

JUNE 18, 2018

RULES COMMITTEE PRINT 115–78
TEXT OF AMENDMENT TO H.R. 6

Add at the end the following:

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.—

1 Beginning with the State report required under
2 subsection (d)(1) for 2024, the Secretary shall
3 require States to use all behavioral health meas-
4 ures included in the core set of adult health
5 quality measures and any updates or changes to
6 such measures to report information, using the
7 standardized format for reporting information
8 and procedures developed under subparagraph
9 (A), regarding the quality of behavioral health
10 care for Medicaid eligible adults.”; and

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

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

20 (2) in subsection (d)(1)(A)—

21 (A) by striking “the such plan” and insert-
22 ing “such plan”; and

23 (B) by striking “subsection (a)(5)” and in-
24 serting “subsection (b)(5) and, beginning with
25 the report for 2024, all behavioral health meas-

1 ures included in the core set of adult health
2 quality measures maintained under such sub-
3 section (b)(5) and any updates or changes to
4 such measures (as required under subsection
5 (b)(3))”.

6 **Subtitle B—Medicaid IMD** 7 **Additional Info**

8 **SEC. 5011. SHORT TITLE.**

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

15 **SEC. 5012. MACPAC EXPLORATORY STUDY AND REPORT ON** 16 **INSTITUTIONS FOR MENTAL DISEASES RE-** 17 **QUIREMENTS AND PRACTICES UNDER MED-** 18 **ICAID.**

19 (a) IN GENERAL.—Not later than January 1, 2020,
20 the Medicaid and CHIP Payment and Access Commission
21 established under section 1900 of the Social Security Act
22 (42 U.S.C. 1396) shall conduct an exploratory study,
23 using data from a representative sample of States, and
24 submit to Congress a report on at least the following infor-
25 mation, with respect to services furnished to individuals

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

7 (1) A description of such institutions for mental
8 diseases in each such State, including at a min-
9 imum—

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

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

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

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

20 (A) such services provided at such institu-
21 tion;

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

1 (C) the discharge process used by such in-
2 stitution, including any care continuum of rel-
3 evant services or facilities provided or used in
4 such process.

5 (3) A description of—

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

9 (B) any other Medicaid funding sources
10 used by each such State for funding such insti-
11 tutions, such as supplemental payments.

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

18 (5) A summary of State standards (such as
19 quality standards, clinical standards, and facility
20 standards) that such institutions must meet to re-
21 ceive payment under such State plans (or waivers)
22 and how each such State determines if such stand-
23 ards have been met.

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

1 such as how State Medicaid programs may improve
2 care and improve standards and including a rec-
3 ommendation for how the Centers for Medicare &
4 Medicaid Services can improve data collection from
5 such programs to address any gaps in information.

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

15 (c) **DEFINITIONS.**—In this section:

16 (1) **REPRESENTATIVE SAMPLE OF STATES.**—
17 The term “representative sample of States” means
18 a non-probability sample in which at least two
19 States are selected based on the knowledge and pro-
20 fessional judgment of the selector.

21 (2) **STATE.**—The term “State” means each of
22 the 50 States, the District of Columbia, and any
23 commonwealth or territory of the United States.

24 (3) **INSTITUTION FOR MENTAL DISEASES.**—The
25 term “institution for mental diseases” has the mean-

1 ing given such term in section 435.1009 of title 42,
2 Code of Federal Regulations, or any successor regu-
3 lation.

4 **Subtitle C—CHIP Mental Health** 5 **Parity**

6 **SEC. 5021. SHORT TITLE.**

7 This subtitle may be cited as the “CHIP Mental
8 Health Parity Act”.

9 **SEC. 5022. ENSURING ACCESS TO MENTAL HEALTH AND** 10 **SUBSTANCE USE DISORDER SERVICES FOR** 11 **CHILDREN AND PREGNANT WOMEN UNDER** 12 **THE CHILDREN’S HEALTH INSURANCE PRO-** 13 **GRAM.**

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

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

19 (b) **MENTAL HEALTH AND SUBSTANCE USE DIS-**
20 **ORDER SERVICES.**—

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

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

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

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

16 “(A) include coverage of mental health
17 services (including behavioral health treatment)
18 necessary to prevent, diagnose, and treat a
19 broad range of mental health symptoms and
20 disorders, including substance use disorders;
21 and

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

24 (2) CONFORMING AMENDMENTS.—

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

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

8 (i) in paragraph (18), by striking
9 “substance abuse” each place it appears
10 and inserting “substance use”; and

11 (ii) in paragraph (19), by striking
12 “substance abuse” and inserting “sub-
13 stance use”.

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

18 (c) ASSURING ACCESS TO CARE.—Section
19 2102(a)(7)(B) of the Social Security Act (42 U.S.C.
20 1397bb(c)(2)) is amended by striking “section
21 2103(c)(5)” and inserting “paragraphs (5) and (6) of sec-
22 tion 2103(c)”.

23 (d) MENTAL HEALTH SERVICES PARITY.—Subpara-
24 graph (A) of paragraph (7) of section 2103(c) of the So-

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

3 “(A) IN GENERAL.—A State child health
4 plan shall ensure that the financial require-
5 ments and treatment limitations applicable to
6 mental health and substance use disorder serv-
7 ices (as described in paragraph (5)) provided
8 under such plan comply with the requirements
9 of section 2726(a) of the Public Health Service
10 Act in the same manner as such requirements
11 or limitations apply to a group health plan
12 under such section.”.

13 (e) EFFECTIVE DATE.—

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

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

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

12 **Subtitle D—Medicaid Reentry**

13 **SEC. 5031. SHORT TITLE.**

14 This subtitle may be cited as the “Medicaid Reentry
15 Act”.

16 **SEC. 5032. PROMOTING STATE INNOVATIONS TO EASE** 17 **TRANSITIONS INTEGRATION TO THE COMMU-** 18 **NITY FOR CERTAIN INDIVIDUALS.**

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

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

22 Not later than 6 months after the date of the enact-
23 ment of this Act, the Secretary of Health and
24 Human Services shall convene a stakeholder group
25 of representatives of managed care organizations,

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

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

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

19 (2) STATE MEDICAID PROGRAM INNOVATION.—
20 The Secretary of Health and Human Services shall
21 work with States on innovative strategies to help in-
22 dividuals who are inmates of public institutions and
23 otherwise eligible for medical assistance under the
24 Medicaid program under title XIX of the Social Se-
25 curity Act transition, with respect to enrollment for

1 medical assistance under such program, seamlessly
2 to the community.

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

19 (1) providing assistance and education for en-
20 rollment under a State plan under the Medicaid pro-
21 gram under title XIX of such Act for such individ-
22 uals during such period; and

23 (2) providing health care services for such indi-
24 viduals during such period.

1 (c) RULE OF CONSTRUCTION.—Nothing under title
2 XIX of the Social Security Act or any other provision of
3 law precludes a State from reclassifying or suspending
4 (rather than terminating) eligibility of an individual for
5 medical assistance under title XIX of the Social Security
6 Act while such individual is an inmate of a public institu-
7 tion.

8 **Subtitle E—Medicaid Partnership**

9 **SEC. 5041. SHORT TITLE.**

10 This subtitle may be cited as the “Medicaid Providers
11 Are Required To Note Experiences in Record Systems to
12 Help In-need Patients Act” or the “Medicaid PARTNER-
13 SHIP Act”.

14 **SEC. 5042. MEDICAID PROVIDERS ARE REQUIRED TO NOTE** 15 **EXPERIENCES IN RECORD SYSTEMS TO HELP** 16 **IN-NEED PATIENTS.**

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

1 **“SEC. 1944. REQUIREMENTS RELATING TO QUALIFIED PRE-**
2 **SCRIPTION DRUG MONITORING PROGRAMS**
3 **AND PRESCRIBING CERTAIN CONTROLLED**
4 **SUBSTANCES.**

5 “(a) IN GENERAL.—Beginning October 1, 2021, a
6 State shall, subject to subsection (d), require each covered
7 provider to check, in accordance with such timing, man-
8 ner, and form as specified by the State, the prescription
9 drug history of a covered individual being treated by the
10 covered provider through a qualified prescription drug
11 monitoring program described in subsection (b) before
12 prescribing to such individual a controlled substance.

13 “(b) QUALIFIED PRESCRIPTION DRUG MONITORING
14 PROGRAM DESCRIBED.—A qualified prescription drug
15 monitoring program described in this subsection is, with
16 respect to a State, a prescription drug monitoring pro-
17 gram administered by the State that, at a minimum, satis-
18 fies each of the following criteria:

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

23 “(A) Information regarding the prescrip-
24 tion drug history of a covered individual with
25 respect to controlled substances.

1 “(B) The number and type of controlled
2 substances prescribed to and filled for the cov-
3 ered individual during at least the most recent
4 12-month period.

5 “(C) The name, location, and contact in-
6 formation (or other identifying number selected
7 by the State, such as a national provider identi-
8 fier issued by the National Plan and Provider
9 Enumeration System of the Centers for Medi-
10 care & Medicaid Services) of each covered pro-
11 vider who prescribed a controlled substance to
12 the covered individual during at least the most
13 recent 12-month period.

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

19 A qualified prescription drug monitoring program de-
20 scribed in this subsection, with respect to a State, may
21 have in place, in accordance with applicable State and
22 Federal law, a data sharing agreement with the State
23 Medicaid program that allows the medical director and
24 pharmacy director of such program (and any designee of
25 such a director who reports directly to such director) to

1 access the information described in paragraph (1) in an
2 electronic format. The State Medicaid program under this
3 title may facilitate reasonable and limited access, as deter-
4 mined by the State and ensuring documented beneficiary
5 protections regarding the use of such data, to such quali-
6 fied prescription drug monitoring program for the medical
7 director or pharmacy director of any managed care entity
8 (as defined under section 1932(a)(1)(B)) that has a con-
9 tract with the State under section 1903(m) or under sec-
10 tion 1905(t)(3), or the medical director or pharmacy direc-
11 tor of any entity has a contract to manage the pharma-
12 ceutical benefit with respect to individuals enrolled in the
13 State plan (or waiver of the State plan). All applicable
14 State and Federal security and privacy laws shall apply
15 to the directors or designees of such directors of any State
16 Medicaid program or entity accessing a qualified prescrip-
17 tion drug monitoring program under this section.

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

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

3 “(d) ENSURING ACCESS.—In order to ensure reason-
4 able access to health care, the Secretary shall waive the
5 application of the requirement under subsection (a), with
6 respect to a State, in the case of natural disasters and
7 similar situations, and in the case of the provision of emer-
8 gency services (as defined for purposes of section 1860D–
9 4(c)(5)(D)(ii)(II)).

10 “(e) REPORTS.—

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

17 “(A) The percentage of covered providers
18 (as determined pursuant to a process estab-
19 lished by the State) who checked the prescrip-
20 tion drug history of a covered individual
21 through a qualified prescription drug moni-
22 toring program described in subsection (b) be-
23 fore prescribing to such individual a controlled
24 substance.

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

3 “(i) the quantity of daily morphine
4 milligram equivalents prescribed for con-
5 trolled substances;

6 “(ii) the number and quantity of daily
7 morphine milligram equivalents prescribed
8 for controlled substances per covered indi-
9 vidual; and

10 “(iii) the types of controlled sub-
11 stances prescribed, including the dates of
12 such prescriptions, the supplies authorized
13 (including the duration of such supplies),
14 and the period of validity of such prescrip-
15 tions, in different populations (such as in-
16 dividuals who are elderly, individuals with
17 disabilities, and individuals who are en-
18 rolled under both this title and title
19 XVIII).

20 “(C) Whether or not the State requires
21 (and a detailed explanation as to why the State
22 does or does not require) pharmacists to check
23 the prescription drug history of a covered indi-
24 vidual through a qualified drug management

1 program before dispensing a controlled sub-
2 stance to such individual.

3 “(2) REPORT BY CMS.—Not later than October
4 1, 2023, the Administrator of the Centers for Medi-
5 care & Medicaid Services shall publish on the pub-
6 licly available website of the Centers for Medicare &
7 Medicaid Services a report including the following
8 information:

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

13 “(B) Best practices for how States and
14 covered providers should use such qualified pre-
15 scription drug monitoring programs to reduce
16 the occurrence of abuse of controlled sub-
17 stances.

18 “(f) INCREASE TO FEDERAL MATCHING RATE FOR
19 CERTAIN EXPENDITURES RELATING TO QUALIFIED PRE-
20 SCRIPTON DRUG MANAGEMENT PROGRAMS.—The Sec-
21 retary shall increase the Federal medical assistance per-
22 centage or Federal matching rate that would otherwise
23 apply to a State under section 1903(a) for a calendar
24 quarter occurring during the period beginning October 1,
25 2018, and ending September 30, 2021, for expenditures

1 by the State for activities under the State plan (or waiver
2 of the State plan) to implement a prescription drug man-
3 agement program that satisfies the criteria described in
4 paragraphs (1) and (2) of subsection (b) if the State (in
5 this subsection referred to as the ‘administering State’)
6 has in place agreements with all States that are contig-
7 uous to such administering State that, when combined, en-
8 able covered providers in all such contiguous States to ac-
9 cess, through the prescription drug management program,
10 the information that is described in subsection (b)(1) of
11 covered individuals of such administering State and that
12 covered providers in such administering State are able to
13 access through such program. In no case shall an increase
14 under this subsection result in a Federal medical assist-
15 ance percentage or Federal matching rate that exceeds
16 100 percent.

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

22 “(h) DEFINITIONS.—In this section:

23 “(1) CONTROLLED SUBSTANCE.—The term
24 ‘controlled substance’ means a drug that is included
25 in schedule II of section 202(c) of the Controlled

1 Substances Act and, at the option of the State in-
2 volved, a drug included in schedule III or IV of such
3 section.

4 “(2) COVERED INDIVIDUAL.—The term ‘cov-
5 ered individual’ means, with respect to a State, an
6 individual who is enrolled in the State plan (or
7 under a waiver of such plan). Such term does not in-
8 clude an individual who—

9 “(A) is receiving—

10 “(i) hospice or palliative care; or

11 “(ii) treatment for cancer;

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

17 “(C) the State elects to treat as exempted
18 from such term.

19 “(3) COVERED PROVIDER.—

20 “(A) IN GENERAL.—The term ‘covered
21 provider’ means, subject to subparagraph (B),
22 with respect to a State, a health care provider
23 who is participating under the State plan (or
24 waiver of the State plan) and licensed, reg-
25 istered, or otherwise permitted by the State to

1 prescribe a controlled substance (or the des-
2 ignee of such provider).

3 “(B) EXCEPTIONS.—

4 “(i) IN GENERAL.—Beginning Octo-
5 ber 1, 2021, for purposes of this section,
6 such term does not include a health care
7 provider included in any type of health
8 care provider determined by the Secretary
9 to be exempt from application of this sec-
10 tion under clause (ii).

11 “(ii) EXCEPTIONS PROCESS.—Not
12 later than October 1, 2020, the Secretary,
13 after consultation with the National Asso-
14 ciation of Medicaid Directors, national
15 health care provider associations, Medicaid
16 beneficiary advocates, and advocates for in-
17 dividuals with rare diseases, shall deter-
18 mine, based on such consultations, the
19 types of health care providers (if any) that
20 should be exempted from the definition of
21 the term ‘covered provider’ for purposes of
22 this section.”.

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

1 for Disease Control and Prevention, shall issue guidance
2 on best practices on the uses of prescription drug moni-
3 toring programs required of prescribers and on protecting
4 the privacy of Medicaid beneficiary information main-
5 tained in and accessed through prescription drug moni-
6 toring programs.

7 (c) DEVELOPMENT OF MODEL STATE PRACTICES.—

8 (1) IN GENERAL.—Not later than October 1,
9 2020, the Secretary of Health and Human Services
10 shall develop and publish model practices to assist
11 State Medicaid program operations in identifying
12 and implementing strategies to utilize data sharing
13 agreements described in the matter following para-
14 graph (2) of section 1944(b) of the Social Security
15 Act, as added by subsection (a), for the following
16 purposes:

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

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

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

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

4 (iii) pay for prescription drugs with
5 cash.

6 (C) Any other purposes specified by the
7 Secretary.

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

10 (A) shall include strategies for assisting
11 States in allowing the medical director or phar-
12 macy director (or designees of such a director)
13 of managed care organizations or pharma-
14 ceutical benefit managers to access information
15 with respect to all covered individuals served by
16 such managed care organizations or pharma-
17 ceutical benefit managers to access as a single
18 data set, in an electronic format; and

19 (B) shall include any appropriate bene-
20 ficiary protections and privacy guidelines.

21 (3) CONSULTATION.—In developing model prac-
22 tices under this subsection, the Secretary shall con-
23 sult with the National Association of Medicaid Di-
24 rectors, managed care entities (as defined in section
25 1932(a)(1)(B) of the Social Security Act) with con-

1 tracts with States pursuant to section 1903(m) of
2 such Act, pharmaceutical benefit managers, physi-
3 cians and other health care providers, beneficiary
4 advocates, and individuals with expertise in health
5 care technology related to prescription drug moni-
6 toring programs and electronic health records.

7 (d) REPORT BY COMPTROLLER GENERAL.—Not later
8 than October 1, 2020, the Comptroller General of the
9 United States shall issue a report examining the operation
10 of prescription drug monitoring programs administered by
11 States, including data security and access standards used
12 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 one 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 cessing 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 sepa-
2 rate payment for such therapies, if medically appro-
3 priate 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 Medi-
7 care and Medicaid Innovation and other federally
8 authorized demonstration projects, including value-
9 based models, that may encourage the use of appro-
10 priate 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 pay-
18 ment 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 under-
23 served communities to the full range of medication-
24 assisted 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)), the Secretary shall provide for
19 the transfer from the Federal Supplementary Med-
20 ical Insurance Trust Fund under section 1841 of
21 \$5,000,000 to the Centers for Medicare & Medicaid
22 Services Program Management Account.

23 “(2) CARE MANAGEMENT FEES AND INCEN-
24 TIVES.—For the purposes of making payments
25 under subsection (e), the Secretary shall provide for

1 the transfer from the Federal Supplementary Med-
2 ical Insurance Trust Fund under section 1841 of
3 \$10,000,000 for each of fiscal years 2021 through
4 2024.

5 “(3) AVAILABILITY.—Amounts transferred
6 under this subsection for a fiscal year shall be avail-
7 able until expended.

8 “(i) WAIVERS.—The Secretary may waive any provi-
9 sion of this title as may be necessary to carry out the Pro-
10 gram under this section.”.

11 **Subtitle F—Responsible Education**
12 **Achieves Care and Healthy Out-**
13 **comes for Users’ Treatment**

14 **SEC. 6051. SHORT TITLE.**

15 This subtitle may be cited as the “Responsible Edu-
16 cation Achieves Care and Healthy Outcomes for Users’
17 Treatment Act of 2018” or the “REACH OUT Act of
18 2018”.

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

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

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

3 (b) USE OF FUNDS.—Grants, contracts, and coopera-
4 tive agreements awarded under subsection (a) shall be
5 used to support eligible entities through technical assist-
6 ance—

7 (1) to educate and provide outreach to outlier
8 prescribers of opioids about best practices for pre-
9 scribing opioids;

10 (2) to educate and provide outreach to outlier
11 prescribers of opioids about non-opioid pain manage-
12 ment therapies; and

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

15 (c) APPLICATION.—Each eligible entity seeking to re-
16 ceive a grant, contract, or cooperative agreement under
17 subsection (a) shall submit to the Secretary an applica-
18 tion, at such time, in such manner, and containing such
19 information as the Secretary may require.

