physician,
4 pharmacist, or other person that dispenses a con-
5 trolled substance to an ultimate user.

6 “(4) The term ‘interstate interoperability’ with
7 respect to a PDMP means the ability of the PDMP
8 to electronically share reported information with an-
9 other State if the information concerns either the
10 dispensing of a controlled substance to an ultimate
11 user who resides in such other State, or the dis-
12 pensing of a controlled substance prescribed by a
13 practitioner whose principal place of business is lo-
14 cated in such other State.

15 “(5) The term ‘intrastate interoperability’ with
16 respect to a PDMP means the integration of PDMP
17 data within electronic health records and health in-
18 formation technology infrastructure or linking of a
19 PDMP to other data systems within the State, in-
20 cluding the State’s Medicaid program, workers’ com-
21 pensation programs, and medical examiners or coro-
22 ners.

23 “(6) The term ‘nonidentifiable information’
24 means information that does not identify a practi-
25 tioner, dispenser, or an ultimate user and with re-

1 spect to which there is no reasonable basis to believe
2 that the information can be used to identify a practi-
3 tioner, dispenser, or an ultimate user.

4 “(7) The term ‘PDMP’ means a prescription
5 drug monitoring program that is State-controlled.

6 “(8) The term ‘practitioner’ means a physician,
7 dentist, veterinarian, scientific investigator, phar-
8 macy, hospital, or other person licensed, registered,
9 or otherwise permitted, by the United States or the
10 jurisdiction in which the individual practices or does
11 research, to distribute, dispense, conduct research
12 with respect to, administer, or use in teaching or
13 chemical analysis, a controlled substance in the
14 course of professional practice or research.

15 “(9) The term ‘State’ means each of the 50
16 States, the District of Columbia, and any common-
17 wealth or territory of the United States.

18 “(10) The term ‘ultimate user’ means a person
19 who has obtained from a dispenser, and who pos-
20 sesses, a controlled substance for the person’s own
21 use, for the use of a member of the person’s house-
22 hold, or for the use of an animal owned by the per-
23 son or by a member of the person’s household.

24 “(11) The term ‘clinical workflow’ means the
25 integration of automated queries for prescription

1 drug monitoring programs data and analytics into
 2 health information technologies such as electronic
 3 health record systems, health information exchanges,
 4 and/or pharmacy dispensing software systems, thus
 5 streamlining provider access through automated que-
 6 ries.”.

7 **Subtitle V—Securing Opioids and**
 8 **Unused Narcotics With Delib-**
 9 **erate Disposal and Packaging**

10 **SEC. 7211. SHORT TITLE.**

11 This subtitle may be cited as the “Securing Opioids
 12 and Unused Narcotics with Deliberate Disposal and Pack-
 13 aging Act of 2018” or the “SOUND Disposal and Pack-
 14 aging Act”.

15 **SEC. 7212. IMPROVED TECHNOLOGIES, CONTROLS, OR**
 16 **MEASURES WITH RESPECT TO THE PACK-**
 17 **AGING OR DISPOSAL OF CERTAIN DRUGS.**

18 (a) IN GENERAL.—Chapter V of the Federal Food,
 19 Drug, and Cosmetic Act is amended by inserting after sec-
 20 tion 505–1 (21 U.S.C. 355–1) the following new section:

21 **“SEC. 505–2. SAFETY-ENHANCING PACKAGING AND DIS-**
 22 **POSAL FEATURES.**

23 “(a) ORDERS.—

24 “(1) IN GENERAL.—The Secretary may issue
 25 an order requiring the holder of a covered applica-

1 tion to implement or modify one or more tech-
2 nologies, controls, or measures with respect to the
3 packaging or disposal of one or more drugs identi-
4 fied in the covered application, if the Secretary de-
5 termines such technologies, controls, or measures to
6 be appropriate to help mitigate the risk of abuse or
7 misuse of such drug or drugs, which may include by
8 reducing the availability of unused drugs.

9 “(2) PRIOR CONSULTATION.—The Secretary
10 may not issue an order under paragraph (1) unless
11 the Secretary has consulted with relevant stake-
12 holders, through a public meeting, workshop, or oth-
13 erwise, about matters that are relevant to the sub-
14 ject of the order.

15 “(3) ASSURING ACCESS AND MINIMIZING BUR-
16 DEN.—Technologies, controls, or measures required
17 under paragraph (1) shall—

18 “(A) be commensurate with the specific
19 risk of abuse or misuse of the drug listed in the
20 covered application;

21 “(B) considering such risk, not be unduly
22 burdensome on patient access to the drug, con-
23 sidering in particular any available evidence re-
24 garding the expected or demonstrated public

1 health impact of such technologies, controls, or
2 measures; and

3 “(C) reduce the risk of abuse or misuse of
4 such drug.

5 “(4) ORDER CONTENTS.—An order issued
6 under paragraph (1) may—

7 “(A) provide for a range of options for im-
8 plementing or modifying the technologies, con-
9 trols, or measures required to be implemented
10 by such order; and

11 “(B) incorporate by reference standards
12 regarding packaging or disposal set forth in an
13 official compendium, established by a nationally
14 or internationally recognized standard develop-
15 ment organization, or described on the public
16 website of the Food and Drug Administration,
17 so long as the order includes the rationale for
18 incorporation of such standard.

19 “(5) ORDERS APPLICABLE TO DRUG CLASS.—
20 When a concern about the risk of abuse or misuse
21 of a drug relates to a pharmacological class, the Sec-
22 retary may, after consultation with relevant stake-
23 holders, issue an order under paragraph (1) which
24 applies to the pharmacological class.

1 “(b) COMPLIANCE.—The holder of a covered applica-
2 tion shall—

3 “(1) submit a supplement containing proposed
4 changes to the covered application to comply with an
5 order issued under subsection (a) not later than—

6 “(A) 180 calendar days after the date on
7 which the order is issued; or

8 “(B)(i) such longer time period as speci-
9 fied by the Secretary in such order; or

10 “(ii) if a request for an alternative date is
11 submitted by the holder of such application not
12 later than 60 calendar days after the date on
13 which such order is issued—

14 “(I) such requested alternative date if
15 agreed to by the Secretary; or

16 “(II) another date as specified by the
17 Secretary; and

18 “(2) implement the changes approved pursuant
19 to such supplement not later than the later of—

20 “(A) 90 calendar days after the date on
21 which the supplement is approved; or

22 “(B) the end of such longer period as is—

23 “(i) determined to be appropriate by
24 the Secretary; or

1 “(ii) approved by the Secretary pursu-
2 ant to a request by the holder of the cov-
3 ered application that explains why such
4 longer period is needed, including to satisfy
5 any other applicable Federal statutory or
6 regulatory requirements.

7 “(c) ALTERNATIVE MEASURES.—The holder of the
8 covered application may propose, and the Secretary shall
9 approve, technologies, controls, or measures regarding
10 packaging, storage, or disposal other than those specified
11 in the applicable order issued under subsection (a), if such
12 technologies, controls, or measures are supported by data
13 and information demonstrating that such alternative tech-
14 nologies, controls, or measures can be expected to mitigate
15 the risk of abuse or misuse of the drug or drugs involved,
16 including by reducing the availability of unused drugs, to
17 at least the same extent as the technologies, controls, or
18 measures specified in such order.

19 “(d) DISPUTE RESOLUTION.—If a dispute arises in
20 connection with a supplement submitted under subsection
21 (b), the holder of the covered application may appeal a
22 determination made with respect to such supplement using
23 applicable dispute resolution procedures specified by the
24 Secretary in regulations or guidance.

25 “(e) DEFINITIONS.—In this section—

1 “(1) the term ‘covered application’ means an
2 application submitted under subsection (b) or (j) of
3 section 505 for approval under such section or an
4 application submitted under section 351 of Public
5 Health Service Act for approval under such section,
6 with respect to a drug that is or contains an opioid
7 for which a listing in schedule II or III (on a tem-
8 porary or permanent basis) is in effect under section
9 202 of the Controlled Substances Act; and

10 “(2) the term ‘relevant stakeholders’ may in-
11 clude scientific experts within the drug manufac-
12 turing industry; brand and generic drug manufactur-
13 ers; standard development organizations; wholesalers
14 and distributors; payers; health care providers; phar-
15 macists; pharmacies; manufacturers; poison centers;
16 and representatives of the National Institute on
17 Drug Abuse, the National Institutes of Health, the
18 Centers for Disease Control and Prevention, the
19 Centers for Medicare & Medicaid Services, the Drug
20 Enforcement Agency, the Consumer Product Safety
21 Commission, individuals who specialize in treating
22 addiction, and patient and caregiver groups.”.

23 (b) PROHIBITED ACTS.—Section 501 of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 351) is amend-
25 ed by inserting after paragraph (j) the following:

1 “(k) If it is a drug approved under a covered applica-
2 tion (as defined in section 505–2(e)), the holder of which
3 does not meet the requirements of paragraphs (1) and (2)
4 of subsection (b) of such section.”.

5 (c) REQUIRED CONTENT OF AN ABBREVIATED NEW
6 DRUG APPLICATION.—Section 505(j)(2)(A) of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 355(j)(2)(A)) is amended—

9 (1) in clause (vii)(IV), by striking “and” at the
10 end;

11 (2) in clause (viii), by striking the period at the
12 end and inserting “; and”; and

13 (3) by adding at the end the following:

14 “(ix) if the drug is or contains an opioid for
15 which a listing in schedule II or III (on a temporary
16 or permanent basis) is in effect under section 202 of
17 the Controlled Substances Act, information to show
18 that the applicant has proposed technologies, con-
19 trols, or measures related to the packaging or dis-
20 posal of the drug that provide protections com-
21 parable to those provided by the technologies, con-
22 trols, or measures required for the applicable listed
23 drug under section 505–2, if applicable.”.

24 (d) GROUNDS FOR REFUSING TO APPROVE AN AB-
25 BREVIATED NEW DRUG APPLICATION.—Section 505(j)(4)

1 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
2 355(j)(4)), is amended—

3 (1) in subparagraph (J), by striking “or” at the
4 end;

5 (2) in subparagraph (K), by striking the period
6 at the end and inserting “; or”; and

7 (3) by adding at the end the following:

8 “(L) if the drug is a drug described in
9 paragraph (2)(A)(ix) and the applicant has not
10 proposed technologies, controls, or measures re-
11 lated to the packaging or disposal of such drug
12 that the Secretary determines provide protec-
13 tions comparable to those provided by the tech-
14 nologies, controls, or measures required for the
15 applicable listed drug under section 505–2.”.

16 (e) RULES OF CONSTRUCTION.—

17 (1) Any labeling describing technologies, con-
18 trols, or measures related to packaging or disposal
19 intended to mitigate the risk of abuse or misuse of
20 a drug product that is subject to an abbreviated new
21 drug application, including labeling describing dif-
22 ferences from the reference listed drug resulting
23 from the application of section 505–2 of the Federal
24 Food, Drug, and Cosmetic Act, as added by sub-
25 section (a), shall not be construed—

1 (A) as changes to labeling not permissible
2 under clause (v) of section 505(j)(2)(A) of such
3 Act (21 U.S.C. 355(j)(2)(A)), or a change in
4 the conditions of use prescribed, recommended,
5 or suggested in the labeling proposed for the
6 new drug under clause (i) of such section; or

7 (B) to preclude approval of an abbreviated
8 new drug application under subparagraph (B)
9 or (G) of section 505(j)(4) of such Act (21
10 U.S.C. 355(j)(4)).

11 (2) For a covered application that is an applica-
12 tion submitted under subsection (j) of section 505 of
13 the Federal Food, Drug, and Cosmetic Act (21
14 U.S.C. 355), subsection (j)(2)(A) of such section
15 505 shall not be construed to limit the type of data
16 or information the Secretary of Health and Human
17 Services may request or consider in connection with
18 making any determination under section 505–2.

19 (f) GAO REPORT.—Not later than 12 months after
20 the date of enactment of this Act, the Comptroller General
21 of the United States shall prepare and submit to the Con-
22 gress a report containing—

23 (1) a description of available evidence, if any,
24 on the effectiveness of site-of-use, in-home controlled

1 substance disposal products and packaging tech-
2 nologies;

3 (2) identification of ways in which such disposal
4 products intended for use by patients, consumers,
5 and other end users that are not registrants under
6 the Controlled Substances Act, are made available to
7 the public and barriers to the use of such disposal
8 products;

9 (3) identification of ways in which packaging
10 technologies are made available to the public and
11 barriers to the use of such technologies;

12 (4) a description of Federal oversight, if any, of
13 site-of-use, in-home controlled substance disposal
14 products, including—

15 (A) identification of the Federal agencies
16 that oversee such products;

17 (B) identification of the methods of dis-
18 posal of controlled substances recommended by
19 these agencies for site-of-use, in-home disposal;
20 and

21 (C) a description of the effectiveness of
22 such recommendations at preventing the diver-
23 sion of legally prescribed controlled substances;

1 (5) a description of Federal oversight, if any, of
2 controlled substance packaging technologies, includ-
3 ing—

4 (A) identification of the Federal agencies
5 that oversee such technologies;

6 (B) identification of the technologies rec-
7 ommended by these agencies, including unit
8 dose packaging, packaging that provides a set
9 duration, or other packaging systems that may
10 mitigate abuse or misuse; and

11 (C) a description of the effectiveness of
12 such recommendations at preventing the diver-
13 sion of legally prescribed controlled substances;
14 and

15 (6) recommendations on—

16 (A) whether site-of-use, in-home controlled
17 substance disposal products and packaging
18 technologies require Federal oversight and, if
19 so, which agencies should be responsible for
20 such oversight and, as applicable, approval of
21 such products or technologies; and

22 (B) the potential role of the Federal Gov-
23 ernment in evaluating such products to ensure
24 product efficacy.

1 **Subtitle W—Postapproval Study** 2 **Requirements**

3 **SEC. 7221. POSTAPPROVAL STUDY REQUIREMENTS.**

4 (a) **PURPOSES OF STUDY.**—Section 505(o)(3)(B) of
5 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
6 355(o)(3)(B)) is amended by adding at the end the fol-
7 lowing:

8 “(iv) To assess a potential reduction
9 in effectiveness of the drug for the condi-
10 tions of use prescribed, recommended, or
11 suggested in the labeling thereof if—

12 “(I) the drug involved—

13 “(aa) is or contains a sub-
14 stance for which a listing in any
15 schedule is in effect (on a tem-
16 porary or permanent basis) under
17 section 201 of the Controlled
18 Substances Act; or

19 “(bb) is a drug that has not
20 been approved under this section
21 or licensed under section 351 of
22 the Public Health Service Act,
23 for which an application for such
24 approval or licensure is pending
25 or anticipated, and for which the

1 Secretary provides notice to the
2 sponsor that the Secretary in-
3 tends to issue a scientific and
4 medical evaluation and rec-
5 ommend controls under the Con-
6 trolled Substances Act; and
7 “(II) the potential reduction in
8 effectiveness could result in the bene-
9 fits of the drug no longer outweighing
10 the risks.”.

11 (b) ESTABLISHMENT OF REQUIREMENT.—Section
12 505(o)(3)(C) of the Federal Food, Drug, and Cosmetic
13 Act (21 U.S.C. 355(o)(3)(C)) is amended by striking
14 “such requirement” and all that follows through “safety
15 information.” and inserting the following: “such require-
16 ment—

17 “(i) in the case of a purpose described
18 in clause (i), (ii), or (iii) of subparagraph
19 (B), only if the Secretary becomes aware of
20 new safety information; and

21 “(ii) in the case of a purpose de-
22 scribed in clause (iv) of such subpara-
23 graph, if the Secretary determines that
24 new effectiveness information exists.”.

1 (c) APPLICABILITY.—Section 505(o)(3) of the Fed-
2 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(3))
3 is amended by adding at the end the following new sub-
4 paragraph:

5 “(G) APPLICABILITY.—The conduct of a
6 study or clinical trial required pursuant to this
7 paragraph for the purpose specified in subpara-
8 graph (B)(iv) shall not be considered a new
9 clinical investigation for the purpose of a period
10 of exclusivity under clause (iii) or (iv) of sub-
11 section (c)(3)(E) or clause (iii) or (iv) of sub-
12 section (j)(5)(F).”.