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

24 (e) DEFINITIONS.—In this section:

1 (1) ELIGIBLE ENTITY.—The term “eligible enti-
2 ty” means—

3 (A) an organization—

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

8 (ii) that has at least—

9 (I) one individual who is a rep-
10 resentative of consumers on its gov-
11 erning body; and

12 (II) one individual who is a rep-
13 resentative of health care providers on
14 its governing body; or

15 (B) an entity that is a quality improve-
16 ment entity with a contract under part B of
17 title XI of the Social Security Act (42 U.S.C.
18 1320c et seq.).

19 (2) OUTLIER PRESCRIBER OF OPIOIDS.—The
20 term “outlier prescriber of opioids” means a pre-
21 scriber, identified by the Secretary of Health and
22 Human Services (through use of prescriber informa-
23 tion provided by prescriber National Provider Identifi-
24 ers included pursuant to section 1860D–4(c)(4)(A)
25 of the Social Security Act (42 U.S.C. 1395w–

1 104(c)(4)(A)) on claims for covered part D drugs for
2 part D eligible individuals enrolled in prescription
3 drug plans under part D of title XVIII of such Act
4 (42 U.S.C. 1395w–101 et seq.) and MA–PD plans
5 under part C of such title (42 U.S.C. 1395w–21 et
6 seq.)) as prescribing, as compared to other pre-
7 scribers in the specialty of the prescriber and geo-
8 graphic area, amounts of opioids in excess of a
9 threshold (and other criteria) specified by the Sec-
10 retary, after consultation with stakeholders.

11 (3) PRESCRIBERS.—The term “prescriber”
12 means any health care professional, including a
13 nurse practitioner or physician assistant, who is li-
14 censed to prescribe opioids by the State or territory
15 in which such professional practices.

16 (f) FUNDING.—For purposes of implementing this
17 section, the Secretary of Health and Human Services shall
18 provide for the transfer from the Federal Supplementary
19 Medical Insurance Trust Fund established under section
20 1841 of the Social Security Act (42 U.S.C. 1395t) to the
21 Centers for Medicare & Medicaid Services Program Man-
22 agement Account of \$75,000,000 for fiscal year 2019.
23 Amounts transferred under this subparagraph shall re-
24 main available until expended.

1 **Subtitle G—Preventing Addiction**
2 **for Susceptible Seniors**

3 **SEC. 6061. SHORT TITLE.**

4 This subtitle may be cited as the “Preventing Addic-
5 tion for Susceptible Seniors Act of 2018” or the “PASS
6 Act of 2018”.

7 **SEC. 6062. ELECTRONIC PRIOR AUTHORIZATION FOR COV-**
8 **ERED PART D DRUGS.**

9 (a) **INCLUSION IN ELECTRONIC PRESCRIPTION PRO-**
10 **GRAM.**—Section 1860D–4(e)(2) of the Social Security Act
11 (42 U.S.C. 1395w–104(e)(2)) is amended by adding at the
12 end the following new subparagraph:

13 “(E) **ELECTRONIC PRIOR AUTHORIZA-**
14 **TION.**—

15 “(i) **IN GENERAL.**—Not later than
16 January 1, 2021, the program shall pro-
17 vide for the secure electronic transmission
18 of—

19 “(I) a prior authorization request
20 from the prescribing health care pro-
21 fessional for coverage of a covered
22 part D drug for a part D eligible indi-
23 vidual enrolled in a part D plan (as
24 defined in section 1860D–23(a)(5)) to
25 the PDP sponsor or Medicare Advan-

1 tage organization offering such plan;
2 and

3 “(II) a response, in accordance
4 with this subparagraph, from such
5 PDP sponsor or Medicare Advantage
6 organization, respectively, to such pro-
7 fessional.

8 “(ii) ELECTRONIC TRANSMISSION.—

9 “(I) EXCLUSIONS.—For purposes
10 of this subparagraph, a facsimile, a
11 proprietary payer portal that does not
12 meet standards specified by the Sec-
13 retary, or an electronic form shall not
14 be treated as an electronic trans-
15 mission described in clause (i).

16 “(II) STANDARDS.—In order to
17 be treated, for purposes of this sub-
18 paragraph, as an electronic trans-
19 mission described in clause (i), such
20 transmission shall comply with tech-
21 nical standards adopted by the Sec-
22 retary in consultation with the Na-
23 tional Council for Prescription Drug
24 Programs, other standard setting or-
25 ganizations determined appropriate by

1 the Secretary, and stakeholders in-
2 cluding PDP sponsors, Medicare Ad-
3 vantage organizations, health care
4 professionals, and health information
5 technology software vendors.

6 “(III) APPLICATION.—Notwith-
7 standing any other provision of law,
8 for purposes of this subparagraph, the
9 Secretary may require the use of such
10 standards adopted under subclause
11 (II) in lieu of any other applicable
12 standards for an electronic trans-
13 mission described in clause (i) for a
14 covered part D drug for a part D eli-
15 gible individual.”.

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

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

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

3 (2) greater priority should be placed on increas-
4 ing the adoption of use of such electronic prior au-
5 thorizations among prescribers of such drugs, phar-
6 macies, PDP sponsors, and Medicare Advantage or-
7 ganizations.

8 **SEC. 6063. PROGRAM INTEGRITY TRANSPARENCY MEAS-**
9 **URES UNDER MEDICARE PARTS C AND D.**

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

13 “(i) PROGRAM INTEGRITY TRANSPARENCY MEAS-
14 URES.—

15 “(1) PROGRAM INTEGRITY PORTAL.—

16 “(A) IN GENERAL.—Not later than two
17 years after the date of the enactment of this
18 subsection, the Secretary shall, after consulta-
19 tion with stakeholders, establish a secure Inter-
20 net website portal (or other successor tech-
21 nology) that would allow a secure path for com-
22 munication between the Secretary, MA plans
23 under this part, prescription drug plans under
24 part D, and an eligible entity with a contract
25 under section 1893 (such as a Medicare drug

1 integrity contractor or an entity responsible for
2 carrying out program integrity activities under
3 this part and part D) for the purpose of ena-
4 bling through such portal (or other successor
5 technology)—

6 “(i) the referral by such plans of sub-
7 stantiated fraud, waste, and abuse for ini-
8 tiating or assisting investigations con-
9 ducted by the eligible entity; and

10 “(ii) data sharing among such MA
11 plans, prescription drug plans, and the
12 Secretary.

13 “(B) REQUIRED USES OF PORTAL.—The
14 Secretary shall disseminate the following infor-
15 mation to MA plans under this part and pre-
16 scription drug plans under part D through the
17 secure Internet website portal (or other suc-
18 cessor technology) established under subpara-
19 graph (A):

20 “(i) Providers of services and sup-
21 pliers that have been referred pursuant to
22 subparagraph (A)(i) during the previous
23 12-month period.

24 “(ii) Providers of services and sup-
25 pliers who are the subject of an active ex-

1 clusion under section 1128 or who are sub-
2 ject to a suspension of payment under this
3 title pursuant to section 1862(o) or other-
4 wise.

5 “(iii) Providers of services and sup-
6 pliers who are the subject of an active rev-
7 ocation of participation under this title, in-
8 cluding for not satisfying conditions of par-
9 ticipation.

10 “(iv) In the case of such a plan that
11 makes a referral under subparagraph
12 (A)(i) through the portal (or other suc-
13 cessor technology) with respect to activities
14 of substantiated fraud, waste, or abuse of
15 a provider of services or supplier, if such
16 provider or supplier has been the subject of
17 an administrative action under this title or
18 title XI with respect to similar activities, a
19 notification to such plan of such action so
20 taken.

21 “(C) RULEMAKING.—For purposes of this
22 paragraph, the Secretary shall, through rule-
23 making, specify what constitutes substantiated
24 fraud, waste, and abuse, using guidance such as
25 what is provided in the Medicare Program In-

1 tegrity Manual 4.7.1. In carrying out this sub-
2 section, a fraud hotline tip (as defined by the
3 Secretary) without further evidence shall not be
4 treated as sufficient evidence for substantiated
5 fraud, waste, or abuse

6 “(D) HIPAA COMPLIANT INFORMATION
7 ONLY.—For purposes of this subsection, com-
8 munications may only occur if the communica-
9 tions are permitted under the Federal regula-
10 tions (concerning the privacy of individually
11 identifiable health information) promulgated
12 under section 264(c) of the Health Insurance
13 Portability and Accountability Act of 1996.

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

1 “(A) include administrative actions, perti-
2 nent information related to opioid overpre-
3 scribing, and other data determined appropriate
4 by the Secretary in consultation with stake-
5 holders; and

6 “(B) be anonymized information submitted
7 by plans without identifying the source of such
8 information.

9 “(3) CLARIFICATION.—Nothing in this sub-
10 section shall be construed as precluding or otherwise
11 affecting referrals described in subparagraph (A)
12 that may otherwise be made to law enforcement en-
13 tities or to the Secretary.”.

14 (b) CONTRACT REQUIREMENT TO COMMUNICATE
15 PLAN CORRECTIVE ACTIONS AGAINST OPIOID OVER-PRE-
16 SCRIBERS.—Section 1857(e) of the Social Security Act
17 (42 U.S.C. 1395w-27(e)) is amended by adding at the end
18 the following new paragraph:

19 “(5) COMMUNICATING PLAN CORRECTIVE AC-
20 TIONS AGAINST OPIOIDS OVER-PRESCRIBERS.—

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

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

5 “(B) PROCESS.—Not later than January
6 1, 2021, the Secretary shall, in consultation
7 with stakeholders, establish a process under
8 which MA plans and prescription drug plans
9 shall submit to the Secretary information de-
10 scribed in subparagraph (A).

11 “(C) REGULATIONS.—For purposes of this
12 paragraph, including as applied under section
13 1860D–12(b)(3)(D), the Secretary shall, pursu-
14 ant to rulemaking—

15 “(i) specify a definition for the term
16 ‘high volume of opioids’ and a method for
17 determining if a provider of services pre-
18 scribes such a high volume; and

19 “(ii) establish the process described in
20 subparagraph (B) and the types of infor-
21 mation that shall be submitted through
22 such process.”.

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

1 amended by adding at the end the following new sub-
2 section:

3 “(m) PROGRAM INTEGRITY TRANSPARENCY MEAS-
4 URES.—For program integrity transparency measures ap-
5 plied with respect to prescription drug plan and MA plans,
6 see section 1859(i).”.

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

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

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

15 (2) by striking “are part D eligible individuals
16 who—” and inserting “are the following:

17 (I) Part D eligible individuals
18 who—”; and

19 (3) by adding at the end the following new sub-
20 clause:

21 (II) Beginning January 1,
22 2021, at-risk beneficiaries for pre-
23 scription drug abuse (as defined in
24 paragraph (5)(C)).”.

1 **SEC. 6065. MEDICARE NOTIFICATIONS TO OUTLIER PRE-**
2 **SCRIBERS OF OPIOIDS.**

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

6 “(D) OUTLIER PRESCRIBER NOTIFICA-
7 TION.—

8 “(i) NOTIFICATION.—Beginning not
9 later than two years after the date of the
10 enactment of this subparagraph, the Sec-
11 retary shall, in the case of a prescriber
12 identified by the Secretary under clause
13 (ii) to be an outlier prescriber of opioids,
14 provide, subject to clause (iv), an annual
15 notification to such prescriber that such
16 prescriber has been so identified and that
17 includes resources on proper prescribing
18 methods and other information specified in
19 accordance with clause (iii).

20 “(ii) IDENTIFICATION OF OUTLIER
21 PRESCRIBERS OF OPIOIDS.—

22 “(I) IN GENERAL.—The Sec-
23 retary shall, subject to subclause (III),
24 using the valid prescriber National
25 Provider Identifiers included pursuant
26 to subparagraph (A) on claims for

1 covered part D drugs for part D eligi-
2 ble individuals enrolled in prescription
3 drug plans under this part or MA–PD
4 plans under part C and based on the
5 threshold established under subclause
6 (II), conduct an analysis to identify
7 prescribers that are outlier opioid pre-
8 scribers for a period specified by the
9 Secretary.

10 “(II) ESTABLISHMENT OF
11 THRESHOLD.—For purposes of sub-
12 clause (I) and subject to subclause
13 (III), the Secretary shall, after con-
14 sultation with stakeholders, establish
15 a threshold, based on prescriber spe-
16 cialty and geographic area, for identi-
17 fying whether a prescriber in a spe-
18 cialty and geographic area is an
19 outlier prescriber of opioids as com-
20 pared to other prescribers of opioids
21 within such specialty and area.

22 “(III) EXCLUSIONS.—The Sec-
23 retary may exclude the following indi-
24 viduals and prescribers from the anal-
25 ysis under this clause:

1 “(aa) Individuals receiving
2 hospice services.

3 “(bb) Individuals with a
4 cancer diagnosis.

5 “(cc) Prescribers who are
6 the subject of an investigation by
7 the Centers for Medicare & Med-
8 icaid Services or the Office of In-
9 spector General of the Depart-
10 ment of Health and Human
11 Services.

12 “(iii) CONTENTS OF NOTIFICATION.—
13 The Secretary shall, based on input from
14 stakeholders, specify the resources and
15 other information to be included in notifi-
16 cations provided under clause (i).

17 “(iv) MODIFICATIONS AND EXPAN-
18 SIONS.—

19 “(I) FREQUENCY.—Beginning 5
20 years after the date of the enactment
21 of this subparagraph, the Secretary
22 may change the frequency of the noti-
23 fications described in clause (i) based
24 on stakeholder input.

1 “(II) EXPANSION TO OTHER
2 PRESCRIPTIONS.—The Secretary may
3 expand notifications under this sub-
4 paragraph to include identifications
5 and notifications with respect to con-
6 current prescriptions of covered Part
7 D drugs used in combination with
8 opioids that are considered to have
9 adverse side effects when so used in
10 such combination, as determined by
11 the Secretary.

12 “(v) OPIOIDS DEFINED.—For pur-
13 poses of this subparagraph, the term
14 ‘opioids’ has such meaning as specified by
15 the Secretary through program instruction
16 or otherwise.”.

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

18 No additional funds are authorized to be appro-
19 priated to carry out the requirements of this subtitle and
20 the amendments made by this subtitle. Such requirements
21 shall be carried out using amounts otherwise authorized
22 to be appropriated.

1 **Subtitle H—Expanding Oversight**
2 **of Opioid Prescribing and Payment**

3 **SEC. 6071. SHORT TITLE.**

4 This subtitle may be cited as the “Expanding Over-
5 sight of Opioid Prescribing and Payment Act of 2018”.

6 **SEC. 6072. MEDICARE PAYMENT ADVISORY COMMISSION**
7 **REPORT ON OPIOID PAYMENT, ADVERSE IN-**
8 **CENTIVES, AND DATA UNDER THE MEDICARE**
9 **PROGRAM.**

10 Not later than March 15, 2019, the Medicare Pay-
11 ment Advisory Commission shall submit to Congress a re-
12 port on, with respect to the Medicare program under title
13 XVIII of the Social Security Act, the following:

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

18 (2) The identification of incentives under the
19 hospital inpatient prospective payment system under
20 section 1886 of the Social Security Act (42 U.S.C.
21 1395ww) and incentives under the hospital out-
22 patient prospective payment system under section
23 1833(t) of such Act (42 U.S.C. 1395l(t)) for pre-
24 scribing opioids and incentives under each such sys-
25 tem for prescribing non-opioid treatments, and rec-

1 ommendations as the Commission deems appropriate
2 for addressing any of such incentives that are ad-
3 verse incentives.

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

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

10 No additional funds are authorized to be appro-
11 priated to carry out the requirements of this subtitle. Such
12 requirements shall be carried out using amounts otherwise
13 authorized to be appropriated.

14 **Subtitle I—Dr. Todd Graham Pain**
15 **Management, Treatment, and**
16 **Recovery**

17 **SEC. 6081. SHORT TITLE.**

18 This subtitle may be cited as the “Dr. Todd Graham
19 Pain Management, Treatment, and Recovery Act of
20 2018”.

1 **SEC. 6082. REVIEW AND ADJUSTMENT OF PAYMENTS**
2 **UNDER THE MEDICARE OUTPATIENT PRO-**
3 **SPECTIVE PAYMENT SYSTEM TO AVOID FI-**
4 **NANCIAL INCENTIVES TO USE OPIOIDS IN-**
5 **STEAD OF NON-OPIOID ALTERNATIVE TREAT-**
6 **MENTS.**

7 (a) OUTPATIENT PROSPECTIVE PAYMENT SYS-
8 TEM.—Section 1833(t) of the Social Security Act (42
9 U.S.C. 1395l(t)) is amended by adding at the end the fol-
10 lowing new paragraph:

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

13 “(A) IN GENERAL.—With respect to pay-
14 ments made under this subsection for covered
15 OPD services (or groups of services), including
16 covered OPD services assigned to a comprehen-
17 sive ambulatory payment classification, the Sec-
18 retary—

19 “(i) shall, as soon as practicable, con-
20 duct a review (part of which may include
21 a request for information) of payments for
22 opioids and evidence-based non-opioid al-
23 ternatives for pain management (including
24 drugs and devices, nerve blocks, surgical
25 injections, and neuromodulation) with a
26 goal of ensuring that there are not finan-

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

3 “(ii) may, as the Secretary determines
4 appropriate, conduct subsequent reviews of
5 such payments; and

6 “(iii) shall consider the extent to
7 which revisions under this subsection to
8 such payments (such as the creation of ad-
9 ditional groups of covered OPD services to
10 classify separately those procedures that
11 utilize opioids and non-opioid alternatives
12 for pain management) would reduce pay-
13 ment incentives to use opioids instead of
14 non-opioid alternatives for pain manage-
15 ment.

16 “(B) PRIORITY.—In conducting the review
17 under clause (i) of subparagraph (A) and con-
18 sidering revisions under clause (iii) of such sub-
19 paragraph, the Secretary shall focus on covered
20 OPD services (or groups of services) assigned
21 to a comprehensive ambulatory payment classi-
22 fication, ambulatory payment classifications
23 that primarily include surgical services, and
24 other services determined by the Secretary

1 which generally involve treatment for pain man-
2 agement.

3 “(C) REVISIONS.—If the Secretary identi-
4 fies revisions to payments pursuant to subpara-
5 graph (A)(iii), the Secretary shall, as deter-
6 mined appropriate, begin making such revisions
7 for services furnished on or after January 1,
8 2020. Revisions under the previous sentence
9 shall be treated as adjustments for purposes of
10 application of paragraph (9)(B).

11 “(D) RULES OF CONSTRUCTION.—Nothing
12 in this paragraph shall be construed to preclude
13 the Secretary—

14 “(i) from conducting a demonstration
15 before making the revisions described in
16 subparagraph (C); or

17 “(ii) prior to implementation of this
18 paragraph, from changing payments under
19 this subsection for covered OPD services
20 (or groups of services) which include
21 opioids or non-opioid alternatives for pain
22 management.”.

23 (b) AMBULATORY SURGICAL CENTERS.—Section
24 1833(i) of the Social Security Act (42 U.S.C. 1395l(i))

1 is amended by adding at the end the following new para-
2 graph:

3 “(8) The Secretary shall conduct a similar type of
4 review as required under paragraph (22) of section
5 1833(t), including the second sentence of subparagraph
6 (C) of such paragraph, to payment for services under this
7 subsection, and make such revisions under this paragraph,
8 in an appropriate manner (as determined by the Sec-
9 retary).”.