13 (d) NEW EFFECTIVENESS INFORMATION DE-
14 FINED.—Section 505(o)(2) of the Federal Food, Drug,
15 and Cosmetic Act (21 U.S.C. 355(o)(2)) is amended by
16 adding at the end the following new subparagraph:

17 “(D) NEW EFFECTIVENESS INFORMA-
18 TION.—The term ‘new effectiveness informa-
19 tion’, with respect to a drug that is or contains
20 a controlled substance for which a listing in any
21 schedule is in effect (on a temporary or perma-
22 nent basis) under section 201 of the Controlled
23 Substances Act, means new information about
24 the effectiveness of the drug, including a new
25 analysis of existing information, derived from—

1 “(i) a clinical trial; an adverse event
2 report; a postapproval study or clinical
3 trial (including a study or clinical trial
4 under paragraph (3));

5 “(ii) peer-reviewed biomedical lit-
6 erature;

7 “(iii) data derived from the
8 postmarket risk identification and analysis
9 system under subsection (k); or

10 “(iv) other scientific data determined
11 to be appropriate by the Secretary.”.

12 (e) CONFORMING AMENDMENTS WITH RESPECT TO
13 LABELING CHANGES.—Section 505(o)(4) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 355(o)(4)) is
15 amended—

16 (1) in subparagraph (A)—

17 (A) in the heading, by inserting “OR NEW
18 EFFECTIVENESS” after “SAFETY”;

19 (B) by striking “safety information” and
20 inserting “new safety information or new effec-
21 tiveness information such”; and

22 (C) by striking “believes should be” and
23 inserting “believes changes should be made to”;

24 (2) in subparagraph (B)(i)—

1 (A) by striking “new safety information”
2 and by inserting “new safety information or
3 new effectiveness information”; and

4 (B) by inserting “indications,” after
5 “boxed warnings,”;

6 (3) in subparagraph (C), by inserting “or new
7 effectiveness information” after “safety informa-
8 tion”; and

9 (4) in subparagraph (E), by inserting “or new
10 effectiveness information” after “safety informa-
11 tion”.

12 (f) **RULE OF CONSTRUCTION.**—Nothing in the
13 amendments made by this section shall be construed to
14 alter, in any manner, the meaning or application of the
15 provisions of paragraph (3) of section 505(o) of the Fed-
16 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(o))
17 with respect to the authority of the Secretary of Health
18 and Human Services to require a postapproval study or
19 clinical trial for a purpose specified in clauses (i) through
20 (iii) of subparagraph (B) of such paragraph (3) or para-
21 graph (4) of such section 505(o) with respect to the Sec-
22 retary’s authority to require safety labeling changes.

1 **TITLE VIII—MISCELLANEOUS**
2 **Subtitle A—Synthetics Trafficking**
3 **and Overdose Prevention**

4 **SEC. 8001. SHORT TITLE; TABLE OF CONTENTS.**

5 This subtitle may be cited as the “Synthetics Traf-
6 ficking and Overdose Prevention Act of 2018” or “STOP
7 Act of 2018”.

8 **SEC. 8002. CUSTOMS FEES.**

9 (a) IN GENERAL.—Section 13031(b)(9) of the Con-
10 solidated Omnibus Budget Reconciliation Act of 1985 (19
11 U.S.C. 58c(b)(9)) is amended by adding at the end the
12 following:

13 “(D)(i) With respect to the processing of items
14 that are sent to the United States through the inter-
15 national postal network by ‘Inbound Express Mail
16 service’ or ‘Inbound EMS’ (as that service is de-
17 scribed in the mail classification schedule referred to
18 in section 3631 of title 39, United States Code), the
19 following payments are required:

20 “(I) \$1 per Inbound EMS item.

21 “(II) If an Inbound EMS item is formally
22 entered, the fee provided for under subsection
23 (a)(9), if applicable.

24 “(ii) Notwithstanding section 451 of the Tariff
25 Act of 1930 (19 U.S.C. 1451), the payments re-

1 quired by clause (i), as allocated pursuant to clause
2 (iii)(I), shall be the only payments required for reim-
3 bursement of U.S. Customs and Border Protection
4 for customs services provided in connection with the
5 processing of an Inbound EMS item.

6 “(iii)(I) The payments required by clause (i)(I)
7 shall be allocated as follows:

8 “(aa) 50 percent of the amount of the pay-
9 ments shall be paid on a quarterly basis by the
10 United States Postal Service to the Commis-
11 sioner of U.S. Customs and Border Protection
12 in accordance with regulations prescribed by the
13 Secretary of the Treasury to reimburse U.S.
14 Customs and Border Protection for customs
15 services provided in connection with the proc-
16 essing of Inbound EMS items.

17 “(bb) 50 percent of the amount of the pay-
18 ments shall be retained by the Postal Service to
19 reimburse the Postal Service for services pro-
20 vided in connection with the customs processing
21 of Inbound EMS items.

22 “(II) Payments received by U.S. Customs and
23 Border Protection under subclause (I)(aa) shall, in
24 accordance with section 524 of the Tariff Act of
25 1930 (19 U.S.C. 1524), be deposited in the Customs

1 User Fee Account and used to directly reimburse
2 each appropriation for the amount paid out of that
3 appropriation for the costs incurred in providing
4 services to international mail facilities. Amounts de-
5 posited in accordance with the preceding sentence
6 shall be available until expended for the provision of
7 such services.

8 “(III) Payments retained by the Postal Service
9 under subclause (I)(bb) shall be used to directly re-
10 imburse the Postal Service for the costs incurred in
11 providing services in connection with the customs
12 processing of Inbound EMS items.

13 “(iv) Beginning in fiscal year 2021, the Sec-
14 retary, in consultation with the Postmaster General,
15 may adjust, not more frequently than once each fis-
16 cal year, the amount described in clause (i)(I) to an
17 amount commensurate with the costs of services pro-
18 vided in connection with the customs processing of
19 Inbound EMS items, consistent with the obligations
20 of the United States under international agree-
21 ments.”.

22 (b) CONFORMING AMENDMENTS.—Section 13031(a)
23 of the Consolidated Omnibus Budget Reconciliation Act
24 of 1985 (19 U.S.C. 58c(a)) is amended—

1 (1) in paragraph (6), by inserting “(other than
2 an item subject to a fee under subsection
3 (b)(9)(D))” after “customs officer”; and

4 (2) in paragraph (10)—

5 (A) in subparagraph (C), in the matter
6 preceding clause (i), by inserting “(other than
7 Inbound EMS items described in subsection
8 (b)(9)(D))” after “release”; and

9 (B) in the flush at the end, by inserting
10 “or of Inbound EMS items described in sub-
11 section (b)(9)(D),” after “(C),”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 this section shall take effect on January 1, 2020.

14 **SEC. 8003. MANDATORY ADVANCE ELECTRONIC INFORMA-**
15 **TION FOR POSTAL SHIPMENTS.**

16 (a) MANDATORY ADVANCE ELECTRONIC INFORMA-
17 TION.—

18 (1) IN GENERAL.—Section 343(a)(3)(K) of the
19 Trade Act of 2002 (Public Law 107–210; 19 U.S.C.
20 2071 note) is amended to read as follows:

21 “(K)(i) The Secretary shall prescribe regu-
22 lations requiring the United States Postal Serv-
23 ice to transmit the information described in
24 paragraphs (1) and (2) to the Commissioner of
25 U.S. Customs and Border Protection for inter-

1 national mail shipments by the Postal Service
2 (including shipments to the Postal Service from
3 foreign postal operators that are transported by
4 private carrier) consistent with the require-
5 ments of this subparagraph.

6 “(ii) In prescribing regulations under
7 clause (i), the Secretary shall impose require-
8 ments for the transmission to the Commissioner
9 of information described in paragraphs (1) and
10 (2) for mail shipments described in clause (i)
11 that are comparable to the requirements for the
12 transmission of such information imposed on
13 similar non-mail shipments of cargo, taking into
14 account the parameters set forth in subpara-
15 graphs (A) through (J).

16 “(iii) The regulations prescribed under
17 clause (i) shall require the transmission of the
18 information described in paragraphs (1) and (2)
19 with respect to a shipment as soon as prac-
20 ticable in relation to the transportation of the
21 shipment, consistent with subparagraph (H).

22 “(iv) Regulations prescribed under clause
23 (i) shall allow for the requirements for the
24 transmission to the Commissioner of informa-
25 tion described in paragraphs (1) and (2) for

1 mail shipments described in clause (i) to be im-
2 plemented in phases, as appropriate, by—

3 “(I) setting incremental targets for in-
4 creasing the percentage of such shipments
5 for which information is required to be
6 transmitted to the Commissioner; and

7 “(II) taking into consideration—

8 “(aa) the risk posed by such
9 shipments;

10 “(bb) the volume of mail shipped
11 to the United States by or through a
12 particular country; and

13 “(cc) the capacities of foreign
14 postal operators to provide that infor-
15 mation to the Postal Service.

16 “(v)(I) Notwithstanding clause (iv), the
17 Postal Service shall, not later than December
18 31, 2018, arrange for the transmission to the
19 Commissioner of the information described in
20 paragraphs (1) and (2) for not less than 70
21 percent of the aggregate number of mail ship-
22 ments, including 100 percent of mail shipments
23 from the People’s Republic of China, described
24 in clause (i).

1 “(II) If the requirements of subclause (I)
2 are not met, the Comptroller General of the
3 United States shall submit to the appropriate
4 congressional committees, not later than June
5 30, 2019, a report—

6 “(aa) assessing the reasons for the
7 failure to meet those requirements; and

8 “(bb) identifying recommendations to
9 improve the collection by the Postal Serv-
10 ice of the information described in para-
11 graphs (1) and (2).

12 “(vi)(I) Notwithstanding clause (iv), the
13 Postal Service shall, not later than December
14 31, 2020, arrange for the transmission to the
15 Commissioner of the information described in
16 paragraphs (1) and (2) for 100 percent of the
17 aggregate number of mail shipments described
18 in clause (i).

19 “(II) The Commissioner, in consultation
20 with the Postmaster General, may determine to
21 exclude a country from the requirement de-
22 scribed in subclause (I) to transmit information
23 for mail shipments described in clause (i) from
24 the country if the Commissioner determines
25 that the country—

1 “(aa) does not have the capacity to
2 collect and transmit such information;

3 “(bb) represents a low risk for mail
4 shipments that violate relevant United
5 States laws and regulations; and

6 “(cc) accounts for low volumes of mail
7 shipments that can be effectively screened
8 for compliance with relevant United States
9 laws and regulations through an alternate
10 means.

11 “(III) The Commissioner shall, at a min-
12 imum on an annual basis, re-evaluate any de-
13 termination made under subclause (II) to ex-
14 clude a country from the requirement described
15 in subclause (I). If, at any time, the Commis-
16 sioner determines that a country no longer
17 meets the requirements under subclause (II),
18 the Commissioner may not further exclude the
19 country from the requirement described in sub-
20 clause (I).

21 “(IV) The Commissioner shall, on an an-
22 nual basis, submit to the appropriate congress-
23 sional committees—

24 “(aa) a list of countries with respect
25 to which the Commissioner has made a de-

1 termination under subclause (II) to exclude
2 the countries from the requirement de-
3 scribed in subclause (I); and

4 “(bb) information used to support
5 such determination with respect to such
6 countries.

7 “(vii)(I) The Postmaster General shall, in
8 consultation with the Commissioner, refuse any
9 shipments received after December 31, 2020,
10 for which the information described in para-
11 graphs (1) and (2) is not transmitted as re-
12 quired under this subparagraph, except as pro-
13 vided in subclause (II).

14 “(II) If remedial action is warranted in
15 lieu of refusal of shipments pursuant to sub-
16 clause (I), the Postmaster General and the
17 Commissioner shall take remedial action with
18 respect to the shipments, including destruction,
19 seizure, controlled delivery or other law enforce-
20 ment initiatives, or correction of the failure to
21 provide the information described in paragraphs
22 (1) and (2) with respect to the shipments.

23 “(viii) Nothing in this subparagraph shall
24 be construed to limit the authority of the Sec-
25 retary to obtain information relating to inter-

1 national mail shipments from private carriers or
2 other appropriate parties.

3 “(ix) In this subparagraph, the term ‘ap-
4 appropriate congressional committees’ means—

5 “(I) the Committee on Finance and
6 the Committee on Homeland Security and
7 Governmental Affairs of the Senate; and

8 “(II) the Committee on Ways and
9 Means, the Committee on Oversight and
10 Government Reform, and the Committee
11 on Homeland Security of the House of
12 Representatives.”.

13 (2) JOINT STRATEGIC PLAN ON MANDATORY
14 ADVANCE INFORMATION.—Not later than 60 days
15 after the date of the enactment of this Act, the Sec-
16 retary of Homeland Security and the Postmaster
17 General shall develop and submit to the appropriate
18 congressional committees a joint strategic plan de-
19 tailing specific performance measures for achiev-
20 ing—

21 (A) the transmission of information as re-
22 quired by section 343(a)(3)(K) of the Trade
23 Act of 2002, as amended by paragraph (1); and

24 (B) the presentation by the Postal Service
25 to U.S. Customs and Border Protection of all

1 mail targeted by U.S. Customs and Border Pro-
2 tection for inspection.

3 (b) CAPACITY BUILDING.—

4 (1) IN GENERAL.—Section 343(a) of the Trade
5 Act of 2002 (Public Law 107–210; 19 U.S.C. 2071
6 note) is amended by adding at the end the following:

7 “(5) CAPACITY BUILDING.—

8 “(A) IN GENERAL.—The Secretary, with
9 the concurrence of the Secretary of State, and
10 in coordination with the Postmaster General
11 and the heads of other Federal agencies, as ap-
12 propriate, may provide technical assistance,
13 equipment, technology, and training to enhance
14 the capacity of foreign postal operators—

15 “(i) to gather and provide the infor-
16 mation required by paragraph (3)(K); and

17 “(ii) to otherwise gather and provide
18 postal shipment information related to—

19 “(I) terrorism;

20 “(II) items the importation or in-
21 troduction of which into the United
22 States is prohibited or restricted, in-
23 cluding controlled substances; and

24 “(III) such other concerns as the
25 Secretary determines appropriate.

1 “(B) PROVISION OF EQUIPMENT AND
2 TECHNOLOGY.—With respect to the provision of
3 equipment and technology under subparagraph
4 (A), the Secretary may lease, loan, provide, or
5 otherwise assist in the deployment of such
6 equipment and technology under such terms
7 and conditions as the Secretary may prescribe,
8 including nonreimbursable loans or the transfer
9 of ownership of equipment and technology.”.

10 (2) JOINT STRATEGIC PLAN ON CAPACITY
11 BUILDING.—Not later than 1 year after the date of
12 the enactment of this Act, the Secretary of Home-
13 land Security and the Postmaster General shall, in
14 consultation with the Secretary of State, jointly de-
15 velop and submit to the appropriate congressional
16 committees a joint strategic plan—

17 (A) detailing the extent to which U.S. Cus-
18 toms and Border Protection and the United
19 States Postal Service are engaged in capacity
20 building efforts under section 343(a)(5) of the
21 Trade Act of 2002, as added by paragraph (1);

22 (B) describing plans for future capacity
23 building efforts; and

24 (C) assessing how capacity building has in-
25 creased the ability of U.S. Customs and Border

1 Protection and the Postal Service to advance
2 the goals of this subtitle and the amendments
3 made by this subtitle.

4 (c) REPORT AND CONSULTATIONS BY SECRETARY OF
5 HOMELAND SECURITY AND POSTMASTER GENERAL.—

6 (1) REPORT.—Not later than 180 days after
7 the date of the enactment of this Act, and annually
8 thereafter until 3 years after the Postmaster Gen-
9 eral has met the requirement under clause (vi) of
10 subparagraph (K) of section 343(a)(3) of the Trade
11 Act of 2002, as amended by subsection (a)(1), the
12 Secretary of Homeland Security and the Postmaster
13 General shall, in consultation with the Secretary of
14 State, jointly submit to the appropriate congress-
15 sional committees a report on compliance with that
16 subparagraph that includes the following:

17 (A) An assessment of the status of the reg-
18 ulations required to be promulgated under that
19 subparagraph.

20 (B) An update regarding new and existing
21 agreements reached with foreign postal opera-
22 tors for the transmission of the information re-
23 quired by that subparagraph.

24 (C) A summary of deliberations between
25 the United States Postal Service and foreign

1 postal operators with respect to issues relating
2 to the transmission of that information.

3 (D) A summary of the progress made in
4 achieving the transmission of that information
5 for the percentage of shipments required by
6 that subparagraph.

7 (E) An assessment of the quality of that
8 information being received by foreign postal op-
9 erators, as determined by the Secretary of
10 Homeland Security, and actions taken to im-
11 prove the quality of that information.

12 (F) A summary of policies established by
13 the Universal Postal Union that may affect the
14 ability of the Postmaster General to obtain the
15 transmission of that information.

16 (G) A summary of the use of technology to
17 detect illicit synthetic opioids and other illegal
18 substances in international mail parcels and
19 planned acquisitions and advancements in such
20 technology.

21 (H) Such other information as the Sec-
22 retary of Homeland Security and the Post-
23 master General consider appropriate with re-
24 spect to obtaining the transmission of informa-
25 tion required by that subparagraph.