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

14 (a) **FEDERALLY QUALIFIED HEALTH CENTERS.—**
15 Section 1834(o) of the Social Security Act (42 U.S.C.
16 1395m(o)) is amended by adding at the end the following
17 new paragraph:

18 “(3) **ADDITIONAL PAYMENTS FOR CERTAIN**
19 **FQHCS WITH PHYSICIANS OR OTHER PRACTITIONERS**
20 **RECEIVING DATA 2000 WAIVERS.—**

21 “(A) **IN GENERAL.—**In the case of a Fed-
22 erally qualified health center with respect to
23 which, beginning on or after January 1, 2019,
24 Federally-qualified health center services (as de-
25 fined in section 1861(aa)(3)) are furnished for

1 the treatment of opioid use disorder by a physi-
2 cian or practitioner who meets the requirements
3 described in subparagraph (C) the Secretary
4 shall, subject to availability of funds under sub-
5 paragraph (D), make a payment (at such time
6 and in such manner as specified by the Sec-
7 retary) to such Federally qualified health center
8 after receiving and approving an application
9 submitted by such Federally qualified health
10 center under subparagraph (B). Such a pay-
11 ment shall be in an amount determined by the
12 Secretary, based on an estimate of the average
13 costs of training for purposes of receiving a
14 waiver described in subparagraph (C)(ii). Such
15 a payment may be made only one time with re-
16 spect to each such physician or practitioner.

17 “(B) APPLICATION.—In order to receive a
18 payment described in subparagraph (A), a Fed-
19 erally-qualified health center shall submit to the
20 Secretary an application for such a payment at
21 such time, in such manner, and containing such
22 information as specified by the Secretary. A
23 Federally-qualified health center may apply for
24 such a payment for each physician or practi-
25 tioner described in subparagraph (A) furnishing

1 services described in such subparagraph at such
2 center.

3 “(C) REQUIREMENTS.—For purposes of
4 subparagraph (A), the requirements described
5 in this subparagraph, with respect to a physi-
6 cian or practitioner, are the following:

7 “(i) The physician or practitioner is
8 employed by or working under contract
9 with a Federally qualified health center de-
10 scribed in subparagraph (A) that submits
11 an application under subparagraph (B).

12 “(ii) The physician or practitioner
13 first receives a waiver under section 303(g)
14 of the Controlled Substances Act on or
15 after January 1, 2019.

16 “(D) FUNDING.—For purposes of making
17 payments under this paragraph, there are ap-
18 propriated, out of amounts in the Treasury not
19 otherwise appropriated, \$6,000,000, which shall
20 remain available until expended.”.

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

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

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

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

6 “(1) IN GENERAL.—In the case of a rural
7 health clinic with respect to which, beginning on or
8 after January 1, 2019, rural health clinic services
9 (as defined in section 1861(aa)(1)) are furnished for
10 the treatment of opioid use disorder by a physician
11 or practitioner who meets the requirements de-
12 scribed in paragraph (3), the Secretary shall, subject
13 to availability of funds under paragraph (4), make
14 a payment (at such time and in such manner as
15 specified by the Secretary) to such rural health clinic
16 after receiving and approving an application de-
17 scribed in paragraph (2). Such payment shall be in
18 an amount determined by the Secretary, based on an
19 estimate of the average costs of training for pur-
20 poses of receiving a waiver described in paragraph
21 (3)(B). Such payment may be made only one time
22 with respect to each such physician or practitioner.

23 “(2) APPLICATION.—In order to receive a pay-
24 ment described in paragraph (1), a rural health clin-
25 ic shall submit to the Secretary an application for

1 such a payment at such time, in such manner, and
2 containing such information as specified by the Sec-
3 retary. A rural health clinic may apply for such a
4 payment for each physician or practitioner described
5 in paragraph (1) furnishing services described in
6 such paragraph at such clinic.

7 “(3) REQUIREMENTS.—For purposes of para-
8 graph (1), the requirements described in this para-
9 graph, with respect to a physician or practitioner,
10 are the following:

11 “(A) The physician or practitioner is em-
12 ployed by or working under contract with a
13 rural health clinic described in paragraph (1)
14 that submits an application under paragraph
15 (2).

16 “(B) The physician or practitioner first re-
17 ceives a waiver under section 303(g) of the
18 Controlled Substances Act on or after January
19 1, 2019.

20 “(4) FUNDING.—For purposes of making pay-
21 ments under this subsection, there are appropriated,
22 out of amounts in the Treasury not otherwise appro-
23 priated, \$2,000,000, which shall remain available
24 until expended.”.

1 **SEC. 6084. STUDYING THE AVAILABILITY OF SUPPLE-**
2 **MENTAL BENEFITS DESIGNED TO TREAT OR**
3 **PREVENT SUBSTANCE USE DISORDERS**
4 **UNDER MEDICARE ADVANTAGE PLANS.**

5 (a) IN GENERAL.—Not later than 2 years after the
6 date of the enactment of this Act, the Secretary of Health
7 and Human Services (in this section referred to as the
8 “Secretary”) shall submit to Congress a report on the
9 availability of supplemental health care benefits (as de-
10 scribed in section 1852(a)(3)(A) of the Social Security Act
11 (42 U.S.C. 1395w–22(a)(3)(A))) designed to treat or pre-
12 vent substance use disorders under Medicare Advantage
13 plans offered under part C of title XVIII of such Act. Such
14 report shall include the analysis described in subsection
15 (c) and any differences in the availability of such benefits
16 under specialized MA plans for special needs individuals
17 (as defined in section 1859(b)(6) of such Act (42 U.S.C.
18 1395w–28(b)(6))) offered to individuals entitled to med-
19 ical assistance under title XIX of such Act and other such
20 Medicare Advantage plans.

21 (b) CONSULTATION.—The Secretary shall develop the
22 report described in subsection (a) in consultation with rel-
23 evant stakeholders, including—

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

1 (2) entities who advocate on behalf of such indi-
2 viduals;

3 (3) Medicare Advantage organizations;

4 (4) pharmacy benefit managers; and

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

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

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

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

19 (B) non-opioid alternatives for the treat-
20 ment of pain.

21 (2) Challenges associated with such plans offer-
22 ing supplemental health care benefits relating to cov-
23 erage of items and services described in subpara-
24 graph (A) or (B) of paragraph (1).

1 (3) The impact, if any, of increasing the appli-
2 cable rebate percentage determined under section
3 1854(b)(1)(C) of the Social Security Act (42 U.S.C.
4 1395w-24(b)(1)(C)) for plans offering such benefits
5 relating to such coverage would have on the avail-
6 ability of such benefits relating to such coverage of-
7 fered under Medicare Advantage plans.

8 (4) Potential ways to improve upon such cov-
9 erage or to incentivize such plans to offer additional
10 supplemental health care benefits relating to such
11 coverage.

12 **SEC. 6085. CLINICAL PSYCHOLOGIST SERVICES MODELS**
13 **UNDER THE CENTER FOR MEDICARE AND**
14 **MEDICAID INNOVATION; GAO STUDY AND RE-**
15 **PORT.**

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

19 “(xxv) Supporting ways to familiarize
20 individuals with the availability of coverage
21 under part B of title XVIII for qualified
22 psychologist services (as defined in section
23 1861(ii)).

24 “(xxvi) Exploring ways to avoid un-
25 necessary hospitalizations or emergency de-

1 partment visits for mental and behavioral
2 health services (such as for treating de-
3 pression) through use of a 24-hour, 7-day
4 a week help line that may inform individ-
5 uals about the availability of treatment op-
6 tions, including the availability of qualified
7 psychologist services (as defined in section
8 1861(ii)).”.

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

16 (1) Information about services furnished by
17 psychiatrists, clinical psychologists, and other profes-
18 sionals.

19 (2) Information about ways that Medicare bene-
20 ficiaries familiarize themselves about the availability
21 of Medicare payment for qualified psychologist serv-
22 ices (as defined in section 1861(ii) of the Social Se-
23 curity Act (42 U.S.C. 1395x(ii)) and ways that the
24 provision of such information could be improved.

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

2 (a) IN GENERAL.—Not later than 1 year after the
3 date of enactment of this Act, the Secretary of Health and
4 Human Services (referred to in this section as the “Sec-
5 retary”) shall conduct a study analyzing best practices as
6 well as payment and coverage for pain management serv-
7 ices under title XVIII of the Social Security Act and sub-
8 mit to the Committee on Ways and Means and the Com-
9 mittee on Energy and Commerce of the House of Rep-
10 resentatives and the Committee on Finance of the Senate
11 a report containing options for revising payment to pro-
12 viders and suppliers of services and coverage related to
13 the use of multi-disciplinary, evidence-based, non-opioid
14 treatments for acute and chronic pain management for in-
15 dividuals entitled to benefits under part A or enrolled
16 under part B of title XVIII of the Social Security Act.
17 The Secretary shall make such report available on the
18 public website of the Centers for Medicare & Medicaid
19 Services.

20 (b) CONSULTATION.—In developing the report de-
21 scribed in subsection (a), the Secretary shall consult
22 with—

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

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

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

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

6 (4) substance abuse and mental health profes-
7 sional organizations;

8 (5) pain management professional organizations
9 and advocacy entities, including individuals who per-
10 sonally suffer chronic pain;

11 (6) medical professional organizations and med-
12 ical specialty organizations;

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

15 (8) organizations with expertise in the develop-
16 ment of innovative medical technologies for pain
17 management;

18 (9) beneficiary advocacy organizations; and

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

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

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

4 (A) Evidence-based treatments and tech-
5 nologies for chronic or acute pain, including
6 such treatments that are covered, not covered,
7 or have limited coverage under such title.

8 (B) Evidence-based treatments and tech-
9 nologies that monitor substance use withdrawal
10 and prevent overdoses of opioids.

11 (C) Evidence-based treatments and tech-
12 nologies that treat substance use disorders.

13 (D) Items and services furnished by practi-
14 tioners through a multi-disciplinary treatment
15 model for pain management, including the pa-
16 tient-centered medical home.

17 (E) Medical devices, non-opioid based
18 drugs, and other therapies (including inter-
19 ventional and integrative pain therapies) ap-
20 proved or cleared by the Food and Drug Ad-
21 ministration for the treatment of pain.

22 (F) Items and services furnished to bene-
23 ficiaries with psychiatric disorders, substance
24 use disorders, or who are at risk of suicide, or
25 have comorbidities and require consultation or

1 management of pain with one or more special-
2 ists in pain management, mental health, or ad-
3 diction treatment.

4 (2) An evaluation of the following:

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

10 (B) Costs and benefits associated with po-
11 tential expansion of coverage under such title to
12 include items and services not covered under
13 such title that may be used for the treatment
14 of pain, such as acupuncture, therapeutic mas-
15 sages, and items and services furnished by inte-
16 grated pain management programs.

17 (C) Pain management guidance published
18 by the Federal Government that may be rel-
19 evant to coverage determinations or other cov-
20 erage requirements under title XVIII of the So-
21 cial Security Act.

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

1 porating into such guidance relevant elements of the
2 “Va/DoD Clinical Practice Guideline for Opioid
3 Therapy for Chronic Pain” published in February
4 2017 by the Department of Veterans Affairs and
5 Department of Defense, including adoption of ele-
6 ments of the Department of Defense and Depart-
7 ment of Veterans Affairs pain rating scale.

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

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

11 (d) OPTIONS.—The options described in this sub-
12 section are, with respect to individuals entitled to benefits
13 under part A or enrolled under part B of title XVIII of
14 the Social Security Act, legislative and administrative op-
15 tions for accomplishing the following:

16 (1) Improving coverage of and payment for pain
17 management therapies without the use of opioids, in-
18 cluding interventional pain therapies, and options to
19 augment opioid therapy with other clinical and com-
20plementary, integrative health services to minimize
21 the risk of substance use disorder, including in a
22 hospital setting.

23 (2) Improving coverage of and payment for
24 medical devices and non-opioid based pharma-
25cological and non-pharmacological therapies ap-

1 proved or cleared by the Food and Drug Administra-
2 tion for the treatment of pain as an alternative or
3 augment to opioid therapy.

4 (3) Improving and disseminating treatment
5 strategies for beneficiaries with psychiatric dis-
6 orders, substance use disorders, or who are at risk
7 of suicide, and treatment strategies to address
8 health disparities related to opioid use and opioid
9 abuse treatment.

10 (4) Improving and disseminating treatment
11 strategies for beneficiaries with comorbidities who
12 require a consultation or comanagement of pain with
13 one or more specialists in pain management, mental
14 health, or addiction treatment, including in a hos-
15 pital setting.

16 (5) Educating providers on risks of coadminis-
17 tration of opioids and other drugs, particularly
18 benzodiazepines.

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

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

1 Medicare program and individuals entitled to bene-
2 fits under part A or under part B of such title on
3 alternative, non-opioid therapies to manage and
4 treat acute and chronic pain.

5 (8) Creating a beneficiary education tool on al-
6 ternatives to opioids for chronic pain management.

7 (e) **IMPACT ANALYSIS.**—The impact analysis de-
8 scribed in this subsection consists of an analysis of any
9 potential effects implementing the options described in
10 subsection (d) would have—

11 (1) on expenditures under the Medicare pro-
12 gram; and

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

16 **Subtitle J—Combating Opioid**
17 **Abuse for Care in Hospitals**

18 **SEC. 6091. SHORT TITLE.**

19 This subtitle may be cited as the “Combating Opioid
20 Abuse for Care in Hospitals Act of 2018” or the “COACH
21 Act of 2018”.

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

5 (a) IN GENERAL.—Not later than January 1, 2019,
6 the Secretary of Health and Human Services (in this sec-
7 tion referred to as the “Secretary”) shall develop and pub-
8 lish on the public website of the Centers for Medicare &
9 Medicaid Services guidance for hospitals receiving pay-
10 ment under part A of title XVIII of the Social Security
11 Act (42 U.S.C. 1395c et seq.) on pain management strate-
12 gies and opioid use disorder prevention strategies with re-
13 spect to individuals entitled to benefits under such part.

14 (b) CONSULTATION.—In developing the guidance de-
15 scribed in subsection (a), the Secretary shall consult with
16 relevant stakeholders, including—

17 (1) medical professional organizations;

18 (2) providers and suppliers of services (as such
19 terms are defined in section 1861 of the Social Secu-
20 rity Act (42 U.S.C. 1395x));

21 (3) health care consumers or groups rep-
22 resenting such consumers; and

23 (4) other entities determined appropriate by the
24 Secretary.

1 (c) CONTENTS.—The guidance described in sub-
2 section (a) shall include, with respect to hospitals and indi-
3 viduals described in such subsection, the following:

4 (1) Best practices regarding evidence-based
5 screening and practitioner education initiatives relat-
6 ing to screening and treatment protocols for opioid
7 use disorder, including—

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

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

13 (C) resources available to such individuals,
14 such as opioid treatment programs, peer sup-
15 port groups, and other recovery programs.

16 (2) Best practices for such hospitals to educate
17 practitioners furnishing items and services at such
18 hospital with respect to pain management and sub-
19 stance use disorders, including education on—

20 (A) the adverse effects of prolonged opioid
21 use;

22 (B) non-opioid, evidence-based, non-phar-
23 macological pain management treatments;

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

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

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

7 (4) A notification template developed by the
8 Secretary, for use as appropriate, for such individ-
9 uals who are prescribed an opioid that—

10 (A) explains the risks and side effects asso-
11 ciated with opioid use (including the risks of
12 addiction and overdose) and the importance of
13 adhering to the prescribed treatment regimen,
14 avoiding medications that may have an adverse
15 interaction with such opioid, and storing such
16 opioid safely and securely;

17 (B) highlights multimodal and evidence-
18 based non-opioid alternatives for pain manage-
19 ment;

20 (C) encourages such individuals to talk to
21 their health care providers about such alter-
22 natives;

23 (D) provides for a method (through signa-
24 ture or otherwise) for such an individual, or

1 person acting on such individual's behalf, to ac-
2 knowledge receipt of such notification template;

3 (E) is worded in an easily understandable
4 manner and made available in multiple lan-
5 guages determined appropriate by the Sec-
6 retary; and

7 (F) includes any other information deter-
8 mined appropriate by the Secretary.

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

12 (A) ways for such hospital to establish tar-
13 get levels, taking into account the specialties of
14 such practitioners and the geographic area in
15 which such hospital is located, with respect to
16 opioids prescribed by such practitioners;

17 (B) guidance on checking the medical
18 records of such individuals against information
19 included in prescription drug monitoring pro-
20 grams;

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

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

1 (6) Other information the Secretary determines
2 appropriate, including any such information from
3 the Opioid Safety Initiative established by the De-
4 partment of Veterans Affairs or the Opioid Overdose
5 Prevention Toolkit published by the Substance
6 Abuse and Mental Health Services Administration.

7 **SEC. 6093. REQUIRING THE REVIEW OF QUALITY MEAS-**
8 **URES RELATING TO OPIOIDS AND OPIOID**
9 **USE DISORDER TREATMENTS FURNISHED**
10 **UNDER THE MEDICARE PROGRAM AND**
11 **OTHER FEDERAL HEALTH CARE PROGRAMS.**

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

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

17 “(1) IN GENERAL.—Not later than 180 days
18 after the date of the enactment of this subsection,
19 the Secretary shall establish a technical expert panel
20 for purposes of reviewing quality measures relating
21 to opioids and opioid use disorders, including care,
22 prevention, diagnosis, health outcomes, and treat-
23 ment furnished to individuals with opioid use dis-
24 orders. The Secretary may use the entity with a con-
25 tract under section 1890(a) and amend such con-

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

3 “(2) REVIEW AND ASSESSMENT.—Not later
4 than 1 year after the date the technical expert panel
5 described in paragraph (1) is established (and peri-
6 odically thereafter as the Secretary determines ap-
7 propriate), the technical expert panel shall—

8 “(A) review quality measures that relate to
9 opioids and opioid use disorders, including ex-
10 isting measures and those under development;

11 “(B) identify gaps in areas of quality
12 measurement that relate to opioids and opioid
13 use disorders, and identify measure develop-
14 ment priorities for such measure gaps; and

15 “(C) make recommendations to the Sec-
16 retary on quality measures with respect to
17 opioids and opioid use disorders for purposes of
18 improving care, prevention, diagnosis, health
19 outcomes, and treatment, including rec-
20 ommendations for revisions of such measures,
21 need for development of new measures, and rec-
22 ommendations for including such measures in
23 the Merit-Based Incentive Payment System
24 under section 1848(q), the alternative payment
25 models under section 1833(z)(3)(C), the shared

1 savings program under section 1899, the qual-
2 ity reporting requirements for inpatient hos-
3 pitals under section 1886(b)(3)(B)(viii), and
4 the hospital value-based purchasing program
5 under section 1886(o).

6 “(3) CONSIDERATION OF MEASURES BY SEC-
7 RETARY.—The Secretary shall consider—

8 “(A) using opioid and opioid use disorder
9 measures (including measures used under the
10 Merit-Based Incentive Payment System under
11 section 1848(q), measures recommended under
12 paragraph (2)(C), and other such measures
13 identified by the Secretary) in alternative pay-
14 ment models under section 1833(z)(3)(C) and
15 in the shared savings program under section
16 1899; and

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

23 “(4) PRIORITIZATION OF MEASURE DEVELOP-
24 MENT.—The Secretary shall prioritize for measure

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

3 (b) EXPEDITED ENDORSEMENT PROCESS FOR
4 OPIOID MEASURES.—Section 1890(b)(2) of the Social Se-
5 curity Act (42 U.S.C. 1395aaa(b)(2)) is amended by add-
6 ing at the end the following new flush sentence:

7 “Such endorsement process shall, as determined
8 practicable by the entity, provide for an expedited
9 process with respect to the endorsement of such
10 measures relating to opioids and opioid use dis-
11 orders.”.

12 **SEC. 6094. TECHNICAL EXPERT PANEL ON REDUCING SUR-**
13 **GICAL SETTING OPIOID USE; DATA COLLEC-**
14 **TION ON PERIOPERATIVE OPIOID USE.**

15 (a) TECHNICAL EXPERT PANEL ON REDUCING SUR-
16 GICAL SETTING OPIOID USE.—

17 (1) IN GENERAL.—Not later than 6 months
18 after the date of the enactment of this Act, the Sec-
19 retary of Health and Human Services shall convene
20 a technical expert panel, including medical and sur-
21 gical specialty societies and hospital organizations,
22 to provide recommendations on reducing opioid use
23 in the inpatient and outpatient surgical settings and
24 on best practices for pain management, including
25 with respect to the following:

1 (A) Approaches that limit patient exposure
2 to opioids during the perioperative period, in-
3 cluding pre-surgical and post-surgical injec-
4 tions, and that identify such patients at risk of
5 opioid use disorder pre-operation.

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

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

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

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

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

1 paragraph (1) and an action plan for broader imple-
2 mentation of pain management protocols that limit
3 the use of opioids in the perioperative setting and
4 upon discharge from such setting.

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

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

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

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

20 (B) opioid consumption, including—

21 (i) perioperative days of therapy;

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

1 (iii) post-discharge prescriptions and
2 other combination drugs that are used be-
3 fore intervention and after intervention;

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

6 (v) quantity consumed and number of
7 refills;

8 (C) regional anesthesia and analgesia prac-
9 tices, including pre-surgical and post-surgical
10 injections;

11 (D) naloxone reversal;

12 (E) post-operative respiratory failure;

13 (F) information about storage and dis-
14 posal; and

15 (G) such other information as the Sec-
16 retary may specify.

17 (3) Recommendations for improving data collec-
18 tion on perioperative opioid use, including an anal-
19 ysis to identify and reduce barriers to collecting, re-
20 porting, and analyzing the data described in para-
21 graph (2), including barriers related to technological
22 availability.

1 **SEC. 6095. REQUIRING THE POSTING AND PERIODIC UP-**
2 **DATE OF OPIOID PRESCRIBING GUIDANCE**
3 **FOR MEDICARE BENEFICIARIES.**

4 (a) IN GENERAL.—Not later than 180 days after the
5 date of the enactment of this Act, the Secretary of Health
6 and Human Services (in this section referred to as the
7 “Secretary”) shall post on the public website of the Cen-
8 ters for Medicare & Medicaid Services all guidance pub-
9 lished by the Department of Health and Human Services
10 on or after January 1, 2016, relating to the prescribing
11 of opioids and applicable to opioid prescriptions for indi-
12 viduals entitled to benefits under part A of title XVIII
13 of the Social Security Act (42 U.S.C. 1395c et seq.) or
14 enrolled under part B of such title of such Act (42 U.S.C.
15 1395j et seq.).

16 (b) UPDATE OF GUIDANCE.—

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

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

25 (A) Medical professional organizations.

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

4 (C) Health care consumers or groups rep-
5 resenting such consumers.

6 (D) Other entities determined appropriate
7 by the Secretary.

8 **Subtitle K—Stop Excessive Nar-**
9 **cotics in Our Retirement Com-**
10 **munities Protection**

11 **SEC. 6101. SHORT TITLE.**

12 This subtitle may be cited as the “Stop Excessive
13 Narcotics in our Retirement Communities Protection Act
14 of 2018” or the “SENIOR Communities Protection Act
15 of 2018”.

16 **SEC. 6102. SUSPENSION OF PAYMENTS BY MEDICARE PRE-**
17 **SCRIPTION DRUG PLANS AND MA-PD PLANS**
18 **PENDING INVESTIGATIONS OF CREDIBLE AL-**
19 **LEGATIONS OF FRAUD BY PHARMACIES.**

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

23 “(7) SUSPENSION OF PAYMENTS PENDING IN-
24 VESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD
25 BY PHARMACIES.—

1 “(A) IN GENERAL.—The provisions of sec-
2 tion 1862(o) shall apply with respect to a PDP
3 sponsor with a contract under this part, a phar-
4 macy, and payments to such pharmacy under
5 this part in the same manner as such provisions
6 apply with respect to the Secretary, a provider
7 of services or supplier, and payments to such
8 provider of services or supplier under this title.

9 “(B) RULE OF CONSTRUCTION.—Nothing
10 in this paragraph shall be construed as limiting
11 the authority of a PDP sponsor to conduct
12 postpayment review.”.

13 (b) APPLICATION TO MA–PD PLANS.—Section
14 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–
15 27(f)(3)) is amended by adding at the end the following
16 new subparagraph:

17 “(D) SUSPENSION OF PAYMENTS PENDING
18 INVESTIGATION OF CREDIBLE ALLEGATIONS OF
19 FRAUD BY PHARMACIES.—Section 1860D–
20 12(b)(7).”.

21 (c) CONFORMING AMENDMENT.—Section 1862(o)(3)
22 of the Social Security Act (42 U.S.C. 1395y(o)(3)) is
23 amended by inserting “, section 1860D–12(b)(7) (includ-
24 ing as applied pursuant to section 1857(f)(3)(D)),” after
25 “this subsection”.

1 (d) CLARIFICATION RELATING TO CREDIBLE ALLE-
2 GATION OF FRAUD.—Section 1862(o) of the Social Secu-
3 rity Act (42 U.S.C. 1395y(o)) is amended by adding at
4 the end the following new paragraph:

5 “(4) CREDIBLE ALLEGATION OF FRAUD.—In
6 carrying out this subsection, section 1860D–
7 12(b)(7) (including as applied pursuant to section
8 1857(f)(3)(D)), and section 1903(i)(2)(C), a fraud
9 hotline tip (as defined by the Secretary) without fur-
10 ther evidence shall not be treated as sufficient evi-
11 dence for a credible allegation of fraud.”

12 (e) EFFECTIVE DATE.—The amendments made by
13 this section shall apply with respect to plan years begin-
14 ning on or after January 1, 2020.

15 **Subtitle L—Providing Reliable Op-**
16 **tions for Patients and Edu-**
17 **catational Resources**

18 **SEC. 6111. SHORT TITLE.**

19 This subtitle may be cited as the “Providing Reliable
20 Options for Patients and Educational Resources Act of
21 2018” or the “PROPER Act of 2018”.

1 **SEC. 6112. REQUIRING MEDICARE ADVANTAGE PLANS AND**
2 **PART D PRESCRIPTION DRUG PLANS TO IN-**
3 **CLUDE INFORMATION ON RISKS ASSOCIATED**
4 **WITH OPIOIDS AND COVERAGE OF NON-**
5 **PHARMACOLOGICAL THERAPIES AND**
6 **NONOPIOID MEDICATIONS OR DEVICES USED**
7 **TO TREAT PAIN.**

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

10 (1) in subparagraph (A), by inserting “, subject
11 to subparagraph (C),” before “including”;

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

14 “(vi) For plan year 2021 and each
15 subsequent plan year, subject to subpara-
16 graph (C), with respect to the treatment of
17 pain—

18 “(I) the risks associated with
19 prolonged opioid use; and

20 “(II) coverage of nonpharma-
21 cological therapies, devices, and
22 nonopioid medications—

23 “(aa) in the case of an MA-
24 PD plan under part C, under
25 such plan; and

1 “(bb) in the case of a pre-
2 scription drug plan, under such
3 plan and under parts A and B.”;
4 and

5 (3) by adding at the end the following new sub-
6 paragraph:

7 “(C) TARGETED PROVISION OF INFORMA-
8 TION.—A PDP sponsor of a prescription drug
9 plan may, in lieu of disclosing the information
10 described in subparagraph (B)(vi) to each en-
11 rollee under the plan, disclose such information
12 through mail or electronic communications to a
13 subset of enrollees under the plan, such as en-
14 rollees who have been prescribed an opioid in
15 the previous two-year period.”.

16 **SEC. 6113. REQUIRING MEDICARE ADVANTAGE PLANS AND**
17 **PRESCRIPTION DRUG PLANS TO PROVIDE IN-**
18 **FORMATION ON THE SAFE DISPOSAL OF PRE-**
19 **SCRIPTION DRUGS.**

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

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

1 “(1) IN GENERAL.—In the case of an individual
2 enrolled under an MA or MA-PD plan who is fur-
3 nished an in-home health risk assessment on or after
4 January 1, 2021, such plan shall ensure that such
5 assessment includes information on the safe disposal
6 of prescription drugs that are controlled substances
7 that meets the criteria established under paragraph
8 (2). Such information shall include information on
9 drug takeback programs that meet such require-
10 ments determined appropriate by the Secretary and
11 information on in-home disposal.

12 “(2) CRITERIA.—The Secretary shall, through
13 rulemaking, establish criteria the Secretary deter-
14 mines appropriate with respect to information pro-
15 vided to an individual to ensure that such informa-
16 tion sufficiently educates such individual on the safe
17 disposal of prescription drugs that are controlled
18 substances.”.

19 (b) PRESCRIPTION DRUG PLANS.—Section 1860D-
20 4(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w-
21 104(c)(2)(B)) is amended—

22 (1) by striking “may include elements that pro-
23 mote”;

1 (2) by redesignating clauses (i) through (iii) as
2 subclauses (I) through (III) and adjusting the mar-
3 gins accordingly;

4 (3) by inserting before subclause (I), as so re-
5 designated, the following new clause:

6 “(i) may include elements that pro-
7 mote—”;

8 (4) in subclause (III), as so redesignated, by
9 striking the period at the end and inserting “; and”;
10 and

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

13 “(ii) with respect to plan years begin-
14 ning on or after January 1, 2021, shall
15 provide for—

16 “(I) the provision of information
17 to the enrollee on the safe disposal of
18 prescription drugs that are controlled
19 substances that meets the criteria es-
20 tablished under section 1852(n)(2),
21 including information on drug
22 takeback programs that meet such re-
23 quirements determined appropriate by
24 the Secretary and information on in-
25 home disposal; and

1 “(II) cost-effective means by
2 which an enrollee may so safely dis-
3 pose of such drugs.”.

4 **SEC. 6114. REVISING MEASURES USED UNDER THE HOS-**
5 **PITAL CONSUMER ASSESSMENT OF**
6 **HEALTHCARE PROVIDERS AND SYSTEMS**
7 **SURVEY RELATING TO PAIN MANAGEMENT.**

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

12 “(XII)(aa) With respect to a Hospital Consumer As-
13 sessment of Healthcare Providers and Systems survey (or
14 a successor survey) conducted on or after January 1,
15 2019, such survey may not include questions about com-
16 munication by hospital staff with an individual about such
17 individual’s pain unless such questions take into account,
18 as applicable, whether an individual experiencing pain was
19 informed about risks associated with the use of opioids
20 and about non-opioid alternatives for the treatment of
21 pain.

22 “(bb) The Secretary shall not include on the Hospital
23 Compare Internet website any measures based on the
24 questions appearing on the Hospital Consumer Assess-
25 ment of Healthcare Providers and Systems survey in 2018

1 about communication by hospital staff with an individual
2 about such individual’s pain.”.

3 (b) RESTRICTION ON USE OF 2018 PAIN QUESTIONS
4 IN THE HOSPITAL VALUE-BASED PURCHASING PRO-
5 GRAM.—Section 1886(o)(2)(B) of the Social Security Act
6 (42 U.S.C. 1395ww(o)(2)(B)) is amended by adding at the
7 end the following new clause:

8 “(iii) HCAHPS PAIN QUESTIONS.—
9 The Secretary may not include under sub-
10 paragraph (A) a measure that is based on
11 the questions appearing on the Hospital
12 Consumer Assessment of Healthcare Pro-
13 viders and Systems survey in 2018 about
14 communication by hospital staff with an
15 individual about the individual’s pain.”.

16 **TITLE VII—OTHER HEALTH**
17 **PROVISIONS**

18 **Subtitle A—Synthetic Drug**
19 **Awareness**

20 **SEC. 7001. SHORT TITLE.**

21 This subtitle may be cited as the “Synthetic Drug
22 Awareness Act of 2018”.

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

3 (a) IN GENERAL.—Not later than three years after
4 the date of the enactment of this Act, the Surgeon General
5 of the Public Health Service shall submit to Congress a
6 report on the health effects of new psychoactive substances
7 (including synthetic drugs) used since January 2010 by
8 persons who are at least 12 years of age but no more than
9 18 years of age.

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

15 **Subtitle B—Empowering Phar-**
16 **macists in the Fight Against**
17 **Opioid Abuse**

18 **SEC. 7011. SHORT TITLE.**

19 This subtitle may be cited as the “Empowering Phar-
20 macists in the Fight Against Opioid Abuse Act”.

21 **SEC. 7012. PROGRAMS AND MATERIALS FOR TRAINING ON**
22 **CERTAIN CIRCUMSTANCES UNDER WHICH A**
23 **PHARMACIST MAY DECLINE TO FILL A PRE-**
24 **SCRIPTION.**

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

1 Human Services, in consultation with the Administrator
2 of the Drug Enforcement Administration, the Commis-
3 sioner of Food and Drugs, the Director of the Centers for
4 Disease Control and Prevention, and the Assistant Sec-
5 retary for Mental Health and Substance Use, shall develop
6 and disseminate programs and materials for training
7 pharmacists, health care providers, and patients on—

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

17 (2) any Federal requirements pertaining to de-
18 clining to fill a prescription under such circum-
19 stances.

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

23 (1) pharmacists on how to decline to fill a pre-
24 scription and actions to take after declining to fill a
25 prescription; and

1 (2) other health care practitioners and the pub-
2 lic on a pharmacist’s responsibility to decline to fill
3 prescriptions in certain circumstances.

4 (c) **STAKEHOLDER INPUT.**—In developing the pro-
5 grams and materials required under subsection (a), the
6 Secretary of Health and Human Services shall seek input
7 from relevant national, State, and local associations,
8 boards of pharmacy, medical societies, licensing boards,
9 health care practitioners, and patients.

10 **Subtitle C—Indexing Narcotics,** 11 **Fentanyl, and Opioids**

12 **SEC. 7021. SHORT TITLE.**

13 This subtitle may be cited as the “Indexing Nar-
14 cotics, Fentanyl, and Opioids Act of 2018” or the “INFO
15 Act”.

16 **SEC. 7022. ESTABLISHMENT OF SUBSTANCE USE DISORDER** 17 **INFORMATION DASHBOARD.**

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

21 **“SEC. 1711. ESTABLISHMENT OF SUBSTANCE USE DIS-** 22 **ORDER INFORMATION DASHBOARD.**

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

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

4 “(1) coordinates information on programs with-
5 in the Department of Health and Human Services
6 related to the reduction of opioid abuse and other
7 substance use disorders;

8 “(2) provides access to publicly available data
9 from other Federal agencies; State, local, and Tribal
10 governments; nonprofit organizations; law enforce-
11 ment; medical experts; public health educators; and
12 research institutions regarding prevention, treat-
13 ment, recovery, and other services for opioid use dis-
14 order and other substance use disorders;

15 “(3) provides comparable data on substance use
16 disorder prevention and treatment strategies in dif-
17 ferent regions and population of the United States;

18 “(4) provides recommendations for health care
19 providers on alternatives to controlled substances for
20 pain management, including approaches studied by
21 the National Institutes of Health Pain Consortium
22 and the National Center for Complimentary and In-
23 tegrative Health; and

1 “(5) provides guidelines and best practices for
2 health care providers regarding treatment of sub-
3 stance use disorders.

4 “(b) CONTROLLED SUBSTANCE DEFINED.—In this
5 section, the term ‘controlled substance’ has the meaning
6 given that term in section 102 of the Controlled Sub-
7 stances Act (21 U.S.C. 802).”.

8 **SEC. 7023. INTERAGENCY SUBSTANCE USE DISORDER CO-**
9 **ORDINATING COMMITTEE.**

10 (a) ESTABLISHMENT.—Not later than three months
11 after the date of the enactment of this Act, the Secretary
12 of Health and Human Services (in this section referred
13 to as the “Secretary”) shall, in consultation with the Di-
14 rector of National Drug Control Policy, establish a com-
15 mittee, to be known as the Interagency Substance Use
16 Disorder Coordinating Committee (in this section referred
17 to as the “Committee”), to coordinate all efforts within
18 the Department of Health and Human Services con-
19 cerning substance use disorder.

20 (b) MEMBERSHIP.—

21 (1) FEDERAL MEMBERS.—The following indi-
22 viduals shall be the Federal members of the Com-
23 mittee:

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

1 (B) The Attorney General of the United
2 States.

3 (C) The Secretary of Labor.

4 (D) The Secretary of Housing and Urban
5 Development.

6 (E) The Secretary of Education.

7 (F) The Secretary of Veterans Affairs.

8 (G) The Commissioner of Social Security.

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

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

13 (J) The Director of the National Institutes
14 of Health and the Directors of such national re-
15 search institutes of the National Institutes of
16 Health as the Secretary determines appropriate.

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

19 (L) The Director of National Drug Control
20 Policy.

21 (M) Representatives of other Federal agen-
22 cies that serve individuals with substance use
23 disorder.

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

4 (A) at least two such members shall be an
5 individual who has received treatment for a di-
6 agnosis of an opioid use disorder;

7 (B) at least two such members shall be an
8 individual who has received treatment for a di-
9 agnosis of a substance use disorder other than
10 an opioid use disorder;

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

13 (D) at least two such members shall be a
14 representative of a leading research, advocacy,
15 or service organization for adults with sub-
16 stance use disorder;

17 (E) at least two such members shall—
18 (i) be a physician, licensed mental
19 health professional, advance practice reg-
20 istered nurse, or physician assistant; and

21 (ii) have experience in treating indi-
22 viduals with opioid use disorder or other
23 substance use disorders;

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

1 who is employed with an opioid treatment pro-
2 gram;

3 (G) at least one such member shall be a
4 substance use disorder treatment professional
5 who has research or clinical experience in work-
6 ing with racial and ethnic minority populations;

7 (H) at least one such member shall be a
8 substance use disorder treatment professional
9 who has research or clinical mental health expe-
10 rience in working with medically underserved
11 populations;

12 (I) at least one such member shall be a
13 State-certified substance use disorder peer sup-
14 port specialist;

15 (J) at least one such member shall be a
16 drug court judge or a judge with experience in
17 adjudicating cases related to substance use dis-
18 order;

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

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

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

3 (c) TERMS.—

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

8 (2) VACANCIES.—A vacancy on the Committee
9 shall be filled in the same manner in which the origi-
10 nal appointment was made. Any individual appointed
11 to fill a vacancy for an unexpired term shall be ap-
12 pointed for the remainder of such term and may
13 serve after the expiration of such term until a suc-
14 cessor has been appointed.