1 (2) CONSULTATIONS.—Not later than 180 days
2 after the date of the enactment of this Act, and
3 every 180 days thereafter until the Postmaster Gen-
4 eral has met the requirement under clause (vi) of
5 section 343(a)(3)(K) of the Trade Act of 2002, as
6 amended by subsection (a)(1), to arrange for the
7 transmission of information with respect to 100 per-
8 cent of the aggregate number of mail shipments de-
9 scribed in clause (i) of that section, the Secretary of
10 Homeland Security and the Postmaster General
11 shall provide briefings to the appropriate congress-
12 sional committees on the progress made in achieving
13 the transmission of that information for that per-
14 centage of shipments.

15 (d) GOVERNMENT ACCOUNTABILITY OFFICE RE-
16 PORT.—Not later than June 30, 2019, the Comptroller
17 General of the United States shall submit to the appro-
18 priate congressional committees a report—

19 (1) assessing the progress of the United States
20 Postal Service in achieving the transmission of the
21 information required by subparagraph (K) of section
22 343(a)(3) of the Trade Act of 2002, as amended by
23 subsection (a)(1), for the percentage of shipments
24 required by that subparagraph;

1 (2) assessing the quality of the information re-
2 ceived from foreign postal operators for targeting
3 purposes;

4 (3) assessing the specific percentage of targeted
5 mail presented by the Postal Service to U.S. Cus-
6 toms and Border Protection for inspection;

7 (4) describing the costs of collecting the infor-
8 mation required by such subparagraph (K) from for-
9 eign postal operators and the costs of implementing
10 the use of that information;

11 (5) assessing the benefits of receiving that in-
12 formation with respect to international mail ship-
13 ments;

14 (6) assessing the feasibility of assessing a cus-
15 toms fee under section 13031(b)(9) of the Consoli-
16 dated Omnibus Budget Reconciliation Act of 1985,
17 as amended by section 8002, on international mail
18 shipments other than Inbound Express Mail service
19 in a manner consistent with the obligations of the
20 United States under international agreements; and

21 (7) identifying recommendations, including rec-
22 ommendations for legislation, to improve the compli-
23 ance of the Postal Service with such subparagraph
24 (K), including an assessment of whether the detec-

1 tion of illicit synthetic opioids in the international
2 mail would be improved by—

3 (A) requiring the Postal Service to serve as
4 the consignee for international mail shipments
5 containing goods; or

6 (B) designating a customs broker to act as
7 an importer of record for international mail
8 shipments containing goods.

9 (e) **TECHNICAL CORRECTION.**—Section 343 of the
10 Trade Act of 2002 (Public Law 107–210; 19 U.S.C. 2071
11 note) is amended in the section heading by striking “**AD-**
12 **VANCED**” and inserting “**ADVANCE**”.

13 (f) **APPROPRIATE CONGRESSIONAL COMMITTEES DE-**
14 **FINED.**—In this section, the term “appropriate congres-
15 sional committees” means—

16 (1) the Committee on Finance and the Com-
17 mittee on Homeland Security and Governmental Af-
18 fairs of the Senate; and

19 (2) the Committee on Ways and Means, the
20 Committee on Oversight and Government Reform,
21 and the Committee on Homeland Security of the
22 House of Representatives.

23 **SEC. 8004. INTERNATIONAL POSTAL AGREEMENTS.**

24 (a) **EXISTING AGREEMENTS.**—

1 (1) IN GENERAL.—In the event that any provi-
2 sion of this subtitle, or any amendment made by this
3 Act, is determined to be in violation of obligations
4 of the United States under any postal treaty, con-
5 vention, or other international agreement related to
6 international postal services, or any amendment to
7 such an agreement, the Secretary of State should
8 negotiate to amend the relevant provisions of the
9 agreement so that the United States is no longer in
10 violation of the agreement.

11 (2) RULE OF CONSTRUCTION.—Nothing in this
12 subsection shall be construed to permit delay in the
13 implementation of this subtitle or any amendment
14 made by this subtitle.

15 (b) FUTURE AGREEMENTS.—

16 (1) CONSULTATIONS.—Before entering into, on
17 or after the date of the enactment of this Act, any
18 postal treaty, convention, or other international
19 agreement related to international postal services, or
20 any amendment to such an agreement, that is re-
21 lated to the ability of the United States to secure
22 the provision of advance electronic information by
23 foreign postal operators, the Secretary of State
24 should consult with the appropriate congressional
25 committees (as defined in section 8003(f)).

1 (2) EXPEDITED NEGOTIATION OF NEW AGREE-
2 MENT.—To the extent that any new postal treaty,
3 convention, or other international agreement related
4 to international postal services would improve the
5 ability of the United States to secure the provision
6 of advance electronic information by foreign postal
7 operators as required by regulations prescribed
8 under section 343(a)(3)(K) of the Trade Act of
9 2002, as amended by section 8003(a)(1), the Sec-
10 retary of State should expeditiously conclude such
11 an agreement.

12 **SEC. 8005. COST RECOUPMENT.**

13 (a) IN GENERAL.—The United States Postal Service
14 shall, to the extent practicable and otherwise recoverable
15 by law, ensure that all costs associated with complying
16 with this subtitle and amendments made by this subtitle
17 are charged directly to foreign shippers or foreign postal
18 operators.

19 (b) COSTS NOT CONSIDERED REVENUE.—The recov-
20 ery of costs under subsection (a) shall not be deemed rev-
21 enue for purposes of subchapter I and II of chapter 36
22 of title 39, United States Code, or regulations prescribed
23 under that chapter.

1 **SEC. 8006. DEVELOPMENT OF TECHNOLOGY TO DETECT IL-**
2 **LICIT NARCOTICS.**

3 (a) IN GENERAL.—The Postmaster General and the
4 Commissioner of U.S. Customs and Border Protection, in
5 coordination with the heads of other agencies as appro-
6 priate, shall collaborate to identify and develop technology
7 for the detection of illicit fentanyl, other synthetic opioids,
8 and other narcotics and psychoactive substances entering
9 the United States by mail.

10 (b) OUTREACH TO PRIVATE SECTOR.—The Post-
11 master General and the Commissioner shall conduct out-
12 reach to private sector entities to gather information re-
13 garding the current state of technology to identify areas
14 for innovation relating to the detection of illicit fentanyl,
15 other synthetic opioids, and other narcotics and
16 psychoactive substances entering the United States.

17 **SEC. 8007. CIVIL PENALTIES FOR POSTAL SHIPMENTS.**

18 Section 436 of the Tariff Act of 1930 (19 U.S.C.
19 1436) is amended by adding at the end the following new
20 subsection:

21 “(e) CIVIL PENALTIES FOR POSTAL SHIPMENTS.—

22 “(1) CIVIL PENALTY.—A civil penalty shall be
23 imposed against the United States Postal Service if
24 the Postal Service accepts a shipment in violation of
25 section 343(a)(3)(K)(vii)(I) of the Trade Act of
26 2002.

1 “(2) MODIFICATION OF CIVIL PENALTY.—

2 “(A) IN GENERAL.—U.S. Customs and
3 Border Protection shall reduce or dismiss a civil
4 penalty imposed pursuant to paragraph (1) if
5 U.S. Customs and Border Protection deter-
6 mines that the United States Postal Service—

7 “(i) has a low error rate in compliance
8 with section 343(a)(3)(K) of the Trade Act
9 of 2002;

10 “(ii) is cooperating with U.S. Customs
11 and Border Protection with respect to the
12 violation of section 343(a)(3)(K)(vii)(I) of
13 the Trade Act of 2002; or

14 “(iii) has taken remedial action to
15 prevent future violations of section
16 343(a)(3)(K)(vii)(I) of the Trade Act of
17 2002.

18 “(B) WRITTEN NOTIFICATION.—U.S. Cus-
19 toms and Border Protection shall issue a writ-
20 ten notification to the Postal Service with re-
21 spect to each exercise of the authority of sub-
22 paragraph (A) to reduce or dismiss a civil pen-
23 alty imposed pursuant to paragraph (1).

1 “(3) ONGOING LACK OF COMPLIANCE.—If U.S.
2 Customs and Border Protection determines that the
3 United States Postal Service—

4 “(A) has repeatedly committed violations
5 of section 343(a)(3)(K)(vii)(I) of the Trade Act
6 of 2002,

7 “(B) has failed to cooperate with U.S.
8 Customs and Border Protection with respect to
9 violations of section 343(a)(3)(K)(vii)(I) of the
10 Trade Act of 2002, and

11 “(C) has an increasing error rate in com-
12 pliance with section 343(a)(3)(K) of the Trade
13 Act of 2002,

14 civil penalties may be imposed against the United
15 States Postal Service until corrective action, satis-
16 factory to U.S. Customs and Border Protection, is
17 taken.”.

18 **SEC. 8008. REPORT ON VIOLATIONS OF ARRIVAL, REPORT-**
19 **ING, ENTRY, AND CLEARANCE REQUIRE-**
20 **MENTS AND FALSITY OR LACK OF MANIFEST.**

21 (a) IN GENERAL.—The Commissioner of U.S. Cus-
22 toms and Border Protection shall submit to the appro-
23 priate congressional committees an annual report that
24 contains the information described in subsection (b) with
25 respect to each violation of section 436 of the Tariff Act

1 of 1930 (19 U.S.C. 1436), as amended by section 8007,
2 and section 584 of such Act (19 U.S.C. 1584) that oc-
3 curred during the previous year.

4 (b) INFORMATION DESCRIBED.—The information de-
5 scribed in this subsection is the following:

6 (1) The name and address of the violator.

7 (2) The specific violation that was committed.

8 (3) The location or port of entry through which
9 the items were transported.

10 (4) An inventory of the items seized, including
11 a description of the items and the quantity seized.

12 (5) The location from which the items origi-
13 nated.

14 (6) The entity responsible for the apprehension
15 or seizure, organized by location or port of entry.

16 (7) The amount of penalties assessed by U.S.
17 Customs and Border Protection, organized by name
18 of the violator and location or port of entry.

19 (8) The amount of penalties that U.S. Customs
20 and Border Protection could have levied, organized
21 by name of the violator and location or port of entry.

22 (9) The rationale for negotiating lower pen-
23 alties, organized by name of the violator and location
24 or port of entry.

1 (c) APPROPRIATE CONGRESSIONAL COMMITTEES DE-
2 FINED.—In this section, the term “appropriate congres-
3 sional committees” means—

4 (1) the Committee on Finance and the Com-
5 mittee on Homeland Security and Governmental Af-
6 fairs of the Senate; and

7 (2) the Committee on Ways and Means, the
8 Committee on Oversight and Government Reform,
9 and the Committee on Homeland Security of the
10 House of Representatives.

11 **SEC. 8009. EFFECTIVE DATE; REGULATIONS.**

12 (a) EFFECTIVE DATE.—This subtitle and the amend-
13 ments made by this subtitle (other than the amendments
14 made by section 8002) shall take effect on the date of the
15 enactment of this Act.

16 (b) REGULATIONS.—Not later than 1 year after the
17 date of the enactment of this Act, such regulations as are
18 necessary to carry out this subtitle and the amendments
19 made by this subtitle shall be prescribed.

1 **Subtitle B—Recognizing Early**
2 **Childhood Trauma Related to**
3 **Substance Abuse**

4 **SEC. 8011. SHORT TITLE.**

5 This subtitle may be cited as the “Recognizing Early
6 Childhood Trauma Related to Substance Abuse Act of
7 2018”.

8 **SEC. 8012. RECOGNIZING EARLY CHILDHOOD TRAUMA RE-**
9 **LATED TO SUBSTANCE ABUSE.**

10 (a) **DISSEMINATION OF INFORMATION.**—The Sec-
11 retary of Health and Human Services shall disseminate
12 information, resources, and, if requested, technical assist-
13 ance to early childhood care and education providers and
14 professionals working with young children on—

15 (1) ways to properly recognize children who
16 may be impacted by trauma related to substance
17 abuse by a family member or other adult; and

18 (2) how to respond appropriately in order to
19 provide for the safety and well-being of young chil-
20 dren and their families.

21 (b) **GOALS.**—The information, resources, and tech-
22 nical assistance provided under subsection (a) shall—

23 (1) educate early childhood care and education
24 providers and professionals working with young chil-
25 dren on understanding and identifying the early

1 signs and risk factors of children who might be im-
2 pacted by trauma due to exposure to substance
3 abuse;

4 (2) suggest age-appropriate communication
5 tools, procedures, and practices for trauma-informed
6 care, including ways to prevent or mitigate the ef-
7 fects of trauma;

8 (3) provide options for responding to children
9 impacted by trauma due to exposure to substance
10 abuse that consider the needs of the child and fam-
11 ily, including recommending resources and referrals
12 for evidence-based services to support such family;
13 and

14 (4) promote whole-family and multi-
15 generational approaches to prevent separation and
16 support re-unification of families whenever possible
17 and in the best interest of the child.

18 (c) RULE OF CONSTRUCTION.—Such information, re-
19 sources, and if applicable, technical assistance, shall not
20 be construed to amend the requirements under—

21 (1) the Child Care and Development Block
22 Grant Act of 1990 (42 U.S.C. 9858 et seq.);

23 (2) the Head Start Act (42 U.S.C. 9831 et
24 seq.); or

1 (3) the Individuals with Disabilities Education
2 Act (20 U.S.C. 1400 et seq.).

3 **Subtitle C—Assisting States’ Imple-**
4 **mentation of Plans of Safe Care**

5 **SEC. 8021. SHORT TITLE.**

6 This subtitle may be cited as the “Assisting States’
7 Implementation of Plans of Safe Care Act”.

8 **SEC. 8022. ASSISTING STATES WITH IMPLEMENTATION OF**
9 **PLANS OF SAFE CARE.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services shall provide written guidance and, if ap-
12 propriate, technical assistance to support States in com-
13 plying with, and implementing, subsections (b)(2)(B)(iii)
14 and (d)(18) of section 106 of the Child Abuse Prevention
15 and Treatment Act (42 U.S.C. 5106a) in order to promote
16 better protections for young children and family-centered
17 responses.

18 (b) REQUIREMENTS.—The guidance and technical as-
19 sistance shall—

20 (1) enhance States’ understanding of require-
21 ments and flexibilities under the law, including clari-
22 fying key terms;

23 (2) address State-identified challenges with de-
24 veloping, implementing, and monitoring plans of safe
25 care;

1 (3) disseminate best practices related to devel-
2 oping and implementing plans of safe care, including
3 differential response, collaboration and coordination,
4 and identification and delivery of services, while rec-
5 ognizing needs of different populations and varying
6 community approaches across States;

7 (4) support collaboration between health care
8 providers, social service agencies, public health agen-
9 cies, and the child welfare system, to promote a fam-
10 ily-centered treatment approach;

11 (5) prevent separation and support reunifica-
12 tion of families if in the best interests of the child;

13 (6) recommend treatment approaches for serv-
14 ing infants, pregnant women, and postpartum
15 women whose infants may be affected by substance
16 use that are designed to keep infants with their
17 mothers and families whenever appropriate, includ-
18 ing recommendations to encourage pregnant women
19 to receive health and other support services during
20 pregnancy;

21 (7) support State efforts to develop technology
22 systems to manage and monitor implementation of
23 plans of safe care; and

24 (8) help States improve the long-term safety
25 and well-being of young children and their families.

1 (c) CONSTRUCTION.—The guidance and technical as-
2 sistance shall not be construed to amend the requirements
3 of the Child Abuse Prevention and Treatment Act (42
4 U.S.C. 5101 et seq.).

5 (d) DEFINITION.—For purposes of this section, the
6 term “State” has the meaning given such term in section
7 3 of the Child Abuse Prevention and Treatment Act (42
8 U.S.C. 5101 note).

9 **Subtitle D—Improving the Federal**
10 **Response to Families Impacted**
11 **by Substance Use Disorder**

12 **SEC. 8031. SHORT TITLE.**

13 This subtitle may be cited as the “Improving the Fed-
14 eral Response to Families Impacted by Substance Use
15 Disorder Act”.

16 **SEC. 8032. INTERAGENCY TASK FORCE TO IMPROVE THE**
17 **FEDERAL RESPONSE TO FAMILIES IMPACTED**
18 **BY SUBSTANCE USE DISORDERS.**

19 (a) ESTABLISHMENT.—There is established a task
20 force, to be known as the “Interagency Task Force to Im-
21 prove the Federal Response to Families Impacted by Sub-
22 stance Use Disorders” (in this section referred to as
23 “Task Force”).

24 (b) RESPONSIBILITIES.—The Task Force—

1 (1) shall identify, evaluate, and recommend
2 ways in which Federal agencies can better coordi-
3 nate responses to substance use disorders and the
4 opioid crisis; and

5 (2) shall carry out the additional duties de-
6 scribed in subsection (d).

7 (c) MEMBERSHIP.—

8 (1) NUMBER AND APPOINTMENT.—The Task
9 Force shall be composed of 12 Federal officials hav-
10 ing responsibility for, or administering programs re-
11 lated to, the duties of the Task Force. The Secretary
12 of Health and Human Services, the Secretary of
13 Education, the Secretary of Agriculture, and the
14 Secretary of Labor shall each appoint two members
15 to the Task Force from among the Federal officials
16 employed by the Department of which they are the
17 head. Additional Federal agency officials appointed
18 by the Secretary of Health and Human Services
19 shall fill the remaining positions of the Task Force.

20 (2) CHAIRPERSON.—The Secretary of Health
21 and Human Services shall designate a Federal offi-
22 cial employed by the Department of Health and
23 Human Services to serve as the chairperson of the
24 Task Force.

1 (3) DEADLINE FOR APPOINTMENT.—Each
2 member shall be appointed to the Task Force not
3 later than 60 days after the date of the enactment
4 of this Act.

5 (4) ADDITIONAL AGENCY INPUT.—The Task
6 Force may seek input from other Federal agencies
7 and offices with experience, expertise, or information
8 relevant in responding to the opioid crisis.

9 (5) VACANCIES.—A vacancy in the Task Force
10 shall be filled in the manner in which the original
11 appointment was made.

12 (6) PROHIBITION OF COMPENSATION.—Mem-
13 bers of the Task Force may not receive pay, allow-
14 ances, or benefits by reason of their service on the
15 Task Force.

16 (d) DUTIES.—The Task Force shall carry out the fol-
17 lowing duties:

18 (1) Solicit input from stakeholders, including
19 frontline service providers, medical professionals,
20 educators, mental health professionals, researchers,
21 experts in infant, child, and youth trauma, child wel-
22 fare professionals, and the public, in order to inform
23 the activities of the Task Force.

24 (2) Develop a strategy on how the Task Force
25 and participating Federal agencies will collaborate,

1 prioritize, and implement a coordinated Federal ap-
2 proach with regard to responding to substance use
3 disorders, including opioid misuse, that shall in-
4 clude—

5 (A) identifying options for the coordination
6 of existing grants that support infants, chil-
7 dren, and youth, and their families as appro-
8 priate, who have experienced, or are at risk of
9 experiencing, exposure to substance abuse dis-
10 orders, including opioid misuse; and

11 (B) other ways to improve coordination,
12 planning, and communication within and across
13 Federal agencies, offices, and programs, to bet-
14 ter serve children and families impacted by sub-
15 stance use disorders, including opioid misuse.

16 (3) Based off the strategy developed under
17 paragraph (2), evaluate and recommend opportuni-
18 ties for local- and State-level partnerships, profes-
19 sional development, or best practices that—

20 (A) are designed to quickly identify and
21 refer children and families, as appropriate, who
22 have experienced or are at risk of experiencing
23 exposure to substance abuse;

24 (B) utilize and develop partnerships with
25 early childhood education programs, local social

1 services organizations, and health care services
2 aimed at preventing or mitigating the effects of
3 exposure to substance use disorders, including
4 opioid misuse;

5 (C) offer community-based prevention ac-
6 tivities, including educating families and chil-
7 dren on the effects of exposure to substance use
8 disorders, including opioid misuse, and how to
9 build resilience and coping skills to mitigate
10 those effects;

11 (D) in accordance with Federal privacy
12 protections, utilize non-personally identifiable
13 data from screenings, referrals, or the provision
14 of services and supports to evaluate and im-
15 prove processes addressing exposure to sub-
16 stance use disorders, including opioid misuse;
17 and

18 (E) are designed to prevent separation and
19 support reunification of families if in the best
20 interest of the child.

21 (4) In fulfilling the requirements of paragraphs
22 (2) and (3), consider evidence-based, evidence-in-
23 formed, and promising best practices related to iden-
24 tifying, referring, and supporting children and fami-
25 lies at risk of experiencing exposure to substance

1 abuse or experiencing substance use disorder, includ-
2 ing opioid misuse, including—

3 (A) prevention strategies for those at risk
4 of experiencing or being exposed to substance
5 abuse, including misuse of opioids;

6 (B) whole-family and multi-generational
7 approaches;

8 (C) community-based initiatives;

9 (D) referral to, and implementation of,
10 trauma-informed practices and supports; and

11 (E) multi-generational practices that assist
12 parents, foster parents, and kinship and other
13 caregivers

14 (e) FACA.—The Federal Advisory Committee Act (5
15 U.S.C. App. 2) shall not apply to the Task Force.

16 (f) ACTION PLAN; REPORTS.—The Task Force—

17 (1) shall prepare a detailed action plan to be
18 implemented by participating Federal agencies to
19 create a collaborative, coordinated response to the
20 opioid crisis, which shall include—

21 (A) relevant information identified and col-
22 lected under subsection (d);

23 (B) a proposed timeline for implementing
24 recommendations and efforts identified under
25 subsection (d); and

1 (C) a description of how other Federal
2 agencies and offices with experience, expertise,
3 or information relevant in responding to the
4 opioid crisis that have provided input under
5 subsection (c)(4) will be participating in the co-
6 ordinated approach;

7 (2) shall submit to the Congress a report de-
8 scribing the action plan prepared under paragraph
9 (1), including, where applicable, identification of any
10 recommendations included in such plan that require
11 additional legislative authority to implement; and

12 (3) shall submit a report to the Governors de-
13 scribing the opportunities for local- and State-level
14 partnerships, professional development, or best prac-
15 tices recommended under subsection (d)(3).

16 (g) DISSEMINATION.—

17 (1) IN GENERAL.—The action plan and reports
18 required under subsection (f) shall be—

19 (A) disseminated widely, including among
20 the participating Federal agencies and the Gov-
21 ernors; and

22 (B) be made publicly available online in an
23 accessible format.

24 (2) DEADLINE.—The action plan and reports
25 required under subsection (f) may be released on

1 separate dates but shall be released not later than
2 9 months after the date of the enactment of this
3 Act.

4 (h) TERMINATION.—The Task Force shall terminate
5 30 days after the dissemination of the action plan and re-
6 ports under subsection (g).

7 (i) FUNDING.—The administrative expenses of the
8 Task Force shall be paid out of existing Department of
9 Health and Human Services funds or appropriations.

10 (j) DEFINITIONS.—For purposes of this section:

11 (1) The term “Governor” means the chief execu-
12 tive officer of a State.

13 (2) The term “participating Federal agencies”
14 means all the Executive agencies (as defined in sec-
15 tion 105 of title 5, United States Code) whose offi-
16 cials have been appointed to the Task Force.

17 (3) The term “State” means each of the several
18 States, the District of Columbia, the Commonwealth
19 of Puerto Rico, the Virgin Islands, Guam, American
20 Samoa, and the Commonwealth of the Northern
21 Mariana Islands.

1 **Subtitle E—Establishment of an**
2 **Advisory Committee on Opioids**
3 **and the Workplace**

4 **SEC. 8041. ESTABLISHMENT OF AN ADVISORY COMMITTEE**
5 **ON OPIOIDS AND THE WORKPLACE.**

6 (a) ESTABLISHMENT.—Not later than 90 days after
7 enactment of this Act, the Secretary of Labor shall estab-
8 lish an Advisory Committee on Opioids and the Workplace
9 (referred to in this subtitle as the “Advisory Committee”)
10 to advise the Secretary on actions the Department of
11 Labor can take to provide informational resources and
12 best practices on how to appropriately address the impact
13 of opioid abuse on the workplace and support workers
14 abusing opioids.

15 (b) MEMBERSHIP.—

16 (1) COMPOSITION.—The Secretary of Labor
17 shall appoint as members of the Advisory Committee
18 19 individuals with expertise in employment, work-
19 place health programs, human resources, substance
20 use disorder, and other relevant fields. The Advisory
21 Committee shall be composed as follows:

22 (A) Four of the members shall be individ-
23 uals representative of employers or other orga-
24 nizations representing employers.

1 (B) Four of the members shall be individ-
2 uals representative of workers or other organi-
3 zations representing workers, of which at least
4 two must be representatives designated by labor
5 organizations.

6 (C) Three of the members shall be individ-
7 uals representative of health benefit plans, em-
8 ployee assistance plan providers, workers' com-
9 pensation program administrators, and work-
10 place safety and health professionals.

11 (D) Eight of the members shall be individ-
12 uals representative of substance abuse treat-
13 ment and recovery experts, including medical
14 doctors, licensed addiction therapists, and sci-
15 entific and academic researchers, of which one
16 individual may be a representative of a local or
17 State government agency that oversees or co-
18 ordinates programs that address substance use
19 disorder.

20 (2) CHAIR.—From the members appointed
21 under paragraph (1), the Secretary of Labor shall
22 appoint a chairperson.

23 (3) TERMS.—Each member of the Advisory
24 Committee shall serve for a term of 3 years. A mem-

1 ber appointed to fill a vacancy shall be appointed
2 only for the remainder of such term.

3 (4) QUORUM.—A majority of members of the
4 Advisory Committee shall constitute a quorum and
5 action shall be taken only by a majority vote of the
6 members.

7 (5) VOTING.—The Advisory Committee shall es-
8 tablish voting procedures.

9 (6) NO COMPENSATION.—Members of the Advi-
10 sory Committee shall serve without compensation.

11 (7) DISCLOSURE.—Every member of the Advi-
12 sory Committee must disclose the entity, if applica-
13 ble, that he or she is representing.

14 (c) DUTIES.—

15 (1) ADVISEMENT.—

16 (A) IN GENERAL.—The Advisory Com-
17 mittee established under subsection (a) shall
18 advise the Secretary of Labor on actions the
19 Department of Labor can take to provide infor-
20 mational resources and best practices on how to
21 appropriately address the impact of opioid
22 abuse on the workplace and support workers
23 abusing opioids.

1 (B) CONSIDERATIONS.—In providing such
2 advice, the Advisory Committee shall take into
3 account—

4 (i) evidence-based and other employer
5 substance abuse policies and best practices
6 regarding opioid use or abuse, including
7 benefits provided by employee assistance
8 programs or other employer-provided bene-
9 fits, programs, or resources;

10 (ii) the effect of opioid use or abuse
11 on the safety of the workplace as well as
12 policies and procedures addressing work-
13 place safety and health;

14 (iii) the impact of opioid abuse on
15 productivity and absenteeism, and assess-
16 ments of model human resources policies
17 that support workers abusing opioids, such
18 as policies that facilitate seeking and re-
19 ceiving treatment and returning to work;

20 (iv) the extent to which alternative
21 pain management treatments other than
22 opioids are or should be covered by em-
23 ployer-sponsored health plans;

24 (v) the legal requirements protecting
25 employee privacy and health information in

1 the workplace, as well as the legal require-
2 ments related to nondiscrimination;

3 (vi) potential interactions of opioid
4 abuse with other substance use disorders;

5 (vii) any additional benefits or re-
6 sources available to an employee abusing
7 opioids that promote retaining employment
8 or reentering the workforce;

9 (viii) evidence-based initiatives that
10 engage employers, employees, and commu-
11 nity leaders to promote early identification
12 of opioid abuse, intervention, treatment,
13 and recovery;

14 (ix) workplace policies regarding
15 opioid abuse that reduce stigmatization
16 among fellow employees and management;
17 and

18 (x) the legal requirements of the Men-
19 tal Health Parity and Addiction Equity
20 Act and other laws related to health cov-
21 erage of substance abuse and mental
22 health services and medications.

23 (2) REPORT.—Prior to its termination as pro-
24 vided in subsection (j), the Advisory Committee shall
25 issue a report to the Secretary of Labor and to the

1 Committee on Education and the Workforce of the
2 House of Representatives and the Committee on
3 Health, Education, Labor, and Pensions of the Sen-
4 ate, detailing successful programs and policies in-
5 volving workplace resources and benefits, including
6 recommendations or examples of best practices for
7 how employers can support and respond to employ-
8 ees impacted by opioid abuse.

9 (d) MEETINGS.—The Advisory Committee shall meet
10 at least twice a year at the call of the chairperson.

11 (e) STAFF SUPPORT.—The Secretary of Labor shall
12 make available staff necessary for the Advisory Committee
13 to carry out its responsibilities.

14 (f) FEDERAL ADVISORY COMMITTEE ACT.—The
15 Federal Advisory Committee Act shall apply to the Advi-
16 sory Committee established under this subtitle.

17 (g) NO APPROPRIATED FUNDS.—No additional
18 funds are authorized to be appropriated to carry out this
19 subtitle. Expenses of the Advisory Committee shall be paid
20 with funds otherwise appropriated to Departmental Man-
21 agement within the Department of Labor.

22 (h) EX OFFICIO.—Three nonvoting representatives
23 from agencies within the Department of Health and
24 Human Services whose responsibilities include opioid pre-
25 scribing guidelines, workplace safety, and monitoring of

1 substance abuse and prevention programs shall be ap-
2 pointed by the Secretary of Labor and designated as ex
3 officio members.

4 (i) AGENDA.—The Secretary of Labor or a represent-
5 ative of the Secretary shall consult with the Chair in es-
6 tablishing the agenda for Committee meetings.

7 (j) TERMINATION.—The Advisory Committee estab-
8 lished under this subtitle shall terminate 3 years after the
9 date of enactment of this Act.

10 **Subtitle F—Veterans Treatment** 11 **Court Improvement**

12 **SEC. 8051. SHORT TITLE.**

13 This subtitle may be cited as the “Veterans Treat-
14 ment Court Improvement Act of 2018”.

15 **SEC. 8052. HIRING BY DEPARTMENT OF VETERANS AFFAIRS** 16 **OF ADDITIONAL VETERANS JUSTICE OUT-** 17 **REACH SPECIALISTS.**

18 (a) HIRING OF ADDITIONAL VETERANS JUSTICE
19 OUTREACH SPECIALISTS.—

20 (1) IN GENERAL.—Not later than 1 year after
21 the date of the enactment of this Act, the Secretary
22 of Veterans Affairs shall hire not fewer than 50 Vet-
23 erans Justice Outreach Specialists and place each
24 such Veterans Justice Outreach Specialist at an eli-

1 gible Department of Veterans Affairs medical center
2 in accordance with this section.

3 (2) REQUIREMENTS.—The Secretary shall en-
4 sure that each Veterans Justice Outreach Specialist
5 employed under paragraph (1)—

6 (A) serves, either exclusively or in addition
7 to other duties, as part of a justice team in a
8 veterans treatment court or other veteran-fo-
9 cused court; and

10 (B) otherwise meets Department hiring
11 guidelines for Veterans Justice Outreach Spe-
12 cialists.

13 (b) ELIGIBLE DEPARTMENT OF VETERANS AFFAIRS
14 MEDICAL CENTERS.—For purposes of this section, an eli-
15 gible Department of Veterans Affairs medical center is
16 any Department of Veterans Affairs medical center that—

17 (1) complies with all Department guidelines and
18 regulations for placement of a Veterans Justice Out-
19 reach Specialist;

20 (2) works within a local criminal justice system
21 with justice-involved veterans;

22 (3) maintains an affiliation with one or more
23 veterans treatment courts or other veteran-focused
24 courts; and

25 (4) either—

1 (A) routinely provides Veterans Justice
2 Outreach Specialists to serve as part of a jus-
3 tice team in a veterans treatment court or other
4 veteran-focused court; or

5 (B) establishes a plan that is approved by
6 the Secretary to provide Veterans Justice Out-
7 reach Specialists employed under subsection
8 (a)(1) to serve as part of a justice team in a
9 veterans treatment court or other veteran-fo-
10 cused court.

11 (c) PLACEMENT PRIORITY.—The Secretary shall
12 prioritize the placement of Veterans Justice Spe-
13 cialists employed under subsection (a)(1) at eligible De-
14 partment of Veterans Affairs medical centers that have
15 or intend to establish an affiliation, for the purpose of car-
16 rying out the Veterans Justice Outreach Program, with
17 a veterans treatment court, or other veteran-focused court,
18 that—

19 (1) was established on or after the date of the
20 enactment of this Act; or

21 (2)(A) was established before the date of the
22 enactment of this Act; and

23 (B) is not fully staffed with Veterans Justice
24 Outreach Specialists.

25 (d) REPORTS.—

1 (1) REPORT BY SECRETARY OF VETERANS AF-
2 FAIRS.—

3 (A) IN GENERAL.—Not later than 1 year
4 after the date of the enactment of this Act, the
5 Secretary of Veterans Affairs shall submit to
6 Congress a report on the implementation of this
7 section and its effect on the Veterans Justice
8 Outreach Program.