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

17 (e) DUTIES.—The Committee shall—

18 (1) monitor opioid use disorder and other sub-
19 stance use disorder research, services, and support
20 and prevention activities across all relevant Federal
21 agencies, including coordination of Federal activities
22 with respect to opioid use disorder and other sub-
23 stance use disorders;

24 (2) identify and provide to the Secretary rec-
25 ommendations for improving Federal grants and

1 programs for the prevention and treatment of, and
2 recovery from, opioid use disorder and other sub-
3 stance use disorders;

4 (3) review substance use disorder prevention
5 and treatment strategies in different regions and
6 populations in the United States and evaluate the
7 extent to which Federal substance use disorder pre-
8 vention and treatment strategies are aligned with
9 State and local substance use disorder prevention
10 and treatment strategies;

11 (4) make recommendations to the Secretary re-
12 garding any appropriate changes with respect to the
13 activities and strategies described in paragraphs (1)
14 through (3);

15 (5) make recommendations to the Secretary re-
16 garding public participation in decisions relating to
17 opioid use disorder and other substance use dis-
18 orders and the process by which public feedback can
19 be better integrated into such decisions; and

20 (6) make recommendations to ensure that
21 opioid use disorder and other substance use disorder
22 research, services, and support and prevention activi-
23 ties of the Department of Health and Human Serv-
24 ices and other Federal agencies are not unneces-
25 sarily duplicative.

1 (f) ANNUAL REPORT.—

2 (1) IN GENERAL.—Not later than one year
3 after the date of the enactment of this Act, and an-
4 nually thereafter for the life of the Committee, the
5 Committee shall publish on the public information
6 dashboard established under section 7022(a) a re-
7 port summarizing the activities carried out by the
8 Committee pursuant to subsection (e), including any
9 findings resulting from such activities.

10 (2) RECOMMENDATION FOR COMMITTEE EX-
11 TENSION.—After the publication of the second re-
12 port of the Committee under paragraph (1), the Sec-
13 retary shall submit to Congress a recommendation
14 on whether or not the operations of the Committee
15 should continue after the termination date described
16 in subsection (i).

17 (g) WORKING GROUPS.—The Committee may estab-
18 lish working groups for purposes of carrying out the duties
19 described in subsection (e). Any such working group shall
20 be composed of members of the Committee (or the des-
21 ignees of such members) and may hold such meetings as
22 are necessary to enable the working group to carry out
23 the duties delegated to the working group.

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

1 apply to the Committee only to the extent that the provi-
2 sions of such Act do not conflict with the requirements
3 of this section.

4 (i) SUNSET.—The Committee shall terminate on the
5 date that is six years after the date on which the Com-
6 mittee is established under subsection (a).

7 **Subtitle D—Ensuring Access to**
8 **Quality Sober Living**

9 **SEC. 7031. SHORT TITLE.**

10 This subtitle may be cited as the “Ensuring Access
11 to Quality Sober Living Act of 2018”.

12 **SEC. 7032. NATIONAL RECOVERY HOUSING BEST PRAC-**
13 **TICES.**

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

16 **“SEC. 399V-7. NATIONAL RECOVERY HOUSING BEST PRAC-**
17 **TICES.**

18 “(a) BEST PRACTICES.—The Secretary of Health
19 and Human Services, in consultation with the Secretary
20 for Housing and Urban Development, patients with a his-
21 tory of opioid use disorder, and other stakeholders, which
22 may include State accrediting entities and reputable pro-
23 viders, analysts, and stakeholders of recovery housing
24 services, such as the National Alliance for Recovery Resi-
25 dences, shall identify or facilitate the development of best

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

4 “(b) DISSEMINATION.—The Secretary shall dissemi-
5 nate the best practices identified or developed under sub-
6 section (a) to—

7 “(1) State agencies, which may include the pro-
8 vision of technical assistance to State agencies seek-
9 ing to adopt or implement such best practices;

10 “(2) recovery housing entities; and

11 “(3) the public, as appropriate.

12 “(c) DEFINITIONS.—In this section:

13 “(1) The term ‘recovery housing’ means a
14 shared living environment free from alcohol and il-
15 licit drug use and centered on peer support and con-
16 nection to services, including medication-assisted
17 treatment services, that promote sustained recovery
18 from substance use disorders.

19 “(2) The term ‘State’ includes any of the sev-
20 eral States, the District of Columbia, each Indian
21 tribe or tribal organization (as those terms are de-
22 fined in section 4 of the Indian Self-Determination
23 and Education Assistance Act), and any territory or
24 possession of the United States.

1 “(d) AUTHORIZATION OF APPROPRIATIONS.—To
2 carry out this section, there is authorized to be appro-
3 priated \$3,000,000 for the period of fiscal years 2019
4 through 2021.”.

5 **Subtitle E—Advancing Cutting** 6 **Edge Research**

7 **SEC. 7041. SHORT TITLE.**

8 This subtitle may be cited as the “Advancing Cutting
9 Edge Research Act” or the “ACE Research Act”.

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

11 Section 402(n)(1) of the Public Health Service Act
12 (42 U.S.C. 282(n)(1)) is amended—

- 13 (1) in subparagraph (A), by striking “or”;
14 (2) in subparagraph (B), by striking the period
15 and inserting “; or”; and
16 (3) by adding at the end the following:

17 “(C) high impact cutting-edge research
18 that fosters scientific creativity and increases
19 fundamental biological understanding leading to
20 the prevention, diagnosis, or treatment of dis-
21 eases and disorders, or research urgently re-
22 quired to respond to a public health threat.”.

23 **Subtitle F—Jessie’s Law**

24 **SEC. 7051. SHORT TITLE.**

25 This subtitle may be cited as “Jessie’s Law”.

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

3 (a) BEST PRACTICES.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this Act, the Secretary of
6 Health and Human Services, in consultation with
7 appropriate stakeholders, including a patient with a
8 history of opioid use disorder, an expert in electronic
9 health records, an expert in the confidentiality of pa-
10 tient health information and records, and a health
11 care provider, shall identify or facilitate the develop-
12 ment of best practices regarding—

13 (A) the circumstances under which infor-
14 mation that a patient has provided to a health
15 care provider regarding such patient's history of
16 opioid use disorder should, only at the patient's
17 request, be prominently displayed in the med-
18 ical records (including electronic health records)
19 of such patient;

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

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

25 (2) DISSEMINATION.—The Secretary shall dis-
26 seminate the best practices developed under para-

1 graph (1) to health care providers and State agen-
2 cies.

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

7 (1) The potential for addiction relapse or over-
8 dose, including overdose death, when opioid medica-
9 tions are prescribed to a patient recovering from
10 opioid use disorder.

11 (2) The benefits of displaying information
12 about a patient's opioid use disorder history in a
13 manner similar to other potentially lethal medical
14 concerns, including drug allergies and contraindica-
15 tions.

16 (3) The importance of prominently displaying
17 information about a patient's opioid use disorder
18 when a physician or medical professional is pre-
19 scribing medication, including methods for avoiding
20 alert fatigue in providers.

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

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

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

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

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

11 (a) PROMOTING AWARENESS OF AUTHORIZED DIS-
12 CLOSURES DURING EMERGENCIES.—The Secretary of
13 Health and Human Services, acting through the Adminis-
14 trator of the Centers for Medicare & Medicaid Services
15 and the Administrator of the Health Resources and Serv-
16 ices Administration, shall annually develop and dissemi-
17 nate written materials (electronically or by other means)
18 to health care providers regarding permitted disclosures
19 under Federal health care privacy law during emergencies,
20 including overdoses, of certain health information to fami-
21 lies, caregivers, and health care providers.

22 (b) USE OF MATERIAL.—For the purposes of car-
23 rying out subsection (a), the Secretary of Health and
24 Human Services may use material produced under section

1 11004 of the 21st Century Cures Act (42 U.S.C. 1320d–
2 2 note).

3 **Subtitle G—Safe Disposal of**
4 **Unused Medication**

5 **SEC. 7061. SHORT TITLE.**

6 This subtitle may be cited as the “Safe Disposal of
7 Unused Medication Act”.

8 **SEC. 7062. DISPOSAL OF CONTROLLED SUBSTANCES OF A**
9 **DECEASED HOSPICE PATIENT BY EMPLOY-**
10 **EES OF A QUALIFIED HOSPICE PROGRAM.**

11 Subsection (g) of section 302 of the Controlled Sub-
12 stances Act (21 U.S.C. 822) is amended by adding at the
13 end the following:

14 “(5)(A) In the case of a person receiving hospice care,
15 an employee of a qualified hospice program, acting within
16 the scope of employment, may handle, without being reg-
17 istered under this section, any controlled substance that
18 was lawfully dispensed to the person receiving hospice
19 care, for the purpose of disposal of the controlled sub-
20 stance after the death of such person, so long as such dis-
21 posal occurs onsite in accordance with all applicable Fed-
22 eral, State, Tribal, and local law.

23 “(B) For the purposes of this paragraph:

1 “(i) The terms ‘hospice care’ and ‘hospice pro-
2 gram’ have the meanings given to those terms in
3 section 1861(dd) of the Social Security Act.

4 “(ii) The term ‘employee of a qualified hospice
5 program’ means a physician, nurse, or other person
6 who—

7 “(I) is employed by, or pursuant to ar-
8 rangements made by, a qualified hospice pro-
9 gram;

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

13 “(bb) is acting within the scope of such
14 employment in accordance with applicable State
15 law; and

16 “(III) has completed training through the
17 qualified hospice program regarding the dis-
18 posal of controlled substances in a secure and
19 responsible manner so as to discourage abuse,
20 misuse, or diversion.

21 “(iii) The term ‘qualified hospice program’
22 means a hospice program that—

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

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

3 “(II) at the time when the controlled sub-
4 stances are first ordered—

5 “(aa) provides a copy of the written
6 policies and procedures to the patient or
7 patient representative and family;

8 “(bb) discusses the policies and proce-
9 dures with the patient or representative
10 and the family in a language and manner
11 that they understand to ensure that these
12 parties are educated regarding the safe
13 disposal of controlled substances; and

14 “(cc) documents in the patient's clin-
15 ical record that the written policies and
16 procedures were provided and discussed;
17 and

18 “(III) at the time following the disposal of
19 the controlled substances—

20 “(aa) documents in the patient's clin-
21 ical record the type of controlled sub-
22 stance, dosage, route of administration,
23 and quantity so disposed; and

24 “(bb) the time, date, and manner in
25 which that disposal occurred.”.

1 **Subtitle H—Substance Use Dis-**
2 **order Workforce Loan Repay-**
3 **ment**

4 **SEC. 7071. SHORT TITLE.**

5 This subtitle may be cited as the “Substance Use
6 Disorder Workforce Loan Repayment Act of 2018”.

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

9 Title VII of the Public Health Service Act is amend-
10 ed—

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

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

14 **“PART F—SUBSTANCE USE DISORDER**
15 **TREATMENT EMPLOYEES**

16 **“SEC. 781. LOAN REPAYMENT PROGRAM FOR SUBSTANCE**
17 **USE DISORDER TREATMENT EMPLOYEES.**

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

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

1 “(2) the individuals each agree to complete a
2 period of service in a substance use disorder treat-
3 ment job, as described in subsection (d).

4 “(b) PAYMENTS.—For each year of obligated service
5 by an individual pursuant to an agreement under sub-
6 section (a), the Secretary shall make a payment to such
7 individual as follows:

8 “(1) SERVICE IN A SHORTAGE AREA.—The Sec-
9 retary shall pay—

10 “(A) for each year of obligated service by
11 an individual pursuant to an agreement under
12 subsection (a), $\frac{1}{6}$ of the principal of and inter-
13 est on each eligible loan of the individual which
14 is outstanding on the date the individual began
15 service pursuant to the agreement; and

16 “(B) for completion of the sixth and final
17 year of such service, the remainder of such
18 principal and interest.

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

22 “(c) ELIGIBLE LOANS.—The loans eligible for repay-
23 ment under this section are each of the following:

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

1 “(2) Any loan under part E of title VIII (relat-
2 ing to nursing student loans).

3 “(3) Any Federal Direct Stafford Loan, Fed-
4 eral Direct PLUS Loan, or Federal Direct Unsub-
5 sidized Stafford Loan, or Federal Direct Consolida-
6 tion Loan (as such terms are used in section 455 of
7 the Higher Education Act of 1965).

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

10 “(5) Any other Federal loan as determined ap-
11 propriate by the Secretary.

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

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

20 “(2) a county (or a municipality, if not con-
21 tained within any county) where the mean drug
22 overdose death rate per 100,000 people over the past
23 3 years for which official data is available from the
24 State, is higher than the most recent available na-
25 tional average overdose death rate per 100,000 peo-

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

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

6 “(1) this subsection; and

7 “(2) any Federally supported loan forgiveness
8 program, including under section 338B, 338I, or
9 846 of this Act, or section 428J, 428 L, 455(m), or
10 460 of the Higher Education Act of 1965.

11 “(f) BREACH.—

12 “(1) LIQUIDATED DAMAGES FORMULA.—The
13 Secretary may establish a liquidated damages for-
14 mula to be used in the event of a breach of an
15 agreement entered into under subsection (a).

16 “(2) LIMITATION.—The failure by an individual
17 to complete the full period of service obligated pur-
18 suant to such an agreement, taken alone, shall not
19 constitute a breach of the agreement, so long as the
20 individual completed in good faith the years of serv-
21 ice for which payments were made to the individual
22 under this section.

23 “(g) ADDITIONAL CRITERIA.—The Secretary—

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

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

3 “(2) shall give notice to the committees speci-
4 fied in subsection (h) of any criteria and rules so es-
5 tablished.

6 “(h) REPORT TO CONGRESS.—Not later than 5 years
7 after the date of enactment of the Substance Use Disorder
8 Workforce Loan Repayment Act of 2018, and every other
9 year thereafter, the Secretary shall prepare and submit
10 to the Committee on Energy and Commerce of the House
11 of Representatives and the Committee on Health, Edu-
12 cation, Labor, and Pensions of the Senate a report on—

13 “(1) the number and location of borrowers who
14 have qualified for loan repayments under this sec-
15 tion; and

16 “(2) the impact of this section on the avail-
17 ability of substance use disorder treatment employ-
18 ees nationally and in shortage areas and counties de-
19 scribed in subsection (d).

20 “(i) DEFINITION.—In this section:

21 “(1) The term ‘municipality’ means a city,
22 town, or other public body created by or pursuant to
23 State law, or an Indian Tribe.

1 “(2) The term ‘substance use disorder treat-
2 ment job’ means a full-time job (including a fellow-
3 ship)—

4 “(A) where the primary intent and func-
5 tion of the job is the direct treatment or recov-
6 ery support of patients with or in recovery from
7 a substance use disorder, such as a physician,
8 physician assistant, registered nurse, nurse
9 practitioner, advanced practice registered nurse,
10 social worker, recovery coach, mental health
11 counselor, addictions counselor, psychologist or
12 other behavioral health professional, or any
13 other relevant professional as determine by the
14 Secretary; and

15 “(B) which is located at a substance use
16 disorder treatment program, private physician
17 practice, hospital or health system-affiliated in-
18 patient treatment center or outpatient clinic
19 (including an academic medical center-affiliated
20 treatment program), correctional facility or pro-
21 gram, youth detention center or program, inpa-
22 tient psychiatric facility, crisis stabilization
23 unit, community health center, community men-
24 tal health or other specialty community behav-
25 ioral health center, recovery center, school, com-

1 community-based organization, telehealth platform,
2 migrant health center, health program or facil-
3 ity operated by a tribe or tribal organization,
4 Federal medical facility, or any other facility as
5 determined appropriate for purposes of this sec-
6 tion by the Secretary.

7 “(j) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to carry out this section
9 \$25,000,000 for each of fiscal years 2019 through 2028.”.

10 **Subtitle I—Preventing Overdoses** 11 **While in Emergency Rooms**

12 **SEC. 7081. SHORT TITLE.**

13 This subtitle may be cited as the “Preventing
14 Overdoses While in Emergency Rooms Act of 2018”.

15 **SEC. 7082. PROGRAM TO SUPPORT EMERGENCY ROOM DIS-** 16 **CHARGE AND CARE COORDINATION FOR** 17 **DRUG OVERDOSE PATIENTS.**

18 (a) IN GENERAL.—The Secretary of Health and
19 Human Services shall establish a program (in this subtitle
20 referred to as the “Program”) to develop protocols for dis-
21 charging patients who have presented with a drug over-
22 dose and enhance the integration and coordination of care
23 and treatment options for individuals with substance use
24 disorder after discharge.

25 (b) GRANT ESTABLISHMENT AND PARTICIPATION.—

1 (1) IN GENERAL.—In carrying out the Pro-
2 gram, the Secretary shall award grants on a com-
3 petitive basis to not more than 20 eligible entities
4 described in paragraph (2).

5 (2) ELIGIBILITY.—

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

9 (i) a health care site described in sub-
10 paragraph (B); or

11 (ii) a health care site coordinator de-
12 scribed in subparagraph (C).

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

16 (i) submit an application to the Sec-
17 retary at such time, in such manner, and
18 containing such information as specified by
19 the Secretary;

20 (ii) have an emergency department;

21 (iii)(I) have a licensed health care pro-
22 fessional onsite who has a waiver under
23 section 303(g) of the Controlled Sub-
24 stances Act (21 U.S.C. 823(g)) to dispense
25 or prescribe covered drugs; or

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

6 (iv) have in place an agreement with
7 a sufficient number and range of entities
8 certified under applicable State and Fed-
9 eral law, such as pursuant to registration
10 or a waiver under section 303(g) of the
11 Controlled Substances Act (21 U.S.C.
12 823(g)) or certification as described in sec-
13 tion 8.2 of title 42 of the Code of Federal
14 Regulations, to provide treatment for sub-
15 stance use disorder such that the entity or
16 the resulting network of entities with an
17 agreement with the hospital cumulatively
18 are capable of providing all evidence-based
19 services for the treatment of substance use
20 disorder, as medically appropriate for the
21 individual involved, including—

22 (I) medication-assisted treat-
23 ment;

24 (II) withdrawal and detoxifica-
25 tion services that include patient eval-

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

3 (III) counseling;

4 (v) deploy onsite peer recovery special-
5 ists to help connect patients with treat-
6 ment and recovery support services; and

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

10 (C) HEALTH CARE SITE COORDINATORS.—

11 To be eligible for a grant under this section, a
12 health care site coordinator shall—

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

18 (ii) submit an application to the Sec-
19 retary at such time, in such manner, and
20 containing such information as specified by
21 the Secretary; and

22 (iii) have an agreement with multiple
23 eligible health care sites described in sub-
24 paragraph (B).

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

5 (A) The eligible health care site is, or the
6 eligible health care site coordinator has an
7 agreement described in paragraph (2)(C)(iii)
8 with a site that is, a critical access hospital (as
9 defined in section 1861(mm)(1) of the Social
10 Security Act (42 U.S.C. 1395x(mm)(1))), a
11 low-volume hospital (as defined in section
12 1886(d)(12)(C)(i) of such Act (42 U.S.C.
13 1395ww(d)(12)(C)(i))), or a sole community
14 hospital (as defined in section
15 1886(d)(5)(D)(iii) of such Act (42 U.S.C.
16 1395ww(d)(5)(D)(iii))).

17 (B) The eligible health care site or the eli-
18 gible health care site coordinator is located in
19 a geographic area with a drug overdose rate
20 that is higher than the national rate, or in a ge-
21 ographic area with a rate of emergency depart-
22 ment visits for overdoses that is higher than the
23 national rate, as determined by the Secretary
24 based on the most recent data from the Centers
25 for Disease Control and Prevention.