9 (B) CONTENTS.—The report submitted
10 under paragraph (1) shall include the following:

11 (i) The status of the efforts of the
12 Secretary to hire Veterans Justice Out-
13 reach Specialists pursuant to subsection
14 (a)(1), including the total number of Vet-
15 erans Justice Outreach Specialists hired by
16 the Secretary pursuant to such subsection
17 and the number that the Secretary expects
18 to hire pursuant to such subsection.

19 (ii) The total number of Veterans
20 Justice Outreach Specialists assigned to
21 each Department of Veterans Affairs med-
22 ical center that participates in the Vet-
23 erans Justice Outreach Program, including
24 the number of Veterans Justice Outreach
25 Specialists hired under subsection (a)(1)

1 disaggregated by Department of Veterans
2 Affairs medical center.

3 (iii) The total number of eligible De-
4 partment of Veterans Affairs medical cen-
5 ters that sought placement of a Veterans
6 Justice Outreach Specialist under sub-
7 section (a)(1), how many Veterans Justice
8 Outreach Specialists each such center
9 sought, and how many of such medical
10 centers received no placement of a Vet-
11 erans Justice Outreach Specialist under
12 subsection (a)(1).

13 (iv) For each eligible Department of
14 Veterans Affairs medical center—

15 (I) the number of justice-involved
16 veterans who were served or are ex-
17 pected to be served by a Veterans
18 Justice Outreach Specialist hired
19 under subsection (a)(1); and

20 (II) the number of justice-in-
21 volved veterans who do not have ac-
22 cess to a Veterans Justice Outreach
23 Specialist.

24 (2) REPORT BY COMPTROLLER GENERAL OF
25 THE UNITED STATES.—

1 (A) IN GENERAL.—Not later than 3 years
2 after the date of the enactment of this Act, the
3 Comptroller General of the United States shall
4 submit to Congress a report on the implementa-
5 tion of this section and the effectiveness of the
6 Veterans Justice Outreach Program.

7 (B) CONTENTS.—The report required by
8 subparagraph (A) shall include the following:

9 (i) An assessment of whether the Sec-
10 retary has fulfilled the Secretary’s obliga-
11 tions under this section.

12 (ii) The number of veterans who are
13 served by Veterans Justice Outreach Spe-
14 cialists hired under subsection (a)(1),
15 disaggregated by demographics (including
16 discharge status).

17 (iii) An identification of any sub-
18 groups of veterans who underutilize serv-
19 ices provided under laws administered by
20 the Secretary, including an assessment of
21 whether these veterans have access to Vet-
22 erans Justice Outreach Specialists under
23 the Veterans Justice Outreach Program.

24 (iv) Such recommendations as the
25 Comptroller General may have for the Sec-

1 retary to improve the effectiveness of the
2 Veterans Justice Outreach Program.

3 (e) DEFINITIONS.—In this section:

4 (1) JUSTICE TEAM.—The term “justice team”
5 means the group of individuals, which may include
6 a judge, court coordinator, prosecutor, public de-
7 fender, treatment provider, probation or other law
8 enforcement officer, program mentor, and Veterans
9 Justice Outreach Specialist, who assist justice-in-
10 volved veterans in a veterans treatment court or
11 other veteran-focused court.

12 (2) JUSTICE-INVOLVED VETERAN.—The term
13 “justice-involved veteran” means a veteran with ac-
14 tive, ongoing, or recent contact with some compo-
15 nent of a local criminal justice system.

16 (3) LOCAL CRIMINAL JUSTICE SYSTEM.—The
17 term “local criminal justice system” means law en-
18 forcement, jails, prisons, and Federal, State, and
19 local courts.

20 (4) VETERANS JUSTICE OUTREACH PRO-
21 GRAM.—The term “Veterans Justice Outreach Pro-
22 gram” means the program through which the De-
23 partment of Veterans Affairs identifies justice-in-
24 volved veterans and provides such veterans with ac-
25 cess to Department services.

1 (5) VETERANS JUSTICE OUTREACH SPE-
2 CIALIST.—The term “Veterans Justice Outreach
3 Specialist” means an employee of the Department of
4 Veterans Affairs who serves as a liaison between the
5 Department and the local criminal justice system on
6 behalf of a justice-involved veteran.

7 (6) VETERANS TREATMENT COURT.—The term
8 “veterans treatment court” means a State or local
9 court that is participating in the veterans treatment
10 court program (as defined in section 2991(i)(1) of
11 the Omnibus Crime Control and Safe Streets Act of
12 1968 (42 U.S.C. 3797aa(i)(1))).

13 **Subtitle G—Peer Support Coun-**
14 **seling Program for Women Vet-**
15 **erans**

16 **SEC. 8061. PEER SUPPORT COUNSELING PROGRAM FOR**
17 **WOMEN VETERANS.**

18 (a) IN GENERAL.—Section 1720F(j) of title 38,
19 United States Code, is amended by adding at the end the
20 following new paragraph:

21 “(4)(A) As part of the counseling program under this
22 subsection, the Secretary shall emphasize appointing peer
23 support counselors for women veterans. To the degree
24 practicable, the Secretary shall seek to recruit women peer
25 support counselors with expertise in—

1 “(i) female gender-specific issues and services;

2 “(ii) the provision of information about services
3 and benefits provided under laws administered by
4 the Secretary; or

5 “(iii) employment mentoring.

6 “(B) To the degree practicable, the Secretary shall
7 emphasize facilitating peer support counseling for women
8 veterans who are eligible for counseling and services under
9 section 1720D of this title, have post-traumatic stress dis-
10 order or suffer from another mental health condition, are
11 homeless or at risk of becoming homeless, or are otherwise
12 at increased risk of suicide, as determined by the Sec-
13 retary.

14 “(C) The Secretary shall conduct outreach to inform
15 women veterans about the program and the assistance
16 available under this paragraph.

17 “(D) In carrying out this paragraph, the Secretary
18 shall coordinate with such community organizations, State
19 and local governments, institutions of higher education,
20 chambers of commerce, local business organizations, orga-
21 nizations that provide legal assistance, and other organiza-
22 tions as the Secretary considers appropriate.

23 “(E) In carrying out this paragraph, the Secretary
24 shall provide adequate training for peer support coun-
25 selors, including training carried out under the national

1 program of training required by section 304(c) of the
2 Caregivers and Veterans Omnibus Health Services Act of
3 2010 (38 U.S.C. 1712A note).”.

4 (b) FUNDING.—The Secretary of Veterans Affairs
5 shall carry out paragraph (4) of section 1720F(j) of title
6 38, United States Code, as added by subsection (a), using
7 funds otherwise made available to the Secretary. No addi-
8 tional funds are authorized to be appropriated by reason
9 of such paragraph.

10 (c) REPORT TO CONGRESS.—Not later than 2 years
11 after the date of the enactment of this Act, the Secretary
12 of Veterans Affairs shall submit to the Committees on
13 Veterans’ Affairs of the Senate and House of Representa-
14 tives a report on the peer support counseling program
15 under section 1720F(j) of title 38, United States Code,
16 as amended by this section. Such report shall include—

17 (1) the number of peer support counselors in
18 the program;

19 (2) an assessment of the effectiveness of the
20 program; and

21 (3) a description of the oversight of the pro-
22 gram.

1 **Subtitle H—Treating Barriers to**
2 **Prosperity**

3 **SEC. 8071. SHORT TITLE.**

4 This subtitle may be cited as the “Treating Barriers
5 to Prosperity Act of 2018”.

6 **SEC. 8072. DRUG ABUSE MITIGATION INITIATIVE.**

7 (a) IN GENERAL.—Chapter 145 of title 40, United
8 States Code, is amended by inserting after section 14509
9 the following:

10 **“§ 14510. Drug abuse mitigation initiative**

11 “(a) IN GENERAL.—The Appalachian Regional Com-
12 mission may provide technical assistance to, make grants
13 to, enter into contracts with, or otherwise provide amounts
14 to individuals or entities in the Appalachian region for
15 projects and activities to address drug abuse, including
16 opioid abuse, in the region, including projects and activi-
17 ties—

18 “(1) to facilitate the sharing of best practices
19 among States, counties, and other experts in the re-
20 gion with respect to reducing such abuse;

21 “(2) to initiate or expand programs designed to
22 eliminate or reduce the harm to the workforce and
23 economic growth of the region that results from such
24 abuse;

1 “(3) to attract and retain relevant health care
2 services, businesses, and workers; and

3 “(4) to develop relevant infrastructure, includ-
4 ing broadband infrastructure that supports the use
5 of telemedicine.

6 “(b) LIMITATION ON AVAILABLE AMOUNTS.—Of the
7 cost of any activity eligible for a grant under this sec-
8 tion—

9 “(1) not more than 50 percent may be provided
10 from amounts appropriated to carry out this section;
11 and

12 “(2) notwithstanding paragraph (1)—

13 “(A) in the case of a project to be carried
14 out in a county for which a distressed county
15 designation is in effect under section 14526,
16 not more than 80 percent may be provided from
17 amounts appropriated to carry out this section;
18 and

19 “(B) in the case of a project to be carried
20 out in a county for which an at-risk designation
21 is in effect under section 14526, not more than
22 70 percent may be provided from amounts ap-
23 propriated to carry out this section.

24 “(c) SOURCES OF ASSISTANCE.—Subject to sub-
25 section (b), a grant provided under this section may be

1 provided from amounts made available to carry out this
 2 section in combination with amounts made available—

3 “(1) under any other Federal program (subject
 4 to the availability of subsequent appropriations); or

5 “(2) from any other source.

6 “(d) FEDERAL SHARE.—Notwithstanding any provi-
 7 sion of law limiting the Federal share under any other
 8 Federal program, amounts made available to carry out
 9 this section may be used to increase that Federal share,
 10 as the Appalachian Regional Commission determines to be
 11 appropriate.”.

12 (b) CLERICAL AMENDMENT.—The analysis for chap-
 13 ter 145 of title 40, United States Code, is amended by
 14 inserting after the item relating to section 14509 the fol-
 15 lowing:

“14510. Drug abuse mitigation initiative.”.

16 **Subtitle I—Supporting Grand-**
 17 **parents Raising Grandchildren**

18 **SEC. 8081. SHORT TITLE.**

19 This subtitle may be cited as the “Supporting Grand-
 20 parents Raising Grandchildren Act”.

21 **SEC. 8082. FINDINGS.**

22 Congress finds the following:

23 (1) More than 2,500,000 grandparents in the
 24 United States are the primary caretaker of their

1 grandchildren, and experts report that such numbers
2 are increasing as the opioid epidemic expands.

3 (2) Between 2009 and 2016, the incidence of
4 parental alcohol or other drug use as a contributing
5 factor for children's out-of-home placement rose
6 from 25.4 to 37.4 percent.

7 (3) When children cannot remain safely with
8 their parents, placement with relatives is preferred
9 over placement in foster care with nonrelatives be-
10 cause placement with relatives provides stability for
11 children and helps them maintain family connec-
12 tions.

13 (4) The number of foster children placed with
14 a grandparent or other relative increased from 24
15 percent in 2006 to 32 percent in 2016, according to
16 data from the Department of Health and Human
17 Services.

18 (5) Grandparents' lives are enhanced by caring
19 for their grandchildren; the overwhelming majority
20 of grandparents report experiencing significant bene-
21 fits in serving as their grandchildren's primary care-
22 givers.

23 (6) Providing full-time care to their grand-
24 children may decrease grandparents' ability to ad-

1 dress their own physical and mental health needs
2 and personal well-being.

3 (7) Grandparents would benefit from better co-
4 ordination and dissemination of information and re-
5 sources available to support them in their caregiving
6 responsibilities.

7 **SEC. 8083. ADVISORY COUNCIL TO SUPPORT GRAND-**
8 **PARENTS RAISING GRANDCHILDREN.**

9 (a) **ESTABLISHMENT.**—There is established an Advi-
10 sory Council to Support Grandparents Raising Grand-
11 children.

12 (b) **MEMBERSHIP.**—

13 (1) **IN GENERAL.**—The Advisory Council shall
14 be composed of the following members, or their des-
15 ignee:

16 (A) The Secretary of Health and Human
17 Services.

18 (B) The Secretary of Education.

19 (C) The Administrator of the Administra-
20 tion for Community Living.

21 (D) The Director of the Centers for Dis-
22 ease Control and Prevention.

23 (E) The Assistant Secretary for Mental
24 Health and Substance Use.

1 (F) The Assistant Secretary for the Ad-
2 ministration for Children and Families.

3 (G) A grandparent raising a grandchild.

4 (H) An older relative caregiver of children.

5 (I) As appropriate, the head of other Fed-
6 eral departments, or agencies, identified by the
7 Secretary of Health and Human Services as
8 having responsibilities, or administering pro-
9 grams, relating to current issues affecting
10 grandparents or other older relatives raising
11 children.

12 (2) LEAD AGENCY.—The Department of Health
13 and Human Services shall be the lead agency for the
14 Advisory Council.

15 (c) DUTIES.—

16 (1) IN GENERAL.—

17 (A) INFORMATION.—The Advisory Council
18 shall identify, promote, coordinate, and dissemi-
19 nate to the public information, resources, and
20 the best practices available to help grand-
21 parents and other older relatives—

22 (i) meet the health, educational, nutri-
23 tional, and other needs of the children in
24 their care; and

1 (ii) maintain their own physical and
2 mental health and emotional well-being.

3 (B) OPIOIDS.—In carrying out the duties
4 described in subparagraph (A), the Advisory
5 Council shall consider the needs of those af-
6 fected by the opioid crisis.

7 (C) NATIVE AMERICANS.—In carrying out
8 the duties described in subparagraph (A), the
9 Advisory Council shall consider the needs of
10 members of Native American tribes.

11 (2) REPORT.—

12 (A) IN GENERAL.—Not later than 180
13 days after the date of enactment of this Act,
14 the Advisory Council shall submit a report to—

15 (i) the appropriate committees;

16 (ii) the State agencies that are re-
17 sponsible for carrying out family caregiver
18 programs; and

19 (iii) the public online in an accessible
20 format.

21 (B) REPORT FORMAT.—The report shall
22 include—

23 (i) best practices, resources, and other
24 useful information for grandparents and
25 other older relatives raising children identi-

1 fied under paragraph (1)(A) including, if
2 applicable, any information related to the
3 needs of children who have been impacted
4 by the opioid epidemic;

5 (ii) an identification of any gaps in
6 items under clause (i); and

7 (iii) where applicable, identification of
8 any additional Federal legislative authority
9 necessary to implement the activities de-
10 scribed in clause (i) and (ii).

11 (3) FOLLOW-UP REPORT.—Not later than 2
12 years after the date on which the report required
13 under paragraph (2)(A) is submitted, the Advisory
14 Council shall submit a follow-up report that includes
15 the information identified in paragraph (2)(B) to—

16 (A) the appropriate committees;

17 (B) the State agencies that are responsible
18 for carrying out family caregiver programs; and

19 (C) the public online in an accessible for-
20 mat.

21 (4) PUBLIC INPUT.—

22 (A) IN GENERAL.—The Advisory Council
23 shall establish a process for public input to in-
24 form the development of, and provide updates
25 to, the best practices, resources, and other in-

1 formation described in paragraph (1) that shall
2 include—

3 (i) outreach to States, local entities,
4 and organizations that provide information
5 to, or support for, grandparents or other
6 older relatives raising children; and

7 (ii) outreach to grandparents and
8 other older relatives with experience rais-
9 ing children.

10 (B) NATURE OF OUTREACH.—Such out-
11 reach shall ask individuals to provide input
12 on—

13 (i) information, resources, and best
14 practices available, including identification
15 of any gaps and unmet needs; and

16 (ii) recommendations that would help
17 grandparents and other older relatives bet-
18 ter meet the health, educational, nutri-
19 tional, and other needs of the children in
20 their care, as well as maintain their own
21 physical and mental health and emotional
22 well-being.

23 (d) FACA.—The Advisory Council shall be exempt
24 from the requirements of the Federal Advisory Committee
25 Act (5 U.S.C. App.).

1 (e) FUNDING.—No additional funds are authorized to
2 be appropriated to carry out this subtitle.

3 (f) SUNSET.—The Advisory Council shall terminate
4 on the date that is 3 years after the date of enactment
5 of this Act.

6 **SEC. 8084. DEFINITIONS.**

7 In this subtitle:

8 (1) ADVISORY COUNCIL.—In this subtitle, the
9 term “Advisory Council” means the Advisory Coun-
10 cil to Support Grandparents Raising Grandchildren
11 that is established under section 8083.

12 (2) APPROPRIATE COMMITTEES.—In this sub-
13 title, the term “appropriate committees” means the
14 following:

15 (A) The Special Committee on Aging of
16 the Senate.

17 (B) The Committee on Health, Education,
18 Labor, and Pensions of the Senate.

19 (C) The Committee on Education and the
20 Workforce of the House of Representatives.

21 (D) The Committee on Energy and Com-
22 merce of the House of Representatives.

1 **Subtitle J—Reauthorizing and Ex-**
2 **tending Grants for Recovery**
3 **From Opioid Use Programs**

4 **SEC. 8091. SHORT TITLE.**

5 This subtitle may be cited as the “Reauthorizing and
6 Extending Grants for Recovery from Opioid Use Pro-
7 grams Act of 2018” or the “REGROUP Act of 2018”.

8 **SEC. 8092. REAUTHORIZATION OF THE COMPREHENSIVE**
9 **OPIOID ABUSE GRANT PROGRAM.**

10 Section 1001(a)(27) of the Omnibus Crime Control
11 and Safe Streets Act of 1968 (34 U.S.C. 10261(a)(27))
12 is amended by striking “through 2021” and inserting
13 “and 2018, and \$330,000,000 for each of fiscal years
14 2019 through 2023”.

15 **TITLE IX—SITSA ACT**

16 **SEC. 9001. SHORT TITLE.**

17 This title may be cited as the “Stop the Importation
18 and Trafficking of Synthetic Analogues Act of 2017” or
19 the “SITSA Act”.

20 **SEC. 9002. ESTABLISHMENT OF SCHEDULE A.**

21 Section 202 of the Controlled Substances Act (21
22 U.S.C. 812) is amended—

23 (1) in subsection (a), by striking “five schedules
24 of controlled substances, to be known as schedules I,
25 II, III, IV, and V” and inserting “six schedules of

1 controlled substances, to be known as schedules I,
2 II, III, IV, V, and A”;

3 (2) in subsection (b), by adding at the end the
4 following:

5 “(6) SCHEDULE A.—

6 “(A) IN GENERAL.—The drug or substance—

7 “(i) has—

8 “(I) a chemical structure that is sub-
9 stantially similar to the chemical structure
10 of a controlled substance in schedule I, II,
11 III, IV, or V; and

12 “(II) an actual or predicted stimulant,
13 depressant, or hallucinogenic effect on the
14 central nervous system that is substantially
15 similar to or greater than the stimulant,
16 depressant, or hallucinogenic effect on the
17 central nervous system of a controlled sub-
18 stance in schedule I, II, III, IV, or V; and

19 “(ii) is not—

20 “(I) listed or otherwise included in
21 any other schedule in this section or by
22 regulation of the Attorney General; and

23 “(II) with respect to a particular per-
24 son, subject to an exemption that is in ef-
25 fect for investigational use, for that person,

1 under section 505 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 355)
3 to the extent conduct with respect to such
4 substance is pursuant to such exemption.

5 “(B) PREDICTED STIMULANT, DEPRESSANT, OR
6 HALLUCINOGENIC EFFECT.—For purpose of this
7 paragraph, a predicted stimulant, depressant, or hal-
8 lucinogenic effect on the central nervous system may
9 be based on—

10 “(i) the chemical structure and—

11 “(I) the structure activity relation-
12 ships; or

13 “(II) binding receptor assays and
14 other relevant scientific information about
15 the substance;

16 “(ii)(I) the current or relative potential for
17 abuse of the substance; and

18 “(II) the clandestine importation, manu-
19 facture, or distribution, or diversion from legiti-
20 mate channels, of the substance; or

21 “(iii) the capacity of the substance to
22 cause a state of dependence, including physical
23 or psychological dependence that is similar to or
24 greater than that of a controlled substance in
25 schedule I, II, III, IV, or V.”; and

1 (3) in subsection (c), in the matter preceding
2 schedule I, by striking “IV, and V” and inserting
3 “IV, V, and A”.

4 **SEC. 9003. TEMPORARY AND PERMANENT SCHEDULING OF**
5 **SCHEDULE A SUBSTANCES.**

6 Section 201 of the Controlled Substances Act (21
7 U.S.C. 811) is amended by adding at the end the fol-
8 lowing:

9 “(k) TEMPORARY AND PERMANENT SCHEDULING OF
10 SCHEDULE A SUBSTANCES.—

11 “(1) The Attorney General may issue a tem-
12 porary order adding a drug or substance to schedule
13 A if the Attorney General finds that—

14 “(A) the drug or other substance satisfies
15 the criteria for being considered a schedule A
16 substance; and

17 “(B) adding such drug or substance to
18 schedule A will assist in preventing abuse of the
19 drug or other substance.

20 “(2) A temporary scheduling order issued under
21 paragraph (1) shall not take effect until 30 days
22 after the date of the publication by the Attorney
23 General of a notice in the Federal Register of the in-
24 tention to issue such order and the grounds upon
25 which such order is to be issued. The temporary

1 scheduling order shall expire not later than 5 years
2 after the date it becomes effective, except that the
3 Attorney General may, during the pendency of pro-
4 ceedings under paragraph (5), extend the temporary
5 scheduling order for up to 180 days.

6 “(3) A temporary scheduling order issued under
7 paragraph (1) shall be vacated upon the issuance of
8 a permanent order issued under paragraph (5) with
9 regard to the same substance, or upon the subse-
10 quent issuance of any scheduling order under this
11 section.

12 “(4) A temporary scheduling order issued under
13 paragraph (1) shall not be subject to judicial review.

14 “(5)(A) Beginning no earlier than 3 years after
15 issuing an order temporarily scheduling a drug or
16 other substance under this subsection, the Attorney
17 General may, by rule, issue a permanent order add-
18 ing a drug or other substance to schedule A if such
19 drug or substance satisfies the criteria for being con-
20 sidered a controlled substance in schedule A under
21 this subsection, except as provided in subparagraph
22 (B).

23 “(B) If the Secretary has determined, based on
24 relevant scientific studies and necessary data re-
25 quested by the Secretary and gathered by the Attor-

1 ney General, that a drug or other substance that has
2 been temporarily placed in schedule A does not have
3 sufficient potential for abuse to warrant control in
4 any schedule, and so advises the Attorney General in
5 writing, the Attorney General may not issue a per-
6 manent scheduling order under subparagraph (A)
7 and shall, within 30 days of receiving the Secretary's
8 advice issue an order immediately terminating the
9 temporary scheduling order.

10 “(6) Before initiating proceedings under para-
11 graph (1), the Attorney General shall transmit no-
12 tice of a temporary order proposed to be issued to
13 the Secretary of Health and Human Services. In
14 issuing an order under paragraph (1), the Attorney
15 General shall take into consideration any comments
16 submitted by the Secretary of Health and Human
17 Services in response to a notice transmitted pursu-
18 ant to this paragraph.

19 “(7) On the date of the publication of a notice
20 in the Federal Register pursuant to paragraph (2),
21 the Attorney General shall transmit the same notice
22 to Congress. The temporary scheduling order shall
23 take effect according to paragraph (2), except that
24 the temporary scheduling order may be disapproved
25 by an Act of Congress within 180 days from the

1 date of publication of the notice in the Federal Reg-
2 ister.”.

3 **SEC. 9004. PENALTIES.**

4 (a) CONTROLLED SUBSTANCES ACT.—The Con-
5 trolled Substances Act (21 U.S.C. 801 et seq.) is amend-
6 ed—

7 (1) in section 401(b)(1) (21 U.S.C. 841(b)(1)),
8 by adding at the end the following:

9 “(F)(i) In the case of any controlled substance in
10 schedule A, such person shall be sentenced to a term of
11 imprisonment of not more than 10 years and if death or
12 serious bodily injury results from the use of such sub-
13 stance shall be sentenced to a term of imprisonment of
14 not more than 15 years, a fine not to exceed the greater
15 of that authorized in accordance with the provisions of
16 title 18, United States Code, or \$500,000 if the defendant
17 is an individual or \$2.5 million if the defendant is other
18 than an individual, or both.

19 “(ii) If any person commits such a violation after a
20 prior conviction for a felony drug offense has become final,
21 such person shall be sentenced to a term of imprisonment
22 of not more than 20 years and if death or serious bodily
23 injury results from the use of such substance shall be sen-
24 tenced to a term of imprisonment of not more than 30
25 years, a fine not to exceed the greater of twice that author-

1 ized in accordance with the provisions of title 18, United
2 States Code, or \$1 million if the defendant is an individual
3 or \$5 million if the defendant is other than an individual,
4 or both.

5 “(iii) Any sentence imposing a term of imprisonment
6 under this subparagraph shall, in the absence of such a
7 prior conviction, impose a term of supervised release of
8 not less than 2 years in addition to such term of imprison-
9 ment and shall, if there was such a prior conviction, im-
10 pose a term of supervised release of not less than 4 years
11 in addition to such term of imprisonment.”;

12 (2) in section 403(a) (21 U.S.C. 843(a))—

13 (A) in paragraph (8), by striking “or” at
14 the end;

15 (B) in paragraph (9), by striking the pe-
16 riod at the end and inserting “; or”; and

17 (C) by inserting after paragraph (9) the
18 following:

19 “(10) to export a substance in violation of the
20 controlled substance laws of the country to which
21 the substance is exported.”; and

22 (3) in section 404 (21 U.S.C. 844), by inserting
23 after subsection (a) the following:

24 “(b) A person shall not be subject to a criminal or
25 civil penalty under this title or under any other Federal

1 law solely for possession of a schedule A controlled sub-
2 stance.”.

3 (b) CONTROLLED SUBSTANCES IMPORT AND EXPORT
4 ACT.—Section 1010(b) of the Controlled Substances Im-
5 port and Export Act (21 U.S.C. 960(b)) is amended by
6 adding at the end the following:

7 “(8) In the case of a violation under subsection (a)
8 involving a controlled substance in schedule A, the person
9 committing such violation shall be sentenced to a term of
10 imprisonment of not more than 20 years and if death or
11 serious bodily injury results from the use of such sub-
12 stance shall be sentenced to a term of imprisonment of
13 not more than life, a fine not to exceed the greater of that
14 authorized in accordance with the provisions of title 18,
15 United States Code, or \$1 million if the defendant is an
16 individual or \$5 million if the defendant is other than an
17 individual, or both. If any person commits such a violation
18 after a prior conviction for a felony drug offense has be-
19 come final, such person shall be sentenced to a term of
20 imprisonment of not more than 30 years and if death or
21 serious bodily injury results from the use of such sub-
22 stance shall be sentenced to not more than life imprison-
23 ment, a fine not to exceed the greater of twice that author-
24 ized in accordance with the provisions of title 18, United
25 States Code, or \$2 million if the defendant is an individual

1 or \$10 million if the defendant is other than an individual,
2 or both. Notwithstanding section 3583 of title 18, United
3 States Code, any sentence imposing a term of imprison-
4 ment under this paragraph shall, in the absence of such
5 a prior conviction, impose a term of supervised release of
6 not less than 3 years in addition to such term of imprison-
7 ment and shall, if there was such a prior conviction, im-
8 pose a term of supervised release of not less than 6 years
9 in addition to such term of imprisonment. Notwith-
10 standing the prior sentence, and notwithstanding any
11 other provision of law, the court shall not place on proba-
12 tion or suspend the sentence of any person sentenced
13 under the provisions of this paragraph which provide for
14 a mandatory term of imprisonment if death or serious
15 bodily injury results.”.

16 **SEC. 9005. FALSE LABELING OF SCHEDULE A CONTROLLED**
17 **SUBSTANCES.**

18 (a) IN GENERAL.—Section 305 of the Controlled
19 Substances Act (21 U.S.C. 825) is amended by adding at
20 the end the following:

21 “(f) FALSE LABELING OF SCHEDULE A CON-
22 TROLLED SUBSTANCES.—

23 “(1) It shall be unlawful to import, export,
24 manufacture, distribute, dispense, or possess with
25 intent to manufacture, distribute, or dispense, a

1 schedule A substance or product containing a sched-
2 ule A substance, unless the substance or product
3 bears a label clearly identifying a schedule A sub-
4 stance or product containing a schedule A substance
5 by the nomenclature used by the International
6 Union of Pure and Applied Chemistry (IUPAC).

7 “(2)(A) A product described in subparagraph
8 (B) is exempt from the International Union of Pure
9 and Applied Chemistry nomenclature requirement of
10 this subsection if such product is labeled in the man-
11 ner required under the Federal Food, Drug, and
12 Cosmetic Act.

13 “(B) A product is described in this subpara-
14 graph if the product—

15 “(i) is the subject of an approved applica-
16 tion as described in section 505(b) or (j) of the
17 Federal Food, Drug, and Cosmetic Act; or

18 “(ii) is exempt from the provisions of sec-
19 tion 505 of such Act relating to new drugs be-
20 cause—

21 “(I) it is intended solely for investiga-
22 tional use as described in section 505(i) of
23 such Act; and

24 “(II) such product is being used ex-
25 clusively for purposes of a clinical trial

1 that is the subject of an effective investiga-
2 tional new drug application.”.

3 (b) PENALTIES.—Section 402 of the Controlled Sub-
4 stances Act (21 U.S.C. 842) is amended—

5 (1) in subsection (a)(16), by inserting “or sub-
6 section (f)” after “subsection (e)”; and

7 (2) in subsection (c)(1)(D), by inserting “or a
8 schedule A substance” after “anabolic steroid”.

9 **SEC. 9006. REGISTRATION REQUIREMENTS FOR HANDLERS**
10 **OF SCHEDULE A SUBSTANCES.**

11 (a) CONTROLLED SUBSTANCES ACT.—Section 303 of
12 the Controlled Substances Act (21 U.S.C. 823) is amend-
13 ed by adding at the end the following:

14 “(k)(1) The Attorney General shall register an appli-
15 cant to manufacture schedule A substances if—

16 “(A) the applicant demonstrates that the sched-
17 ule A substances will be used for research, analyt-
18 ical, or industrial purposes approved by the Attorney
19 General; and

20 “(B) the Attorney General determines that such
21 registration is consistent with the public interest and
22 with the United States obligations under inter-
23 national treaties, conventions, or protocols in effect
24 on the date of enactment of this subsection.

1 “(2) In determining the public interest under para-
2 graph (1)(B), the Attorney General shall consider—

3 “(A) maintenance of effective controls against
4 diversion of particular controlled substances and any
5 controlled substance in schedule A compounded
6 therefrom into other than legitimate medical, sci-
7 entific, research, or industrial channels, by limiting
8 the importation and bulk manufacture of such con-
9 trolled substances to a number of establishments
10 which can produce an adequate and uninterrupted
11 supply of these substances under adequately com-
12 petitive conditions for legitimate medical, scientific,
13 research, and industrial purposes;

14 “(B) compliance with applicable State and local
15 law;

16 “(C) promotion of technical advances in the art
17 of manufacturing substances described in subpara-
18 graph (A) and the development of new substances;

19 “(D) prior conviction record of applicant under
20 Federal and State laws relating to the manufacture,
21 distribution, or dispensing of substances described in
22 paragraph (A);

23 “(E) past experience in the manufacture of con-
24 trolled substances, and the existence in the establish-
25 ment of effective control against diversion; and

1 “(F) such other factors as may be relevant to
2 and consistent with the public health and safety.

3 “(3) If an applicant is registered to manufacture con-
4 trolled substances in schedule I or II under subsection (a),
5 the applicant shall not be required to apply for a separate
6 registration under this subsection.

7 “(1)(1) The Attorney General shall register an appli-
8 cant to distribute schedule A substances—

9 “(A) if the applicant demonstrates that the
10 schedule A substances will be used for research, ana-
11 lytical, or industrial purposes approved by the Attor-
12 ney General; and

13 “(B) unless the Attorney General determines
14 that the issuance of such registration is inconsistent
15 with the public interest.

16 “(2) In determining the public interest under para-
17 graph (1)(B), the Attorney General shall consider—

18 “(A) maintenance of effective control against
19 diversion of particular controlled substances into
20 other than legitimate medical, scientific, and indus-
21 trial channels;

22 “(B) compliance with applicable State and local
23 law;

24 “(C) prior conviction record of applicant under
25 Federal or State laws relating to the manufacture,

1 distribution, or dispensing of substances described in
2 subparagraph (A);

3 “(D) past experience in the distribution of con-
4 trolled substances; and

5 “(E) such other factors as may be relevant to
6 and consistent with the public health and safety.

7 “(3) If an applicant is registered to distribute a con-
8 trolled substance in schedule I or II under subsection (b),
9 the applicant shall not be required to apply for a separate
10 registration under this subsection.

11 “(m)(1)(A) Not later than 90 days after the date on
12 which a substance is placed in schedule A, any practitioner
13 who was engaged in research on the substance before the
14 placement of the substance in schedule A and any manu-
15 facturer or distributor who was handling the substance be-
16 fore the placement of the substance in schedule A shall
17 register with the Attorney General.