1 (4) MEDICATION-ASSISTED TREATMENT DE-
2 FINED.—For purposes of this section, the term
3 “medication-assisted treatment” means the use of a
4 drug approved under section 505 of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or
6 a biological product licensed under section 351 of
7 the Public Health Service Act (42 U.S.C. 262), in
8 combination with behavioral health services, to pro-
9 vide an individualized approach to the treatment of
10 substance use disorders, including opioid use dis-
11 orders.

12 (c) PERIOD OF GRANT.—A grant awarded to an eligi-
13 ble entity under this section shall be for a period of at
14 least 2 years.

15 (d) GRANT USES.—

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

19 (A) To establish policies and procedures
20 that address the provision of overdose reversal
21 medication, prescription and dispensing of
22 medication-assisted treatment to an emergency
23 department patient who has had a non-fatal
24 overdose or who is at risk of a drug overdose,
25 and the subsequent referral to evidence-based

1 treatment upon discharge for patients who have
2 experienced a non-fatal drug overdose or who
3 are at risk of a drug overdose.

4 (B) To develop best practices for treating
5 non-fatal drug overdoses, including with respect
6 to care coordination and integrated care models
7 for long term treatment and recovery options
8 for individuals who have experienced a non-fatal
9 drug overdose.

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

13 (A) To hire emergency department peer re-
14 covery specialists; counselors; therapists; social
15 workers; or other licensed medical professionals
16 specializing in the treatment of substance use
17 disorder.

18 (B) To establish integrated models of care
19 for individuals who have experienced a non-fatal
20 drug overdose which may include patient as-
21 sessment, follow up, and transportation to
22 treatment facilities.

23 (C) To provide for options for increasing
24 the availability and access of medication-as-
25 sisted treatment and other evidence-based treat-

1 ment for individuals with substance use dis-
2 orders.

3 (D) To offer consultation with and referral
4 to other supportive services that help in treat-
5 ment and recovery.

6 (e) REPORTING REQUIREMENTS.—

7 (1) REPORTS BY GRANTEES.—Each eligible en-
8 tity awarded a grant under this section shall submit
9 to the Secretary an annual report for each year for
10 which the entity has received such grant that in-
11 cludes information on—

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

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

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

1 uals admitted to such other facilities pursuant
2 to such referrals;

3 (D) the frequency and number of patient
4 readmissions for non-fatal overdoses and sub-
5 stance use disorder;

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

8 (F) the effectiveness of, and any other rel-
9 evant additional data regarding, having an on-
10 site health care professional to administer and
11 begin medication-assisted treatment for sub-
12 stance use disorders.

13 (2) REPORT BY SECRETARY.—Not less than
14 one year after the conclusion of the Program, the
15 Secretary shall submit to Congress a report that in-
16 cludes—

17 (A) findings of the Program;

18 (B) overall patient outcomes under the
19 Program, such as with respect to hospital read-
20 mission;

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

1 (D) an evaluation determining the effec-
2 tiveness of having a practitioner onsite to ad-
3 minister and begin medication-assisted treat-
4 ment for substance use disorder; and

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

8 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
9 authorized to be appropriated to carry out this subtitle
10 \$50,000,000 for the period of fiscal years 2019 through
11 2023.

12 **Subtitle J—Alternatives to Opioids** 13 **in the Emergency Department**

14 **SEC. 7091. SHORT TITLE.**

15 This subtitle may be cited as the “Alternatives to
16 Opioids in the Emergency Department Act” or the
17 “ALTO Act”.

18 **SEC. 7092. EMERGENCY DEPARTMENT ALTERNATIVES TO** 19 **OPIOIDS DEMONSTRATION PROGRAM.**

20 (a) DEMONSTRATION PROGRAM GRANTS.—The Sec-
21 retary of Health and Human Services (in this section re-
22 ferred to as the “Secretary”) shall carry out a demonstra-
23 tion program under which the Secretary shall award
24 grants to hospitals and emergency departments, including
25 freestanding emergency departments, to develop, imple-

1 ment, enhance, or study alternative pain management pro-
2 tocols and treatments that limit the use and prescription
3 of opioids in emergency departments.

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

9 (c) GEOGRAPHIC DIVERSITY.—In awarding grants
10 under this section, the Secretary shall seek to ensure geo-
11 graphical diversity among grant recipients.

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

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

17 (2) train providers and other hospital personnel
18 on protocols and the use of treatments that limit the
19 use and prescription of opioids in the emergency de-
20 partment; and

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

1 (e) CONSULTATION.—The Secretary shall implement
2 a process for recipients of grants under subsection (a) to
3 consult (in a manner that allows for sharing of evidence-
4 based best practices) with each other and with persons
5 having robust knowledge, including emergency depart-
6 ments and physicians that have successfully deployed al-
7 ternative pain management protocols, such as non-drug
8 approaches studied through the National Center for Com-
9 plimentary and Integrative Health including acupuncture
10 that limit the use of opioids. The Secretary shall offer to
11 each recipient of a grant under subsection (a) technical
12 support as necessary.

13 (f) REPORT TO THE SECRETARY.—Each recipient of
14 a grant under this section shall submit to the Secretary
15 (during the period of such grant) annual reports on the
16 progress of the program funded through the grant. These
17 reports shall include, in accordance with State and Fed-
18 eral statutes and regulations regarding disclosure of pa-
19 tient information—

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

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

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

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

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

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

10 (4) data on the opioid prescriptions written, in-
11 cluding—

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

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

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

18 (5) the demographic characteristics of patients
19 who were treated with an alternative pain manage-
20 ment protocol, including age, sex, race, ethnicity,
21 and insurance status and type;

22 (6) data on patients who were eventually pre-
23 scribed opioids after alternative pain management
24 protocols and treatments were employed; and

1 (7) any other information the Secretary deems
2 necessary.

3 (g) REPORT TO CONGRESS.—Not later than one year
4 after completion of the demonstration program under this
5 section, the Secretary shall submit a report to the Con-
6 gress on the results of the demonstration program and in-
7 clude in the report—

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

10 (2) a summary of the reports described in sub-
11 section (f), including standardized data; and

12 (3) recommendations for broader implementa-
13 tion of pain management protocols that limit the use
14 and prescription of opioids in emergency depart-
15 ments or other areas of the health care delivery sys-
16 tem.

17 (h) AUTHORIZATION OF APPROPRIATIONS.—To carry
18 out this section, there is authorized to be appropriated
19 \$10,000,000 for each of fiscal years 2019 through 2021.

1 **Subtitle K—Stop Counterfeit Drugs**
2 **by Regulating and Enhancing**
3 **Enforcement Now**

4 **SEC. 7101. SHORT TITLE.**

5 This subtitle may be cited as the “Stop Counterfeit
6 Drugs by Regulating and Enhancing Enforcement Now
7 Act” or the “SCREEN Act”.

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

10 (a) INCREASING THE MAXIMUM DOLLAR AMOUNT OF
11 DRUGS SUBJECT TO DESTRUCTION.—The sixth sentence
12 in section 801(a) of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 381(a)) is amended by striking “ex-
14 cept that the Secretary” and all that follows through the
15 two periods at the end and inserting “except that the Sec-
16 retary of Health and Human Services may destroy, with-
17 out the opportunity for export, any drug refused admission
18 under this section, if such drug is declared to be valued
19 at an amount that is \$2,500 or less (or such higher
20 amount as the Secretary of the Treasury may set by regu-
21 lation pursuant to section 498(a)(1) of the Tariff Act of
22 1930 or such higher amount as the Commissioner of Food
23 and Drugs may set based on a finding by the Commis-
24 sioner that the higher amount is in the interest of public
25 health), or if such drug is entering the United States by

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

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

11 (c) TECHNICAL AMENDMENTS.—The seventh, eighth,
12 and ninth sentences of section 801(a) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 381(a)) are amend-
14 ed—

15 (1) by striking “a drug” each place it appears
16 and inserting “an article”; and

17 (2) by striking “the drug” each place it appears
18 and inserting “the article”.

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

1 importation of which is permitted under the Controlled
2 Substances Import and Export Act.”.

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

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

9 “(eee) The failure to comply with any order issued
10 under section 569D.”.

11 (b) NOTIFICATION, NONDISTRIBUTION, AND RECALL
12 OF ADULTERATED OR MISBRANDED DRUGS.—Subchapter
13 E of chapter V of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 360bbb et seq.) is amended by adding at
15 the end the following:

16 **“SEC. 569D. NOTIFICATION, NONDISTRIBUTION, AND RE-**
17 **CALL OF ADULTERATED OR MISBRANDED**
18 **DRUGS.**

19 “(a) ORDER TO CEASE DISTRIBUTION AND RE-
20 CALL.—

21 “(1) IN GENERAL.—Upon a determination that
22 the use or consumption of, or exposure to, a drug
23 may present an imminent or substantial hazard to
24 the public health, the Secretary shall issue an order

1 requiring any person who distributes the drug to im-
2 mediately cease distribution of the drug.

3 “(2) HEARING.—An order under paragraph (1)
4 shall provide the person subject to the order with an
5 opportunity for an informal hearing, to be held not
6 later than 10 days after the date of issuance of the
7 order, on—

8 “(A) the actions required by the order; and

9 “(B) whether the order should be amended
10 to require a recall of the drug.

11 “(3) INADEQUATE GROUNDS.—If, after pro-
12 viding an opportunity for a hearing under paragraph
13 (2), the Secretary determines that inadequate
14 grounds exist to support the actions required by the
15 order, the Secretary shall vacate the order.

16 “(4) AMENDMENT TO ORDER TO REQUIRE RE-
17 CALL.—If, after providing an opportunity for an in-
18 formal hearing under paragraph (2), the Secretary
19 determines that the order should be amended to in-
20 clude a recall of the drug with respect to which the
21 order was issued, the Secretary shall—

22 “(A) amend the order to require a recall;

23 and

1 “(B) after consultation with the drug
2 sponsor, specify a timetable in which the recall
3 will occur.

4 “(5) NOTICE TO PERSONS AFFECTED.—An
5 order under this subsection shall require any person
6 who distributes the drug to provide for notice, in-
7 cluding to individuals as appropriate, to persons who
8 may be affected by the order to cease distribution of
9 or recall the drug, as applicable.

10 “(6) ACTION FOLLOWING ORDER.—Any person
11 who is subject to an order under paragraph (1) or
12 (4) shall immediately cease distribution of or recall,
13 as applicable, the drug and provide notification as
14 required by such order.

15 “(b) NOTICE TO CONSUMERS AND HEALTH OFFI-
16 CIALS.—The Secretary shall, as the Secretary determines
17 to be necessary, provide notice of a recall order under this
18 section to—

19 “(1) consumers to whom the drug was, or may
20 have been, distributed; and

21 “(2) appropriate State and local health officials.

22 “(c) ORDER TO RECALL.—

23 “(1) CONTENTS.—An order to recall a drug
24 under subsection (a) shall—

1 “(A) require periodic reports to the Sec-
2 retary describing the progress of the recall; and

3 “(B) provide for notice, including to indi-
4 viduals as appropriate, to persons who may be
5 affected by the recall.

6 “(2) ASSISTANCE ALLOWED.—In providing for
7 notice under paragraph (1)(B), the Secretary may
8 allow for the assistance of health professionals, State
9 or local officials, or other individuals designated by
10 the Secretary.

11 “(3) NONDELEGATION.—An order under this
12 section shall be ordered by the Secretary or an offi-
13 cial designated by the Secretary. An official may not
14 be so designated under this section unless the offi-
15 cial is the Director of the Center for Drug Evalua-
16 tion and Research, is an official senior to such Di-
17 rector, or is so designated by such Director.

18 “(d) SAVINGS CLAUSE.—Nothing contained in this
19 section shall be construed as limiting—

20 “(1) the authority of the Secretary to issue an
21 order to cease distribution of, or to recall, an drug
22 under any other provision of this Act or the Public
23 Health Service Act; or

24 “(2) the ability of the Secretary to request any
25 person to perform a voluntary activity related to any

1 drug subject to this Act or the Public Health Service
2 Act.”.

3 (c) DRUGS SUBJECT TO REFUSAL.—The third sen-
4 tence of subsection (a) of section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6 inserting “or (5) in the case of a drug, such drug is sub-
7 ject to an order under section 568 to cease distribution
8 of or recall the drug,” before “then such article shall be
9 refused admission”.

10 (d) APPLICATION.—Sections 301(eee) and 569D of
11 the Federal Food, Drug, and Cosmetic Act, as added by
12 subsections (a) and (b), shall apply with respect to a drug
13 as of such date, not later than 1 year after the date of
14 the enactment of this Act, as the Secretary of Health and
15 Human Services shall specify.

16 **SEC. 7104. SINGLE SOURCE PATTERN OF SHIPMENTS OF**
17 **ADULTERATED OR MISBRANDED DRUGS.**

18 Section 801 of the Federal Food, Drug, and Cosmetic
19 Act is amended by adding at the end the following:

20 “(t) SINGLE SOURCE PATTERN OF SHIPMENTS OF
21 ADULTERATED OR MISBRANDED DRUGS.—If the Sec-
22 retary identifies a pattern of adulterated or misbranded
23 drugs being offered for import from the same manufac-
24 turer, distributor, or importer, the Secretary may by order
25 choose to treat all drugs being offered for import from

1 such manufacturer, distributor, or importer as adulterated
2 or misbranded unless otherwise demonstrated.”.

3 **SEC. 7105. FUND TO STRENGTHEN EFFORTS OF FDA TO**
4 **COMBAT THE OPIOID AND SUBSTANCE USE**
5 **EPIDEMIC.**

6 Chapter X of the Federal Food, Drug, and Cosmetic
7 Act (21 U.S.C. 391 et seq.) is amended by adding at the
8 end the following:

9 **“SEC. 1015. FUND TO STRENGTHEN EFFORTS OF FDA TO**
10 **COMBAT THE OPIOID AND SUBSTANCE USE**
11 **EPIDEMIC.**

12 “(a) IN GENERAL.—The Commissioner of Food and
13 Drugs shall use any funds appropriated pursuant to the
14 authorization of appropriations under subsection (c) to
15 carry out the programs and activities described in sub-
16 section (d) to strengthen and facilitate the Food and Drug
17 Administration’s efforts to address the opioid and sub-
18 stance use epidemic. Such funds shall be in addition to
19 any funds which are otherwise available to carry out such
20 programs and activities.

21 “(b) FDA OPIOID AND SUBSTANCE USE EPIDEMIC
22 RESPONSE FUND.—

23 “(1) ESTABLISHMENT OF FUND.—There is es-
24 tablished in the Treasury a fund, to be known as the
25 FDA Opioid and Substance Use Epidemic Response

1 Fund (referred to in this subsection as the ‘Fund’),
2 for purposes of funding the programs and activities
3 described in subsection (d).

4 “(2) TRANSFER.—For the period of fiscal years
5 2019 through 2023, \$110,000,000 shall be trans-
6 ferred to the Fund from the general fund of the
7 Treasury.

8 “(3) AMOUNTS DEPOSITED.—Any amounts
9 transferred under paragraph (2) shall remain un-
10 available in the Fund until such amounts are appro-
11 priated pursuant to subsection (c).

12 “(c) APPROPRIATIONS.—

13 “(1) AUTHORIZATION OF APPROPRIATIONS.—
14 For the period of fiscal years 2019 through 2023,
15 there is authorized to be appropriated from the
16 Fund to the Food and Drug Administration, for the
17 purpose of carrying out the programs and activities
18 described in subsection (d), an amount not to exceed
19 the total amount transferred to the Fund under sub-
20 section (b)(2). Notwithstanding subsection (g), such
21 funds shall remain available until expended.

22 “(2) OFFSETTING FUTURE APPROPRIATIONS.—
23 For any of fiscal years 2019 through 2023, for any
24 discretionary appropriation out of the Fund to the
25 Food and Drug Administration pursuant to the au-

1 thorization of appropriations under paragraph (1)
2 for the purpose of carrying out the programs and
3 activities described in subsection (d), the total
4 amount of such appropriations for the applicable fis-
5 cal year (not to exceed the total amount remaining
6 in the Fund) shall be subtracted from the estimate
7 of discretionary budget authority and the resulting
8 outlays for any estimate under the Congressional
9 Budget and Impoundment Control Act of 1974 or
10 the Balanced Budget and Emergency Deficit Control
11 Act of 1985, and the amount transferred to the
12 Fund shall be reduced by the same amount.

13 “(d) FOOD AND DRUG ADMINISTRATION.—The en-
14 tirety of the funds made available pursuant to subsection
15 (c)(1) shall be for the Commissioner of Food and Drugs,
16 pursuant to applicable authorities in the Public Health
17 Service Act (42 U.S.C. 201 et seq.) or this Act and other
18 applicable Federal law, to support widespread innovation
19 in non-opioid and non-addictive medical products for pain
20 treatment, access to opioid addiction treatments, appro-
21 priate use of approved opioids, and efforts to reduce illicit
22 importation of opioids. Such support may include the fol-
23 lowing programs and activities:

1 “(1) Obligating contract funds beginning in fis-
2 cal year 2019 for an educational campaign that
3 will—

4 “(A) educate patients and their families to
5 differentiate opioid medications;

6 “(B) raise awareness about preferred stor-
7 age and disposal methods; and

8 “(C) inform patients, families, and commu-
9 nities about medication-assisted treatment op-
10 tions.

11 “(2) Building the Food and Drug Administra-
12 tion’s presence in international mail facilities, includ-
13 ing through—

14 “(A) improvements in equipment and in-
15 formation technology enhancements to identify
16 unapproved, counterfeit, or other unlawful
17 pharmaceuticals for destruction;

18 “(B) increased and improved surveillance;

19 “(C) renovations at international mail fa-
20 cility locations; and

21 “(D) the purchase of laboratory equip-
22 ment.

23 “(3) Enhancing the identification and targeting
24 of entities offering products and products being of-
25 fered by such entities for import into the United

1 States through review and analysis of Internet
2 websites, import data, and other sources of intel-
3 ligence for purposes of making the best use of the
4 Food and Drug Administration's inspection and ana-
5 lytical resources.

6 “(4) Increasing the number of staff of the Food
7 and Drug Administration to increase the number of
8 packages being examined, ensuring the safety of the
9 staff undertaking such examinations, and ensuring
10 that packages identified as illegal, counterfeit, mis-
11 branded, or adulterated are removed from commerce
12 through available authorities, including administra-
13 tive destruction.

14 “(5) Enhancing the Food and Drug Adminis-
15 tration's criminal investigations resources (including
16 full-time equivalent employees and equipment), im-
17 ports surveillance, and international work.

18 “(6) Obtaining for the Food and Drug Admin-
19 istration equipment and full-time equivalent employ-
20 ees needed to efficiently screen and analyze products
21 offered for import, including by building data librar-
22 ies of new substances and analogues to facilitate
23 identification and evaluation of pharmaceutical-
24 based agents and by purchasing screening tech-
25 nologies for use at international mail facilities.

1 “(7) Operating the Food and Drug Administra-
2 tion’s forensic laboratory facility to ensure adequate
3 laboratory space and functionality for additional
4 work and full-time equivalent employees.

5 “(e) ACCOUNTABILITY AND OVERSIGHT.—

6 “(1) WORK PLAN.—

7 “(A) IN GENERAL.—Not later than 180
8 days after the date of enactment of this Act,
9 the Commissioner of Food and Drugs shall sub-
10 mit to the Committee on Health, Education,
11 Labor and Pensions of the Senate and the
12 Committee on Energy and Commerce of the
13 House of Representatives, a work plan includ-
14 ing the proposed allocation of funds appro-
15 priated pursuant to the authorization of appro-
16 priations under subsection (c) for each of fiscal
17 years 2019 through 2023 and the contents de-
18 scribed in subparagraph (B).