18 “(B)(i) If an applicant described in subparagraph (A)
19 is registered pursuant to subsection (f) to conduct re-
20 search with a controlled substance in schedule I or II on
21 the date on which another substance is placed in schedule
22 A, the applicant may, subject to clause (iii), conduct re-
23 search with that other controlled substance in schedule A
24 while the application for registration pursuant to subpara-
25 graph (A) is pending.

1 “(ii) If an applicant described in subparagraph (A)
2 is registered pursuant to subsection (f) as described in
3 clause (i) to conduct research with a controlled substance
4 in schedule III, IV, or V on the date on which another
5 substance is placed in schedule A, the applicant may, sub-
6 ject to clause (iii), conduct research with that other con-
7 trolled substance in schedule A while the application for
8 registration pursuant to subparagraph (A) is pending,
9 provided the substance for which the applicant is reg-
10 istered to conduct research is in the same schedule as, or
11 a less-restricted schedule than, the controlled substance
12 whose similarity in chemical structure and actual or pre-
13 dicted effect to the controlled substance in schedule A
14 formed the basis for placement of the substance in sched-
15 ule A, as set forth in the order published in the Federal
16 Register placing the substance in schedule A.

17 “(iii) The permission to conduct research pursuant
18 to clause (i) or clause (ii) is conditional on the applicant’s
19 complying with the registration and other requirements
20 for controlled substances in schedule A.

21 “(iv) This subparagraph does not apply to applicants
22 registered pursuant to subsection (f) whose authorization
23 to conduct research with any controlled substances is lim-
24 ited to doing so as a coincident activity pursuant to appli-
25 cable regulations of the Attorney General.

1 “(2)(A) Not later than 60 days after the date on
2 which the Attorney General receives an application for
3 registration to conduct research on a schedule A sub-
4 stance, the Attorney General shall—

5 “(i) grant, or initiate proceedings under section
6 304(c) to deny, the application; or

7 “(ii) request supplemental information from the
8 applicant.

9 “(B) Not later than 30 days after the date on which
10 the Attorney General receives supplemental information
11 requested under subparagraph (A)(ii) in connection with
12 an application described in subparagraph (A), the Attor-
13 ney General shall grant or deny the application.

14 “(n)(1) The Attorney General shall register a sci-
15 entific investigator or a qualified research institution to
16 conduct research with controlled substances in schedule A
17 in accordance with this subsection. In evaluating applica-
18 tions for such registration, the Attorney General shall
19 apply the criteria set forth in subsection (f) of this section
20 that apply to practitioners seeking a registration to con-
21 duct research with a schedule I controlled substance, ex-
22 cept that the applicant shall not be required to submit a
23 research protocol.

24 “(2) If the applicant is not currently registered under
25 subsection (f) to conduct research with a schedule I con-

1 trolled substance, the Attorney General shall refer the ap-
2 plication to the Secretary, who shall determine whether
3 the applicant will be engaged in bona fide research and
4 is qualified to conduct such research. The 60-day period
5 under subsection (m)(2)(A) shall be tolled during the pe-
6 riod beginning on the date on which the Attorney General
7 refers an application to the Secretary under this para-
8 graph, and ending on the date on which the Secretary sub-
9 mits a determination related to such referral to the Attor-
10 ney General.

11 “(3) An applicant who meets the criteria under sub-
12 section (m)(1)(B) with respect to a particular schedule A
13 controlled substance shall be considered qualified to con-
14 duct research with that substance. The Attorney General
15 shall modify such applicant’s registration to include such
16 schedule A controlled substance in accordance with this
17 paragraph. The applicant shall notify the Attorney Gen-
18 eral of his intent to conduct research with a controlled
19 substance in schedule A. Upon receiving such notification,
20 the Attorney General shall modify the practitioner’s exist-
21 ing registration to authorize research with schedule A con-
22 trolled substances, unless the Attorney General determines
23 that the registration modification would be inconsistent
24 with the public interest based on the criteria of subsection
25 (f).

1 “(4) Registrations issued under this subsection to a
2 qualified research institution will apply to all agents and
3 employees of that institution acting within the scope of
4 their professional practice.

5 “(5) At least 30 days prior to conducting any re-
6 search with a controlled substance in schedule A, the reg-
7 istrant shall provide the Attorney General with written no-
8 tification of the following:

9 “(A) The name of and drug code for each sub-
10 stance.

11 “(B) The name of each individual with access
12 to each substance.

13 “(C) The amount of each substance.

14 “(D) Other similar information the Attorney
15 General may require.

16 “(6) The quantity of a schedule A controlled sub-
17 stance possessed by a person registered under this sub-
18 section shall be appropriate for the research being con-
19 ducted, subject to the additional limitations set forth in
20 this paragraph. To reduce the risk of diversion, the Attor-
21 ney General may establish limitations on the quantity of
22 schedule A controlled substances that may be manufac-
23 tured or possessed for purposes of research under this sub-
24 section and shall publish such limitations on the website
25 of the Drug Enforcement Administration. A person reg-

1 istered under this subsection may, based on legitimate re-
2 search needs, apply to the Attorney General to manufac-
3 ture or possess an amount greater than that so specified
4 by the Attorney General. The Attorney General shall
5 specify the manner in which such applications shall be
6 submitted. The Attorney General shall act on an applica-
7 tion filed under this subparagraph within 30 days of re-
8 ceipt of such application. If the Attorney General fails to
9 act within 30 days, the registrant shall be allowed to man-
10 ufacture and possess up to the amount requested. The At-
11 torney General shall have the authority to reverse the in-
12 crease for cause.

13 “(7) The Attorney General shall by regulation specify
14 the manner in which applications for registration under
15 this subsection shall be submitted.

16 “(8) Registrants authorized under this subsection
17 may manufacture and possess schedule A controlled sub-
18 stances up to the approved amounts only for use in their
19 own research setting or institution. Manufacturing for use
20 in any other setting or institution shall require a manufac-
21 turer’s registration under section 303(a).”.

22 (b) CONTROLLED SUBSTANCES IMPORT AND EXPORT
23 ACT.—Section 1008 of the Controlled Substances Import
24 and Export Act (21 U.S.C. 958) is amended by adding
25 at the end the following:

1 “(j)(1) The Attorney General shall register an appli-
2 cant to import or export a schedule A substance if—

3 “(A) the applicant demonstrates that the sched-
4 ule A substances will be used for research, analyt-
5 ical, or industrial purposes approved by the Attorney
6 General; and

7 “(B) the Attorney General determines that such
8 registration is consistent with the public interest and
9 with the United States obligations under inter-
10 national treaties, conventions, or protocols in effect
11 on the date of enactment of this subsection.

12 “(2) In determining the public interest under para-
13 graph (1)(B), the Attorney General shall consider the fac-
14 tors described in subparagraphs (A) through (F) of sec-
15 tion 303(k)(2).

16 “(3) If an applicant is registered to import or export
17 a controlled substance in schedule I or II under subsection
18 (a), the applicant shall not be required to apply for a sepa-
19 rate registration under this subsection.”.

20 **SEC. 9007. ADDITIONAL CONFORMING AMENDMENTS.**

21 (a) CONTROLLED SUBSTANCES ACT.—The Con-
22 trolled Substances Act (21 U.S.C. 801 et seq.) is amend-
23 ed—

24 (1) in section 303(e) (21 U.S.C. 823(e))—

1 (A) by striking “subsections (a) and (b)”
2 and inserting “subsection (a), (b), (k), or (l)”;
3 and

4 (B) by striking “schedule I or II” and in-
5 serting “schedule I, II, or A”;

6 (2) in section 306 (21 U.S.C. 826)—

7 (A) in subsection (a), in the first sentence,
8 by striking “schedules I and II” and inserting
9 “schedules I, II, and A”;

10 (B) in subsection (b), in the second sen-
11 tence, by striking “schedule I or II” and insert-
12 ing “schedule I, II, or A”;

13 (C) in subsection (c), in the first sentence,
14 by striking “schedules I and II” and inserting
15 “schedules I, II, and A”;

16 (D) in subsection (d), in the first sentence,
17 by striking “schedule I or II” and inserting
18 “schedule I, II, or A”;

19 (E) in subsection (e), in the first sentence,
20 by striking “schedule I or II” and inserting
21 “schedule I, II, or A”; and

22 (F) in subsection (f), in the first sentence,
23 by striking “schedules I and II” and inserting
24 “schedules I, II, and A”;

1 (3) in section 308(a) (21 U.S.C. 828(a)), by
2 striking “schedule I or II” and inserting “schedule
3 I, II, or A”;

4 (4) in section 402(b) (21 U.S.C. 842(b)), in the
5 matter preceding paragraph (1), by striking “sched-
6 ule I or II” and inserting “schedule I, II, or A”;

7 (5) in section 403(a)(1) (21 U.S.C. 843(a)(1)),
8 by striking “schedule I or II” and inserting “sched-
9 ule I, II, or A”; and

10 (6) in section 511(f) (21 U.S.C. 881(f)), by
11 striking “schedule I or II” each place it appears and
12 inserting “schedule I, II, or A”.

13 (b) CONTROLLED SUBSTANCES IMPORT EXPORT
14 ACT.—The Controlled Substances Import and Export Act
15 (21 U.S.C. 951 et seq.) is amended—

16 (1) in section 1002(a) (21 U.S.C. 952(a))—

17 (A) in the matter preceding paragraph (1),
18 by striking “schedule I or II” and inserting
19 “schedule I, II, or A”; and

20 (B) in paragraph (2), by striking “sched-
21 ule I or II” and inserting “schedule I, II, or
22 A”;

23 (2) in section 1003 (21 U.S.C. 953)—

1 (A) in subsection (c), in the matter pre-
2 ceding paragraph (1), by striking “schedule I or
3 II” and inserting “schedule I, II, or A”; and

4 (B) in subsection (d), by striking “schedule
5 I or II” and inserting “schedule I, II, or A”;

6 (3) in section 1004(1) (21 U.S.C. 954(1)), by
7 striking “schedule I” and inserting “schedule I or
8 A”;

9 (4) in section 1005 (21 U.S.C. 955), by striking
10 “schedule I or II” and inserting “schedule I, II, or
11 A”; and

12 (5) in section 1009(a) (21 U.S.C. 959(a)), by
13 striking “schedule I or II” and inserting “schedule
14 I, II, or A”.

15 **SEC. 9008. CONTROLLED SUBSTANCE ANALOGUES.**

16 Section 102 of the Controlled Substances Act (21
17 U.S.C. 802) is amended—

18 (1) in paragraph (6), by striking “or V” and in-
19 serting “V, or A”;

20 (2) in paragraph (14)—

21 (A) by striking “schedule I(c) and” and in-
22 serting “schedule I(c), schedule A, and”; and

23 (B) by striking “schedule I(c),” and insert-
24 ing “schedule I(c) and schedule A,”; and

1 (3) in paragraph (32)(A), by striking “(32)(A)”
2 and all that follows through clause (iii) and inserting
3 the following:

4 “(32)(A) Except as provided in subparagraph (C),
5 the term ‘controlled substance analogue’ means a sub-
6 stance whose chemical structure is substantially similar to
7 the chemical structure of a controlled substance in sched-
8 ule I or II—

9 “(i) which has a stimulant, depressant, or hal-
10 lucinogenic effect on the central nervous system that
11 is substantially similar to or greater than the stimu-
12 lant, depressant, or hallucinogenic effect on the cen-
13 tral nervous system of a controlled substance in
14 schedule I or II; or

15 “(ii) with respect to a particular person, which
16 such person represents or intends to have a stimu-
17 lant, depressant, or hallucinogenic effect on the cen-
18 tral nervous system that is substantially similar to
19 or greater than the stimulant, depressant, or hallu-
20 cinogenic effect on the central nervous system of a
21 controlled substance in schedule I or II.”.

22 **SEC. 9009. RULES OF CONSTRUCTION.**

23 Nothing in this title, or the amendments made by this
24 title, may be construed to limit—

1 (1) the prosecution of offenses involving con-
2 trolled substance analogues under the Controlled
3 Substances Act (21 U.S.C. 801 et seq.); or

4 (2) the authority of the Attorney General to
5 temporarily or permanently schedule, reschedule, or
6 decontrol controlled substances under provisions of
7 section 201 of the Controlled Substances Act (21
8 U.S.C. 811) that are in effect on the day before the
9 date of enactment of this title.

10 **SEC. 9010. STUDY BY COMPTROLLER GENERAL.**

11 Not later than 2 years after the date of enactment
12 of this title, the Comptroller General of the United States
13 shall complete a study and submit a report to the Commit-
14 tees on the Judiciary of the House of Representatives and
15 of the Senate regarding the costs associated with the
16 amendments made by section 4, including—

17 (1) the annual amounts expended by Federal
18 agencies in carrying out the amendments;

19 (2) the costs associated with arrests, trials, con-
20 victions, imprisonment, or imposition of other sanc-
21 tions in accordance with the amendments; and

22 (3) the impact (including the fiscal impact) of
23 the amendments on existing correctional facilities
24 and the likelihood that those amendments will create
25 a need for additional capacity for housing prisoners.

1 **SEC. 9011. REPORT ON CONTROLLED SUBSTANCE ANA-**
2 **LOGUES SOLD BY MEANS OF THE INTERNET.**

3 Not later than 1 year after the date of the enactment
4 of this title, and annually thereafter, the Administrator
5 of the Drug Enforcement Administration shall make pub-
6 licly available on the website of the Drug Enforcement Ad-
7 ministration a report on, for the previous year, the lawful
8 and unlawful sale of controlled substance analogues (as
9 defined in section 102 of the Controlled Substances Act
10 (21 U.S.C. 802)) by means of the Internet, including the
11 following information:

12 (1) The types of controlled substance analogues
13 that were sold, and the number of sales for each
14 such substance.

15 (2) The name of each person, entity, or Inter-
16 net site, whether in the United States or abroad,
17 that knowingly or intentionally delivers, distributes,
18 or dispenses, or offers or attempts to deliver, dis-
19 tribute, or dispense, a controlled substance analogue
20 by means of the Internet, whether lawfully or unlaw-
21 fully.

22 (3) An estimate of the total revenue for all of
23 the vendors described in paragraph (2) for all of the
24 sales described in paragraph (1).

1 **SEC. 9012. CONTROLLED SUBSTANCE ANALOGUES.**

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

4 (1) by striking “A controlled” and inserting
5 “(a) IN GENERAL.—A controlled”; and

6 (2) by adding at the end the following:

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

11 “(1) The marketing, advertising, and labeling
12 of the substance.

13 “(2) The known efficacy or usefulness of the
14 substance for the marketed, advertised or labeled
15 purpose.

16 “(3) The difference between the price at which
17 the substance is sold and the price at which the sub-
18 stance it is purported to be or advertised as is nor-
19 mally sold.

20 “(4) The diversion of the substance from legiti-
21 mate channels and the clandestine importation, man-
22 ufacture, or distribution of the substance.

23 “(5) Whether the defendant knew or should
24 have known the substance was intended to be con-
25 sumed by injection, inhalation, ingestion, or any
26 other immediate means.

1 RECOVERING FROM OPIOID USE DISORDERS OR
2 OTHER SUBSTANCE USE DISORDERS.—

3 “(A) ESTABLISHMENT.—The Secretary
4 shall establish a demonstration program under
5 which the Secretary shall set aside, allocate,
6 and distribute directly to eligible entities, from
7 amounts made available for rental assistance
8 under this subsection, the amounts specified in
9 subparagraph (B) for an eligible entity to pro-
10 vide a voucher for such assistance to a covered
11 individual through a supportive housing pro-
12 gram that provides treatment for opioid use dis-
13 orders or other substance use disorders (as ap-
14 plicable), coordination with workforce develop-
15 ment providers, and such assistance, as deter-
16 mined by the entity.

17 “(B) AMOUNT.—The amount specified in
18 this subparagraph is, for fiscal year 2019, the
19 amount necessary to provide the lesser of—

20 “(i) 0.5 percent of the total number of
21 vouchers renewed under this subsection
22 during the fiscal year ending immediately
23 before the date of the enactment of this
24 paragraph; or

25 “(ii) 10,000 vouchers.

1 “(C) CRITERIA FOR ELIGIBLE ENTITIES.—

2 An eligible entity shall—

3 “(i) provide an evidence-based treat-
4 ment program and demonstrate the ability
5 to coordinate with workforce development
6 providers for individuals recovering from
7 an opioid use disorder or other substance
8 use disorder, as applicable, that meet
9 standards established by the Secretary;
10 and

11 “(ii) demonstrate prior experience ad-
12 ministering rental assistance vouchers,
13 demonstrate prior experience administering
14 supportive housing programs under the
15 McKinney-Vento Homeless Act, or dem-
16 onstrate a partnership with a public hous-
17 ing agency or a housing program of a
18 State, unit of local government, or Indian
19 tribe (as such term is defined in section 4
20 of the Native American Housing and Self-
21 Determination Act of 1996 (25 U.S.C.
22 4103)) that ensures effective administra-
23 tion of rental assistance vouchers.