19 “(B) CONTENTS.—The work plan sub-
20 mitted under subparagraph (A) shall include—

21 “(i) the amount of money to be obli-
22 gated or expended out of the Fund in each
23 fiscal year for each program and activity
24 described in subsection (d); and

1 “(ii) a description and justification of
2 each such program and activity.

3 “(2) REPORTS.—

4 “(A) ANNUAL REPORTS.—Not later than
5 October 1 of each of fiscal years 2020 through
6 2024, the Secretary of Health and Human
7 Services shall submit to the Committee on
8 Health, Education, Labor and Pensions of the
9 Senate and the Committee on Energy and Com-
10 merce of the House of Representatives a report
11 that includes—

12 “(i) the amount of money obligated or
13 expended out of the Fund in the prior fis-
14 cal year for each program and activity de-
15 scribed in subsection (d);

16 “(ii) a description of all programs and
17 activities using funds provided pursuant to
18 the authorization of appropriations under
19 subsection (c); and

20 “(iii) how the programs and activities
21 are advancing public health.

22 “(B) ADDITIONAL REPORTS.—At the re-
23 quest of the Committee on Health, Education,
24 Labor and Pensions of the Senate or the Com-
25 mittee on Energy and Commerce of the House

1 of Representatives, the Commissioner shall pro-
2 vide an update in the form of testimony and
3 any additional reports to the respective congress-
4 sional committee regarding the allocation of
5 funding under this section or the description of
6 the programs and activities undertaken with
7 such funding.

8 “(f) LIMITATIONS.—Notwithstanding any transfer
9 authority authorized by this section or any appropriations
10 Act, any funds made available pursuant to the authoriza-
11 tion of appropriations under subsection (c) may not be
12 used for any purpose other than the programs and activi-
13 ties described in subsection (d) to strengthen and facilitate
14 the Food and Drug Administration’s efforts to address the
15 opioid and substance use epidemic.

16 “(g) SUNSET.—This section shall expire on Sep-
17 tember 30, 2022, except that—

18 “(1) this subsection does not apply to reporting
19 under subsection (e)(2); and

20 “(2) this section shall remain in effect until
21 such time, and to such extent, as may be necessary
22 for the funds transferred by subsection (b)(2) to be
23 fully expended.”.

1 **SEC. 7106. CONSIDERATION OF POTENTIAL FOR MISUSE**
2 **AND ABUSE REQUIRED FOR DRUG AP-**
3 **PROVAL.**

4 (a) IN GENERAL.—Section 505(d) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)) is
6 amended—

7 (1) in the first sentence—

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

10 (B) by inserting “or (8) if the drug is or
11 contains a controlled substance for which a list-
12 ing in any schedule is in effect under the Con-
13 trolled Substances Act or that is permanently
14 scheduled pursuant to section 201 of such Act,
15 on the basis of information submitted to him as
16 part of the application, or upon the basis of any
17 other information before him with respect to
18 such drug, the drug is unsafe for use due to the
19 risks of abuse or misuse or there is insufficient
20 information to show that the drug is safe for
21 use considering such risks;” before “he shall
22 issue an order refusing to approve the applica-
23 tion”; and

24 (2) in the second sentence, by striking “(6)”
25 and inserting “(8)”.

1 (b) WITHDRAWAL AUTHORITY.—Section 505(e) of
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 355(e)) is amended in the first sentence—

4 (1) by striking “or (5)” and inserting “(5)”;

5 and

6 (2) by inserting the following: “; or (6) that, in
7 the case of a drug that is or contains a controlled
8 substance for which a listing in any schedule is in
9 effect under the Controlled Substances Act or that
10 is permanently scheduled pursuant to section 201 of
11 such Act, on the basis of new information before him
12 with respect to such drug, evaluated together with
13 the information available to him when the applica-
14 tion was approved, that the drug is unsafe for use
15 due to the risks of abuse or misuse” after “of a ma-
16 terial fact”.

17 (c) RULE OF CONSTRUCTION.—Nothing in the
18 amendments made by this section shall be construed to
19 limit or narrow, in any manner, the meaning or applica-
20 tion of the provisions of paragraphs (1), (2), (3), (4), (5),
21 and (7) of section 505(d) of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 355(d)) or paragraphs (1) and
23 (2) of section 505(e) of such Act (21 U.S.C. 355(e)).

1 **Subtitle L—Treatment, Education,**
2 **and Community Help to Combat**
3 **Addiction**

4 **SEC. 7111. SHORT TITLE.**

5 This subtitle may be cited as the “Treatment, Edu-
6 cation, and Community Help to Combat Addiction Act of
7 2018” or the “TEACH to Combat Addiction Act of
8 2018”.

9 **SEC. 7112. ESTABLISHMENT OF REGIONAL CENTERS OF EX-**
10 **CELLENCE IN SUBSTANCE USE DISORDER**
11 **EDUCATION.**

12 Part D of title V of the Public Health Service Act
13 is amended by inserting after section 549 (42 U.S.C.
14 290ee–4) the following new section:

15 **“SEC. 550. REGIONAL CENTERS OF EXCELLENCE IN SUB-**
16 **STANCE USE DISORDER EDUCATION.**

17 “(a) IN GENERAL.—The Secretary, in consultation
18 with such other agencies as are appropriate, shall, subject
19 to the availability of appropriations, establish a solicitation
20 process and award cooperative agreements to eligible enti-
21 ties for the designation of such entities as Regional Cen-
22 ters of Excellence in Substance Use Disorder Education
23 and support of such regional centers of excellence to en-
24 hance and improve how health professionals are educated
25 in substance use disorder prevention, treatment, and re-

1 covery through development, evaluation, and distribution
2 of evidence-based curricula for health profession schools.
3 An eligible entity designated by the Secretary as a Re-
4 gional Center of Excellence in Substance Use Disorder
5 Education shall carry out the activities described in sub-
6 section (b).

7 “(b) SELECTION OF CENTERS OF EXCELLENCE.—

8 “(1) ELIGIBLE ENTITIES.—To be eligible to re-
9 ceive a cooperative agreement under subsection (a),
10 an entity shall—

11 “(A) be an entity specified by the Sec-
12 retary that offers education to students in var-
13 ious health professions, which may include—

14 “(i) a health system;

15 “(ii) a teaching hospital;

16 “(iii) a medical school;

17 “(iv) a certified behavioral health clin-
18 ic; or

19 “(v) any other health profession
20 school, school of public health, or Coopera-
21 tive Extension Program at institutions of
22 higher education engaged in an aspect of
23 the prevention, treatment, or recovery of
24 substance use disorders;

1 “(B) be accredited by the appropriate edu-
2 cational accreditation body;

3 “(C) demonstrate an existing strategy, and
4 have in place a plan for continuing such strat-
5 egy, or a proposed strategy to implement a cur-
6 riculum based on best practices for substance
7 use disorder prevention, treatment, and recov-
8 ery;

9 “(D) demonstrate community engagement
10 and participation through community partners,
11 including other health profession schools, men-
12 tal health counselors, social workers, peer recov-
13 ery specialists, substance use treatment pro-
14 grams, community health centers, physicians’
15 offices, certified behavioral health clinics, law
16 enforcement, and the business community; and

17 “(E) provide to the Secretary such infor-
18 mation, at such time, and in such manner, as
19 the Secretary may require.

20 “(2) DIVERSITY.—In awarding cooperative
21 agreements under subsection (a), the Secretary shall
22 take into account regional differences among eligible
23 entities and shall make an effort to ensure geo-
24 graphic diversity.

25 “(c) DISSEMINATION OF INFORMATION.—

1 “(1) PUBLIC POSTING.—The Secretary shall
2 make information provided to the Secretary under
3 subsection (b)(1)(E) publically available on the
4 Internet website of the Department of Health and
5 Human Services.

6 “(2) EVALUATION.—The Secretary shall evalu-
7 ate each project carried out by a Regional Center of
8 Excellence in Substance Use Disorder Education
9 under this section and shall disseminate the findings
10 with respect to each such evaluation to appropriate
11 public and private entities.

12 “(d) FUNDING.—There is authorized to be appro-
13 priated to carry out this section, \$4,000,000 for each of
14 fiscal years 2019 through 2023.”.

15 **Subtitle M—Guidance From Na-**
16 **tional Mental Health and Sub-**
17 **stance Use Policy Laboratory**

18 **SEC. 7121. GUIDANCE FROM NATIONAL MENTAL HEALTH**
19 **AND SUBSTANCE USE POLICY LABORATORY.**

20 Section 501A(b) of the Public Health Service Act (42
21 U.S.C. 290aa–0(b)) is amended—

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

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

1 (3) by adding at the end the following:

2 “(7) issue and periodically update guidance for
3 entities applying for grants from the Substance
4 Abuse and Mental Health Services Administration in
5 order to—

6 “(A) encourage the funding of evidence-
7 based practices;

8 “(B) encourage the replication of prom-
9 ising or effective practices; and

10 “(C) inform applicants on how to best ar-
11 ticulate the rationale for the funding of a pro-
12 gram or activity.”.

13 **Subtitle N—Comprehensive Opioid** 14 **Recovery Centers**

15 **SEC. 7131. SHORT TITLE.**

16 This subtitle may be cited as the “Comprehensive
17 Opioid Recovery Centers Act of 2018”.

18 **SEC. 7132. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

19 (a) IN GENERAL.—Part D of title V of the Public
20 Health Service Act is amended by adding at the end the
21 following new section:

22 **“SEC. 550. COMPREHENSIVE OPIOID RECOVERY CENTERS.**

23 “(a) IN GENERAL.—The Secretary shall award
24 grants on a competitive basis to eligible entities to estab-

1 lish or operate a comprehensive opioid recovery center (re-
2 ferred to in this section as a ‘Center’).

3 “(b) GRANT PERIOD.—

4 “(1) IN GENERAL.—A grant awarded under
5 subsection (a) shall be for a period not less than
6 three years and not more than five years.

7 “(2) RENEWAL.—A grant awarded under sub-
8 section (a) may be renewed, on a competitive basis,
9 for additional periods of time, as determined by the
10 Secretary. In determining whether to renew a grant
11 under this paragraph, the Secretary shall consider
12 the data submitted under subsection (h).

13 “(c) MINIMUM NUMBER OF CENTERS.—The Sec-
14 retary shall allocate the amounts made available under
15 subsection (i) in such amounts that not fewer than 10
16 Centers will be established across the United States.

17 “(d) APPLICATION.—In order to be eligible for a
18 grant under subsection (a), an entity shall submit an ap-
19 plication to the Secretary at such time and in such manner
20 as the Secretary may require. Such application shall in-
21 clude—

22 “(1) evidence that such entity carries out, or is
23 capable of coordinating with other entities to carry
24 out, the activities described in subsection (g); and

1 “(2) such other information as the Secretary
2 may require.

3 “(e) PRIORITY.—In awarding grants under sub-
4 section (a), the Secretary shall give priority to eligible enti-
5 ties located in a State or Indian country (as defined in
6 section 1151 of title 18, United States Code)—

7 “(1) with a high per capita drug overdose mor-
8 tality rate, as determined by the Director of the
9 Centers for Disease Control and Prevention; or

10 “(2) based on any other criteria or need, as de-
11 termined by the Secretary.

12 “(f) USE OF GRANT FUNDS.—An eligible entity
13 awarded a grant under subsection (a) shall use the grant
14 funds to establish or operate a Center to carry out the
15 activities described in subsection (g).

16 “(g) CENTER ACTIVITIES AND SERVICES.—Each
17 Center shall, at a minimum, carry out the activities de-
18 scribed in this subsection. In the case of a Center that
19 determines that a service described in paragraph (2) can-
20 not reasonably be carried out by the Center, such Center
21 shall contract with such other entities as may be necessary
22 to ensure that patients have access to the full range of
23 services described in such paragraph.

24 “(1) COMMUNITY OUTREACH.—Each Center
25 shall carry out the following outreach activities:

1 “(A) Train and supervise outreach staff to
2 work with schools, workplaces, faith-based orga-
3 nizations, State and local health departments,
4 law enforcement, and first responders to ensure
5 that such institutions are aware of the services
6 of the Center.

7 “(B) Disseminate and make available on-
8 line evidence-based resources that educate pro-
9 fessionals and the public on opioid use disorder
10 and other substance use disorders.

11 “(2) TREATMENT AND RECOVERY SERVICES.—
12 Each Center shall provide the following treatment
13 and recovery services:

14 “(A) Ensure that intake evaluations meet
15 the clinical needs of patients.

16 “(B) Periodically conduct patient assess-
17 ments to ensure continued and meaningful re-
18 covery, as defined by the Assistant Secretary
19 for Mental Health and Substance Use.

20 “(C) Provide the full continuum of treat-
21 ment services, including—

22 “(i) all drugs approved under section
23 505 of the Federal Food, Drug, and Cos-
24 metic Act and all biological products li-
25 censed under section 351 of this Act, in-

1 cluding methadone, to treat substance use
2 disorders, including opioid use disorder
3 and alcohol use disorder;

4 “(ii) withdrawal management, which
5 shall include medically supervised detoxi-
6 fication that includes patient evaluation,
7 stabilization, and readiness for and entry
8 into treatment;

9 “(iii) counseling and case manage-
10 ment, including counseling and recovery
11 services for any possible co-occurring men-
12 tal illness;

13 “(iv) residential rehabilitation;

14 “(v) recovery housing;

15 “(vi) community-based and peer re-
16 covery support services;

17 “(vii) job training and placement as-
18 sistance to support reintegration into the
19 workforce; and

20 “(viii) other best practices, as deter-
21 mined by the Secretary.

22 “(D) Administer an onsite pharmacy and
23 provide toxicology services.

1 “(E) Establish and operate a secure and
2 confidential electronic health information sys-
3 tem.

4 “(F) Offer family support services such as
5 child care, family counseling, and parenting
6 interventions to help stabilize families impacted
7 by substance use disorder.

8 “(h) DATA REPORTING AND PROGRAM OVER-
9 SIGHT.—With respect to a grant awarded under sub-
10 section (a) to an eligible entity for a Center, not later than
11 90 days after the end of the first year of the grant period,
12 and annually thereafter for the duration of the grant pe-
13 riod (including the duration of any renewal period for such
14 grant), the entity shall submit data, as appropriate, to the
15 Secretary regarding—

16 “(1) the programs and activities funded by the
17 grant;

18 “(2) health outcomes of individuals with a sub-
19 stance use disorder who received services from the
20 Center;

21 “(3) the effectiveness of interventions designed,
22 tested, and evaluated by the Center; and

23 “(4) any other information that the Secretary
24 may require for the purpose of—

1 “(A) evaluating the effectiveness of the
2 Center; and

3 “(B) ensuring that the Center is complying
4 with all the requirements of the grant, including
5 providing the full continuum of services de-
6 scribed in subsection (g)(2)(C) and providing
7 drugs and devices for overdose reversal under
8 such subsection.

9 “(i) AUTHORIZATION OF APPROPRIATIONS.—There is
10 authorized to be appropriated \$10,000,000 for each of fis-
11 cal years 2019 through 2023 for purposes of carrying out
12 this section.”.

13 (b) REPORTS TO CONGRESS.—

14 (1) PRELIMINARY REPORT.—Not later than
15 three years after the date of the enactment of this
16 Act, the Secretary of Health and Human Services
17 shall submit to Congress a preliminary report that
18 analyzes data submitted under section 550(h) of the
19 Public Health Service Act, as added by subsection
20 (a).

21 (2) FINAL REPORT.—Not later than one year
22 after submitting the preliminary report required
23 under paragraph (1), the Secretary of Health and
24 Human Services shall submit to Congress a final re-
25 port that includes—

1 (A) an evaluation of the effectiveness of
2 comprehensive opioid recovery centers estab-
3 lished or operated pursuant to section 550 of
4 the Public Health Service Act, as added by sub-
5 section (a);

6 (B) recommendations on whether the grant
7 program established under such section 550
8 should be reauthorized and expanded; and

9 (C) standards and best practices for the
10 treatment of substance use disorders, as identi-
11 fied through such grant program.

12 **Subtitle O—Poison Center Network** 13 **Enhancement**

14 **SEC. 7141. SHORT TITLE.**

15 This subtitle may be cited as the “Poison Center Net-
16 work Enhancement Act of 2018”.

17 **SEC. 7142. REAUTHORIZATION OF POISON CONTROL CEN-** 18 **TERS NATIONAL TOLL-FREE NUMBER.**

19 Section 1271 of the Public Health Service Act (42
20 U.S.C. 300d–71) is amended to read as follows:

21 **“SEC. 1271. ESTABLISHMENT AND MAINTENANCE OF THE** 22 **NATIONAL TOLL-FREE NUMBER AND EN-** 23 **HANCED COMMUNICATIONS CAPABILITIES.**

24 “(a) IN GENERAL.—The Secretary shall provide co-
25 ordination and assistance to poison control centers for—

1 **“SEC. 1272. NATIONWIDE PUBLIC AWARENESS CAMPAIGN**
2 **TO PROMOTE POISON CONTROL CENTER UTI-**
3 **LIZATION AND THEIR PUBLIC HEALTH EMER-**
4 **GENCY RESPONSE CAPABILITIES.**

5 “(a) IN GENERAL.—The Secretary shall—

6 “(1) carry out, and expand upon, a national
7 public awareness campaign to educate the public and
8 health care providers about—

9 “(A) poisoning, toxic exposure, and drug
10 misuse prevention; and

11 “(B) the availability of poison control cen-
12 ter resources in local communities; and

13 “(2) as part of such campaign, highlight the
14 nationwide toll-free number and enhanced commu-
15 nications capabilities supported under section 1271.

16 “(b) CONSULTATION.—In carrying out and expand-
17 ing upon the national campaign under subsection (a), the
18 Secretary may consult with nationally recognized profes-
19 sional organizations in the field of poison control response
20 for the purpose of determining the best and most effective
21 methods for achieving public awareness.

22 “(c) CONTRACT WITH ENTITY.—The Secretary may
23 carry out subsection (a) by entering into contracts with
24 one or more public or private entities, including nationally
25 recognized professional organizations in the field of poison
26 control and national media firms, for the development and

1 implementation of the awareness campaign under sub-
2 section (a), which may include—

3 “(1) the development and distribution of poi-
4 soning and toxic exposure prevention, poison control
5 center, and public health emergency awareness and
6 response materials;

7 “(2) television, radio, internet, and newspaper
8 public service announcements; and

9 “(3) other means and activities to provide for
10 public and professional awareness and education.

11 “(d) EVALUATION.—The Secretary shall—

12 “(1) establish baseline measures and bench-
13 marks to quantitatively evaluate the impact of the
14 nationwide public awareness campaign carried out
15 under this section; and

16 “(2) on a biennial basis, prepare and submit to
17 the appropriate committees of Congress an evalua-
18 tion of the nationwide public awareness campaign.

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated to carry out this section,
21 \$800,000 for each of fiscal years 2019 through 2023.”.