24 “(D) APPLICATION.—To receive a rental
25 assistance voucher under this paragraph, an eli-

1 eligible entity shall submit an application to the
2 Secretary that shall include—

3 “(i) a description of the terms of
4 treatment program, coordination with
5 workforce development providers, and rent-
6 al assistance to be provided to a covered
7 individual, and assurances that such de-
8 scription shall be communicated to covered
9 individuals that receive vouchers pursuant
10 to the demonstration program established
11 under this paragraph;

12 “(ii) a transitional plan that begins on
13 the date on which a covered individual
14 completes the treatment program of the el-
15 igible entity that includes information on
16 additional treatment, coordination with
17 workforce development opportunities, and
18 housing resources and services available to
19 such covered individual; and

20 “(iii) evidence sufficient to dem-
21 onstrate that the local government having
22 jurisdiction over the location of any sup-
23 portive housing facility to be used by the
24 eligible entity in connection with the dem-

1 onstration program under this paragraph
2 permits such facilities in such location.

3 “(E) SELECTION.—In selecting eligible en-
4 tities to receive rental assistance vouchers
5 under this paragraph, the Secretary shall—

6 “(i) ensure that such eligible enti-
7 ties—

8 “(I) are diverse;

9 “(II) represent an appropriate
10 balance of eligible entities located in
11 urban and rural areas, including trib-
12 al communities;

13 “(III) have adequate resources
14 for treatment, recovery, and sup-
15 portive services;

16 “(IV) fully comply with the Fair
17 Housing Act (42 U.S.C. 3601 et seq.)
18 and the Civil Rights Act of 1964 (42
19 U.S.C. 2000a et seq.);

20 “(V) appropriately reflect the im-
21 pact that opioids are having in tribal
22 communities; and

23 “(VI) provide supportive and
24 transitional housing programs in di-
25 verse geographic regions with high

1 rates of mortality due to opioid use
2 disorders or other substance use dis-
3 orders, as applicable, based on data of
4 the Centers for Disease Control and
5 Prevention; and

6 “(ii) consider, in consultation with the
7 Secretary of Health and Human Services
8 and the Secretary of Labor—

9 “(I) the success of each recipient
10 eligible entity at helping individuals
11 complete the treatment program of
12 the eligible entity and refrain from il-
13 licit opioid or other substance usage,
14 as applicable;

15 “(II) the coordination with work-
16 force development providers by the eli-
17 gible entity;

18 “(III) the percentage of partici-
19 pants in unsubsidized employment
20 during the second and fourth calendar
21 quarter after exit from the program;
22 and

23 “(IV) the percentage of partici-
24 pants in the treatment program of the
25 eligible entity that do not relapse into

1 opioid or other substance usage, as
2 applicable.

3 “(F) REISSUANCE OF VOUCHER.—Upon
4 termination of the provision of rental assistance
5 through a voucher to a covered individual, the
6 eligible entity that initially offered such voucher
7 may use such voucher to provide rental assist-
8 ance to another covered individual.

9 “(G) DURATION.—The Secretary shall not
10 make rental assistance available under this
11 paragraph after the expiration of the 5-year pe-
12 riod beginning on the date of the enactment of
13 this paragraph.

14 “(H) WAIVERS.—The Secretary may,
15 through publication of a notice in the Federal
16 Register, waive or specify alternative require-
17 ments for any provision of statute or regulation
18 governing the use of vouchers under this sub-
19 section (except for requirements relating to fair
20 housing, nondiscrimination, labor standards, or
21 the environment) upon a finding by the Sec-
22 retary that such waiver or alternative require-
23 ment is necessary for the purposes of this para-
24 graph.

25 “(I) REPORTS.—

1 “(i) BY THE ELIGIBLE ENTITY.—An
2 eligible entity that receives a rental assist-
3 ance voucher under this paragraph shall
4 submit to the Secretary—

5 “(I) annually, the transitional
6 plan described in subparagraph
7 (D)(ii) and information on each cov-
8 ered individual’s housing upon termi-
9 nation of the provision of rental as-
10 sistance through a voucher to such
11 covered individual in a manner that
12 protects the privacy of such covered
13 individual; and

14 “(II) not later than 4 years after
15 the date of the enactment of this
16 paragraph, a plan describing the
17 treatment and housing options for any
18 covered individual assisted by such
19 voucher who will not have completed
20 the program before the day that is 5
21 years after such date of enactment.

22 “(ii) BY THE SECRETARY.—The Sec-
23 retary shall submit to Congress a report
24 that analyzes the impact of rental assist-
25 ance provided under this paragraph—

1 “(I) not later than 2 years after
2 the date of the enactment of this
3 paragraph; and

4 “(II) not later than 4 years after
5 the date of the enactment of this
6 paragraph.

7 “(J) DEFINITIONS.—In this paragraph:

8 “(i) ELIGIBLE ENTITY.—The term ‘el-
9 igible entity’ means a tribally designated
10 housing entity (as such term is defined in
11 section 4 of the Native American Housing
12 and Self-Determination Act of 1996 (24
13 U.S.C. 4103)), or a nonprofit organization,
14 that meets the criteria described under
15 subparagraph (C).

16 “(ii) COVERED INDIVIDUAL.—The
17 term ‘covered individual’ means an indi-
18 vidual recovering from an opioid use dis-
19 order or other substance use disorder.”.

20 **SEC. 10003. REPEAL OF RENTAL VOUCHER DEMONSTRATION PROGRAM.**
21

22 Effective the day that is 5 years after the date of
23 the enactment of this title, paragraph (21) of section 8(o)
24 of the United States Housing Act of 1937 (42 U.S.C.
25 1437f(o)), as added by this title, is repealed.

1 **SEC. 10004. DEMONSTRATION CLOSE-OUT.**

2 An eligible entity that provided vouchers for rental
3 assistance under paragraph (21) of section 8(o) of the
4 United States Housing Act of 1937 (42 U.S.C. 1437f(o)),
5 as added by this title, shall return any such vouchers to
6 the Secretary of Housing and Urban Development not
7 later than the day that is 5 years after the date of the
8 enactment of this title for use only for renewals of expiring
9 contracts for such assistance.

10 **SEC. 10005. NO ADDITIONAL FUNDS AUTHORIZED.**

11 No additional funds are authorized to be appro-
12 priated to carry out the requirements of this title and the
13 amendments made by this title. Such requirements shall
14 be carried out using amounts otherwise authorized to be
15 appropriated.

16 **TITLE XI—IMD CARE ACT**

17 **SEC. 11001. SHORT TITLE.**

18 This title may be cited as the “Individuals in Med-
19 icaid Deserve Care that is Appropriate and Responsible
20 in its Execution Act” or the “IMD CARE Act”.

1 **SEC. 11002. MEDICAID STATE PLAN OPTION TO PROVIDE**
2 **SERVICES FOR CERTAIN INDIVIDUALS WITH**
3 **TARGETED SUDS IN INSTITUTIONS FOR MEN-**
4 **TAL DISEASES.**

5 Section 1915 of the Social Security Act (42 U.S.C.
6 1396n) is amended by adding at the end the following new
7 subsection:

8 “(1) STATE PLAN OPTION TO PROVIDE SERVICES
9 FOR CERTAIN INDIVIDUALS IN INSTITUTIONS FOR MEN-
10 TAL DISEASES.—

11 “(1) IN GENERAL.—With respect to calendar
12 quarters beginning during the period beginning Jan-
13 uary 1, 2019, and ending December 31, 2023, a
14 State may elect, through a State plan amendment,
15 to, notwithstanding section 1905(a), provide medical
16 assistance for services furnished in institutions for
17 mental diseases and for other medically necessary
18 services furnished to eligible individuals with tar-
19 geted SUDs, in accordance with the requirements of
20 this subsection.

21 “(2) PAYMENTS.—

22 “(A) IN GENERAL.—Amounts expended
23 under a State plan amendment under para-
24 graph (1) for services described in such para-
25 graph furnished, with respect to a 12-month pe-
26 riod, to an eligible individual with a targeted

1 SUD who is a patient in an institution for men-
2 tal diseases shall be treated as medical assist-
3 ance for which payment is made under section
4 1903(a) but only to the extent that such serv-
5 ices are furnished for not more than a period
6 of 30 days (whether or not consecutive) during
7 such 12-month period.

8 “(B) CLARIFICATION.—Payment made
9 under this paragraph for expenditures under a
10 State plan amendment under this subsection
11 with respect to services described in paragraph
12 (1) furnished to an eligible individual with a
13 targeted SUD shall not affect payment that
14 would otherwise be made under section 1903(a)
15 for expenditures under the State plan (or waiv-
16 er of such plan) for medical assistance for such
17 individual.

18 “(3) INFORMATION REQUIRED IN STATE PLAN
19 AMENDMENT.—

20 “(A) IN GENERAL.—A State electing to
21 provide medical assistance pursuant to this sub-
22 section shall include with the submission of the
23 State plan amendment under paragraph (1) to
24 the Secretary—

1 “(i) a plan on how the State will im-
2 prove access to outpatient care during the
3 period of the State plan amendment, in-
4 cluding a description of—

5 “(I) the process by which eligible
6 individuals with targeted SUDs will
7 make the transition from receiving in-
8 patient services in an institution for
9 mental diseases to appropriate out-
10 patient care; and

11 “(II) the process the State will
12 undertake to ensure eligible individ-
13 uals with targeted SUDs are provided
14 care in the most integrated setting ap-
15 propriate to the needs of the individ-
16 uals; and

17 “(ii) a description of how the State
18 plan amendment ensures an appropriate
19 clinical screening of eligible individuals
20 with targeted SUDs, including assessments
21 to determine level of care and length of
22 stay recommendations based upon the
23 multidimensional assessment criteria of the
24 American Society of Addiction Medicine

1 and to determine the appropriate setting
2 for such care.

3 “(B) REPORT.—Not later than the sooner
4 of December 31, 2024, or 1 year after the date
5 of the termination of a State plan amendment
6 under this subsection, the State shall submit to
7 the Secretary a report that includes at least—

8 “(i) the number of eligible individuals
9 with targeted SUDs who received services
10 pursuant to such State plan amendment;

11 “(ii) the length of the stay of each
12 such individual in an institution for mental
13 diseases;

14 “(iii) the type of outpatient treatment,
15 including medication-assisted treatment,
16 each such individual received after being
17 discharged from such institution;

18 “(iv) the number of eligible individ-
19 uals with any co-occurring disorders who re-
20 ceived services pursuant to such State plan
21 amendment and the co-occurring disorders
22 from which they suffer; and

23 “(v) information regarding the effects
24 of a State plan amendment on access to
25 community care for individuals suffering

1 from a mental disease other than sub-
2 stance use disorder.

3 “(4) DEFINITIONS.—In this subsection:

4 “(A) ELIGIBLE INDIVIDUAL WITH A TAR-
5 GETED SUD.—The term ‘eligible individual with
6 a targeted SUD’ means an individual who—

7 “(i) with respect to a State, is en-
8 rolled for medical assistance under the
9 State plan (or a waiver of such plan);

10 “(ii) is at least 21 years of age;

11 “(iii) has not attained 65 years of
12 age; and

13 “(iv) has been diagnosed with at least
14 one targeted SUD.

15 “(B) INSTITUTION FOR MENTAL DIS-
16 EASES.—The term ‘institution for mental dis-
17 eases’ has the meaning given such term in sec-
18 tion 1905(i).

19 “(C) OPIOID PRESCRIPTION PAIN RE-
20 LIEVER.—The term ‘opioid prescription pain re-
21 liever’ includes hydrocodone products,
22 oxycodone products, tramadol products, codeine
23 products, morphine products, fentanyl products,
24 buprenorphine products, oxymorphone products,
25 meperidine products, hydromorphone products,

1 methadone, and any other prescription pain re-
2 liever identified by the Assistant Secretary for
3 Mental Health and Substance Use.

4 “(D) OTHER MEDICALLY NECESSARY
5 SERVICES.—The term ‘other medically nec-
6 essary services’ means, with respect to an eligi-
7 ble individual with a targeted SUD who is a pa-
8 tient in an institution for mental diseases, items
9 and services that are provided to such indi-
10 vidual outside of such institution to the extent
11 that such items and services would be treated
12 as medical assistance for such individual if such
13 individual were not a patient in such institu-
14 tion.

15 “(E) TARGETED SUD.—

16 “(i) IN GENERAL.—The term ‘tar-
17 geted SUD’ means an opioid use disorder
18 or a cocaine use disorder.

19 “(ii) COCAINE USE DISORDER.—The
20 term ‘cocaine use disorder’ means a dis-
21 order that meets the criteria of the Diag-
22 nostic and Statistical Manual of Mental
23 Disorders, 4th Edition (or a successor edi-
24 tion), for either dependence or abuse for

1 cocaine, including cocaine base (commonly
2 referred to as ‘crack cocaine’).

3 “(iii) OPIOID USE DISORDER.—The
4 term ‘opioid use disorder’ means a disorder
5 that meets the criteria of the Diagnostic
6 and Statistical Manual of Mental Dis-
7 orders, 4th Edition (or a successor edi-
8 tion), for heroin use disorder or pain re-
9 liever use disorder (including with respect
10 to opioid prescription pain relievers).”.

11 **SEC. 11003. PROMOTING VALUE IN MEDICAID MANAGED**
12 **CARE.**

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

16 “(7)(A) With respect to expenditures described in
17 subparagraph (B) that are incurred by a State for any
18 fiscal year after fiscal year 2020 (and before fiscal year
19 2024), in determining the pro rata share to which the
20 United States is equitably entitled under subsection
21 (d)(3), the Secretary shall substitute the Federal medical
22 assistance percentage that applies for such fiscal year to
23 the State under section 1905(b) (without regard to any
24 adjustments to such percentage applicable under such sec-

1 tion or any other provision of law) for the percentage that
2 applies to such expenditures under section 1905(y).

3 “(B) Expenditures described in this subparagraph,
4 with respect to a fiscal year to which subparagraph (A)
5 applies, are expenditures incurred by a State for payment
6 for medical assistance provided to individuals described in
7 subclause (VIII) of section 1902(a)(10)(A)(i) by a man-
8 aged care entity, or other specified entity (as defined in
9 subparagraph (D)(iii)), that are treated as remittances be-
10 cause the State—

11 “(i) has satisfied the requirement of section
12 438.8 of title 42, Code of Federal Regulations (or
13 any successor regulation), by electing—

14 “(I) in the case of a State described in
15 subparagraph (C), to apply a minimum medical
16 loss ratio (as defined in subparagraph (D)(ii))
17 that is at least 85 percent but not greater than
18 the minimum medical loss ratio (as so defined)
19 that such State applied as of May 31, 2018; or

20 “(II) in the case of a State not described
21 in subparagraph (C), to apply a minimum med-
22 ical loss ratio that is equal to 85 percent; and

23 “(ii) recovered all or a portion of the expendi-
24 tures as a result of the entity’s failure to meet such
25 ratio.

1 “(C) For purposes of subparagraph (B), a State de-
2 scribed in this subparagraph is a State that as of May
3 31, 2018, applied a minimum medical loss ratio (as cal-
4 culated under subsection (d) of section 438.8 of title 42,
5 Code of Federal Regulations (as in effect on June 1,
6 2018)) for payment for services provided by entities de-
7 scribed in such subparagraph under the State plan under
8 this title (or a waiver of the plan) that is equal to or great-
9 er than 85 percent.

10 “(D) For purposes of this paragraph:

11 “(i) The term ‘managed care entity’ means a
12 medicaid managed care organization described in
13 section 1932(a)(1)(B)(i).

14 “(ii) The term ‘minimum medical loss ratio’
15 means, with respect to a State, a minimum medical
16 loss ratio (as calculated under subsection (d) of sec-
17 tion 438.8 of title 42, Code of Federal Regulations
18 (as in effect on June 1, 2018)) for payment for serv-
19 ices provided by entities described in subparagraph
20 (B) under the State plan under this title (or a waiv-
21 er of the plan).

22 “(iii) The term ‘other specified entity’ means—

23 “(I) a prepaid inpatient health plan, as de-
24 fined in section 438.2 of title 42, Code of Fed-

Calendar No. 485

115TH CONGRESS
2^D SESSION

H. R. 6

AN ACT

To provide for opioid use disorder prevention, recovery, and treatment, and for other purposes.

JUNE 26, 2018

Read the second time and placed on the calendar