22 **SEC. 7144. REAUTHORIZATION OF THE POISON CONTROL**
23 **CENTER GRANT PROGRAM.**

24 Section 1273 of the Public Health Service Act (42
25 U.S.C. 300d–73) is amended to read as follows:

1 **“SEC. 1273. MAINTENANCE OF THE POISON CONTROL CEN-**
2 **TER GRANT PROGRAM.**

3 “(a) AUTHORIZATION OF PROGRAM.—The Secretary
4 shall award grants to poison control centers accredited
5 under subsection (c) (or granted a waiver under subsection
6 (d)) and nationally recognized professional organizations
7 in the field of poison control for the purposes of—

8 “(1) preventing, and providing treatment rec-
9 ommendations for, poisonings and toxic exposures
10 including opioid and drug misuse;

11 “(2) assisting with public health emergencies,
12 responses, and preparedness; and

13 “(3) complying with the operational require-
14 ments needed to sustain the accreditation of the cen-
15 ter under subsection (c).

16 “(b) ADDITIONAL USES OF FUNDS.—In addition to
17 the purposes described in subsection (a), a poison center
18 or professional organization awarded a grant under such
19 subsection may also use amounts received under such
20 grant—

21 “(1) to research, establish, implement, and
22 evaluate best practices in the United States for poi-
23 soning prevention, poison control center outreach,
24 opioid and drug misuse information and response,
25 and public health emergency, response, and pre-
26 paredness programs;

1 “(2) to research, develop, implement, revise,
2 and communicate standard patient management
3 guidelines for commonly encountered toxic expo-
4 sures;

5 “(3) to improve national toxic exposure and
6 opioid misuse surveillance by enhancing cooperative
7 activities between poison control centers in the
8 United States and the Centers for Disease Control
9 and Prevention and other governmental agencies;

10 “(4) to research, improve, and enhance the
11 communications and response capability and capaci-
12 ty of the Nation’s network of poison control centers
13 to facilitate increased access to the centers through
14 the integration and modernization of the current
15 poison control centers communications and data sys-
16 tem, including enhancing the network’s telephony,
17 internet, data, and social networking technologies;

18 “(5) to develop, support, and enhance tech-
19 nology and capabilities of nationally recognized pro-
20 fessional organizations in the field of poison control
21 to collect national poisoning, toxic occurrence, and
22 related public health data;

23 “(6) to develop initiatives to foster the en-
24 hanced public health utilization of national poison
25 data collected by such organizations;

1 “(7) to support and expand the toxicologic ex-
2 pertise within poison control centers; and

3 “(8) to improve the capacity of poison control
4 centers to answer high volumes of contacts and
5 internet communications, and to sustain and en-
6 hance the poison control center’s network capability
7 to respond during times of national crisis or other
8 public health emergencies.

9 “(c) ACCREDITATION.—Except as provided in sub-
10 section (d), the Secretary may award a grant to a poison
11 control center under subsection (a) only if—

12 “(1) the center has been accredited by a nation-
13 ally recognized professional organization in the field
14 of poison control, and the Secretary has approved
15 the organization as having in effect standards for
16 accreditation that reasonably provide for the protec-
17 tion of the public health with respect to poisoning;
18 or

19 “(2) the center has been accredited by a State
20 government, and the Secretary has approved the
21 State government as having in effect standards for
22 accreditation that reasonably provide for the protec-
23 tion of the public health with respect to poisoning.

24 “(d) WAIVER OF ACCREDITATION REQUIREMENTS.—

1 “(1) IN GENERAL.—The Secretary may grant a
2 waiver of the accreditation requirements of sub-
3 section (c) with respect to a nonaccredited poison
4 control center that applies for a grant under this
5 section if such center can reasonably demonstrate
6 that the center will obtain such an accreditation
7 within a reasonable period of time as determined ap-
8 propriate by the Secretary.

9 “(2) RENEWAL.—The Secretary may renew a
10 waiver under paragraph (1).

11 “(3) LIMITATION.—The Secretary may not,
12 after the date of enactment of the Poison Control
13 Network Enhancement Act of 2018, grant to a poi-
14 son control center waivers or renewals that total
15 more than 5 years.

16 “(e) SUPPLEMENT NOT SUPPLANT.—Amounts made
17 available to a poison control center under this section shall
18 be used to supplement and not supplant other Federal,
19 State, or local funds provided for such center.

20 “(f) MAINTENANCE OF EFFORT.—A poison control
21 center, in utilizing the proceeds of a grant under this sec-
22 tion, shall maintain the annual recurring expenditures of
23 the center for its activities at a level that is not less than
24 80 percent of the average level of such recurring expendi-

1 tures maintained by the center for the preceding 3 fiscal
2 years for which a grant is received.

3 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
4 is authorized to be appropriated to carry out this section,
5 \$28,600,000 for each of fiscal years 2019 through 2023.
6 The Secretary may utilize an amount not to exceed 6 per-
7 cent of the amount appropriated pursuant to the pre-
8 ceding sentence for each fiscal year for coordination, dis-
9 semination, technical assistance, program evaluation, data
10 activities, and other program administration functions,
11 which are determined by the Secretary to be appropriate
12 for carrying out the program under this section.”.

13 **Subtitle P—Eliminating Opioid**
14 **Related Infectious Diseases**

15 **SEC. 7151. SHORT TITLE.**

16 This subtitle may be cited as the “Eliminating Opioid
17 Related Infectious Diseases Act of 2018”.

18 **SEC. 7152. REAUTHORIZATION AND EXPANSION OF PRO-**
19 **GRAM OF SURVEILLANCE AND EDUCATION**
20 **REGARDING INFECTIONS ASSOCIATED WITH**
21 **ILLICIT DRUG USE AND OTHER RISK FAC-**
22 **TORS.**

23 Section 317N of the Public Health Service Act (42
24 U.S.C. 247b–15) is amended to read as follows:

1 **“SEC. 317N. SURVEILLANCE AND EDUCATION REGARDING**
2 **INFECTIONS ASSOCIATED WITH ILLICIT**
3 **DRUG USE AND OTHER RISK FACTORS.**

4 “(a) IN GENERAL.—The Secretary may (directly and
5 through grants to public and nonprofit private entities)
6 provide for programs for the following:

7 “(1) To cooperate with the States and Indian
8 tribes in implementing or maintaining a surveillance
9 system to determine the incidence of infections com-
10 monly associated with illicit drug use, including in-
11 fections commonly associated with injection drug use
12 such as viral hepatitis, human immunodeficiency
13 virus, and infective endocarditis, and to assist the
14 States in determining the prevalence of such infec-
15 tions, which may include the reporting of cases of
16 such infections.

17 “(2) To identify, counsel, and offer testing to
18 individuals who are at risk of infections as a result
19 of injection drug use, receiving blood transfusions
20 prior to July 1992, or other risk factors.

21 “(3) To provide appropriate referrals for coun-
22 seling, testing, and medical treatment of individuals
23 identified under paragraph (2) and to ensure, to the
24 extent practicable, the provision of appropriate fol-
25 low-up services.

1 “(4) To develop and disseminate public infor-
2 mation and education programs for the detection
3 and control of infections described in paragraph (1),
4 with priority given to high-risk populations as deter-
5 mined by the Secretary.

6 “(5) To improve the education, training, and
7 skills of health professionals in the detection and
8 control of infections and the coordination of treat-
9 ment of addiction and infectious diseases described
10 in paragraph (1), with priority given to substance
11 use disorder treatment providers, pediatricians and
12 other primary care providers, obstetrician-gyne-
13 cologists, infectious diseases clinicians, and HIV cli-
14 nicians.

15 “(b) LABORATORY PROCEDURES.—The Secretary
16 may (directly or through grants to public and nonprofit
17 private entities) carry out programs to provide for im-
18 provements in the quality of clinical-laboratory procedures
19 regarding infections described in subsection (a)(1).

20 “(c) DEFINITIONS.—In this section:

21 “(1) The term ‘Indian tribe’ has the meaning
22 given that term in section 4 of the Indian Self-De-
23 termination and Education Assistance Act.

24 “(2) The term ‘injection drug use’ means—

1 “(A) intravenous administration of a sub-
2 stance in schedule I under section 202 of the
3 Controlled Substances Act;

4 “(B) intravenous administration of a sub-
5 stance in schedule II, III, IV, or V under sec-
6 tion 202 of the Controlled Substances Act that
7 has not been approved for intravenous use
8 under—

9 “(i) section 505 of the Federal Food,
10 Drug and Cosmetic Act; or

11 “(ii) section 351 of the Public Health
12 Service Act; or

13 “(C) intravenous administration of a sub-
14 stance in schedule II, III, IV, or V under sec-
15 tion 202 of the Controlled Substances Act that
16 has not been prescribed to the person using the
17 substance.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there are authorized
20 to be appropriated \$40,000,000 for each of the fiscal years
21 2019 through 2023.”.

1 **Subtitle Q—Better Pain**
2 **Management Through Better Data**

3 **SEC. 7161. SHORT TITLE.**

4 This subtitle may be cited as the “Better Pain Man-
5 agement Through Better Data Act of 2018”.

6 **SEC. 7162. GUIDANCE ADDRESSING ALTERNATIVE AP-
7 PROACHES TO DATA COLLECTION AND LA-
8 BELING CLAIMS FOR OPIOID SPARING.**

9 (a) **IN GENERAL.**—For purposes of assisting spon-
10 sors in collecting and incorporating opioid-sparing data in
11 product labeling, the Secretary of Health and Human
12 Services (referred to in this section as the “Secretary”)
13 shall conduct a public meeting and update or issue one
14 or more guidances in accordance with subsection (b).

15 (b) **GUIDANCE.**—

16 (1) **IN GENERAL.**—The Secretary of Health and
17 Human Services, acting through the Commissioner
18 of Food and Drugs, shall update or issue one or
19 more guidances addressing—

20 (A) alternative methods for data collection
21 on opioid sparing;

22 (B) alternative methods for inclusion of
23 such data in product labeling; and

24 (C) investigations other than clinical trials,
25 including partially controlled studies and objec-

1 tive trials without matched controls such as his-
2 torically controlled analyses, open-label studies,
3 and meta-analyses, on opioid sparing for inclu-
4 sion in product labeling.

5 (2) CONTENTS.—The guidances under para-
6 graph (1) shall address—

7 (A) innovative clinical trial designs for
8 ethically and efficiently collecting data on opioid
9 sparing for inclusion in product labeling;

10 (B) primary and secondary endpoints for
11 the reduction of opioid use while maintaining
12 adequate pain control;

13 (C) use of real world evidence, including
14 patient registries, and patient reported out-
15 comes to support inclusion of opioid-sparing
16 data in product labeling; and

17 (D) how sponsors may obtain feedback
18 from the Secretary relating to such issues prior
19 to—

20 (i) commencement of such data collec-
21 tion; or

22 (ii) the submission of resulting data to
23 the Secretary.

24 (3) PUBLIC MEETING.—Prior to updating or
25 issuing the guidances required by paragraph (1), the

1 Secretary shall consult with stakeholders, including
2 representatives of regulated industry, academia, pa-
3 tients, and provider organizations, through a public
4 meeting to be held not later than 12 months after
5 the date of enactment of this Act.

6 (4) TIMING.—The Secretary shall—

7 (A) not later than 12 months after the
8 date of the public meeting required by para-
9 graph (3), update or issue the one or more
10 draft guidances required by paragraph (1); and

11 (B) not later than 12 months after the
12 date on which the public comment period for
13 such draft guidances closes, finalize such guid-
14 ances.

15 (c) DEFINITION.—In this section:

16 (1) The terms “opioid sparing” and “opioid-
17 sparing” refer to the use of drugs or devices (as de-
18 fined in section 201 of the Federal Food, Drug, and
19 Cosmetic Act (21 U.S.C. 321)) that reduce pain
20 while enabling the reduction, replacement, or avoid-
21 ance of oral opioids.

22 (2) The term “Secretary” means the Secretary
23 of Health and Human Services.

1 **Subtitle R—Special Registration**
2 **for Telemedicine Clarification**

3 **SEC. 7171. SHORT TITLE.**

4 This subtitle may be cited as the “Special Registra-
5 tion for Telemedicine Clarification Act of 2018”.

6 **SEC. 7172. DEADLINE FOR INTERIM FINAL REGULATIONS**
7 **FOR A SPECIAL REGISTRATION TO ENGAGE**
8 **IN THE PRACTICE OF TELEMEDICINE.**

9 Section 311(h)(2) of the Controlled Substances Act
10 (21 U.S.C. 831(h)(2)) is amended by striking “The Attor-
11 ney General shall, with the concurrence of the Secretary,
12 promulgate regulations” and inserting “Not later than 1
13 year after the date of enactment of the Special Registra-
14 tion for Telemedicine Clarification Act of 2018, the Attor-
15 ney General shall, with the concurrence of the Secretary,
16 promulgate interim final regulations”.

17 **Subtitle S—Peer Support**
18 **Communities of Recovery**

19 **SEC. 7181. SHORT TITLE.**

20 This subtitle may be cited as the “Peer Support Com-
21 munities of Recovery Act”.

22 **SEC. 7182. BUILDING COMMUNITIES OF RECOVERY.**

23 Section 547 of the Public Health Service Act (42
24 U.S.C. 290ee–2) is amended—

25 (1) in subsection (a)—

1 (A) in the heading, by striking “DEFINI-
2 TION” and inserting “DEFINITIONS”;

3 (B) in the matter preceding paragraph (1),
4 by striking “In this section, the term ‘recovery
5 community organization’ means an independent
6 nonprofit organization that—” and inserting
7 “In this section:”;

8 (C) by redesignating paragraphs (1) and
9 (2) as subparagraphs (A) and (B), respectively,
10 and moving such subparagraphs (as so redesign-
11 ated) 2 ems to the right;

12 (D) by inserting before subparagraph (A)
13 (as so redesignated) the following:

14 “(1) RECOVERY COMMUNITY ORGANIZATION.—
15 The term ‘recovery community organization’ means
16 an independent nonprofit organization that—”;

17 (E) by adding at the end the following:

18 “(2) ELIGIBLE ENTITY.—The term ‘eligible en-
19 tity’ means—

20 “(A) a national nonprofit entity focused on
21 substance use disorder with a network of local
22 affiliates and partners that are geographically
23 and organizationally diverse; or

24 “(B) a nonprofit organization—

1 “(i) focused on substance use dis-
2 order;

3 “(ii) established by individuals in per-
4 sonal or family recovery; and

5 “(iii) serving prevention, treatment,
6 recovery, payor, faith-based, and criminal
7 justice stakeholders in the implementation
8 of local addiction and recovery initiatives.”;

9 (2) in subsection (b)—

10 (A) by striking “The Secretary shall award
11 grants to recovery community organizations”
12 and inserting “The Secretary—

13 “(1) shall award grants to recovery community
14 organizations”;

15 (B) by striking “services.” and inserting
16 “services and allow such organizations to use
17 such grant funds to carry out the activities de-
18 scribed in subparagraphs (A) through (C) of
19 subsection (c)(2); and”;

20 (C) by adding at the end the following:

21 “(2) may award grants to eligible entities for
22 purposes of establishing regional technical assistance
23 centers, in accordance with subsection (c)(2)(D).”;

24 (3) by striking subsection (c);

1 (4) by redesignating subsections (d) and (e) as
2 subsections (c) and (d), respectively;

3 (5) in subsection (c) (as so redesignated)—

4 (A) in paragraph (1), by striking “shall be
5 used” and inserting “to a recovery community
6 organization shall be used”;

7 (B) in paragraph (2)—

8 (i) in subparagraph (A), in the matter
9 preceding clause (i), by inserting before
10 “build” the following: “in the case of a
11 grant awarded to a recovery community or-
12 ganization,”;

13 (ii) in subparagraph (B)—

14 (I) by inserting before “reduce”
15 the following: “in the case of a grant
16 awarded to a recovery community or-
17 ganization,”; and

18 (II) by striking “and” at the end;

19 (iii) in subparagraph (C)—

20 (I) by inserting before “conduct”
21 the following: “in the case of a grant
22 awarded to a recovery community or-
23 ganization,”; and

24 (II) by striking the period at the
25 end and inserting “; and”; and

1 (iv) by adding at the end the fol-
2 lowing:

3 “(D) in the case of a grant awarded to an
4 eligible entity, provide for the establishment of
5 regional technical assistance centers to provide
6 regional technical assistance for the following:

7 “(i) Implementation of regionally driv-
8 en, peer-delivered addiction recovery sup-
9 port services before, during, after, or in
10 conjunction with addiction treatment.

11 “(ii) Establishment of recovery com-
12 munity organizations.

13 “(iii) Establishment of recovery com-
14 munity centers.”; and

15 (6) in subsection (d) (as so redesignated), by
16 inserting before the period the following: “, and
17 \$15,000,000 for each of fiscal years 2019 through
18 2023”.

19 **Subtitle T—Stop Illicit Drug**
20 **Importation**

21 **SEC. 7191. SHORT TITLE.**

22 This short title may be cited as the “Stop Illicit Drug
23 Importation Act of 2018”.

1 **SEC. 7192. DETENTION, REFUSAL, AND DESTRUCTION OF**
2 **DRUGS OFFERED FOR IMPORTATION.**

3 (a) ARTICLES TREATED AS DRUGS FOR PURPOSES
4 OF IMPORTATION.—Section 801 of the Federal Food,
5 Drug, and Cosmetic Act (21 U.S.C. 381) is amended by
6 adding at the end the following:

7 “(t) ARTICLES TREATED AS DRUGS FOR PURPOSES
8 OF THIS SECTION.—

9 “(1) LABELED ARTICLES.—An article shall not
10 be treated as a drug pursuant to this subsection if—

11 “(A) an electronic import entry for such
12 article is submitted using an authorized elec-
13 tronic data interchange system; and

14 “(B) such article is designated in such sys-
15 tem as a drug, device, dietary supplement, or
16 other product that is regulated under this Act.

17 “(2) ARTICLES COVERED.—Subject to para-
18 graph (1), for purposes of this section, an article de-
19 scribed in this paragraph may be treated by the Sec-
20 retary as a drug if it—

21 “(A) is or contains an ingredient that is an
22 active ingredient that is contained within—

23 “(i) a drug that has been approved
24 under section 505 of this Act; or

1 “(ii) a biological product that has
2 been approved under section 351 of the
3 Public Health Service Act;

4 “(B) is or contains an ingredient that is an
5 active ingredient in a drug or biological product
6 if—

7 “(i) an investigational use exemption
8 has been authorized for such drug or bio-
9 logical product under section 505(i) of this
10 Act or section 351(a) of the Public Health
11 Service Act;

12 “(ii) substantial clinical investigation
13 has been instituted for such drug or bio-
14 logical product; and

15 “(iii) the existence of such clinical in-
16 vestigation has been made public; or

17 “(C) is or contains a substance that has a
18 chemical structure that is substantially similar
19 to the chemical structure of an active ingredient
20 in a drug or biological product described in sub-
21 paragraph (A) or (B).

22 “(3) EFFECT.—Except to the extent that an ar-
23 ticle may be treated as a drug pursuant to para-
24 graph (2), this subsection shall not be construed as
25 bearing on or being relevant to the question of

1 whether any article is a drug as defined in section
2 201(g).”.

3 (b) ARTICLES OF CONCERN.—

4 (1) DELIVERY BY TREASURY TO HHS.—The
5 first sentence of section 801(a) of the Federal Food,
6 Drug, and Cosmetic Act (21 U.S.C. 381(a)) is
7 amended by striking “and cosmetics” and inserting
8 “cosmetics, and potential articles of concern (as de-
9 fined in subsection (u))”.

10 (2) REFUSED ADMISSION.—The third sentence
11 of section 801(a) of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 381(a)) is amended by
13 striking “then such article shall be refused admis-
14 sion” and inserting “or (5) such article is an article
15 of concern (as defined in subsection (u)), or (6) such
16 article is a drug that is being imported or offered for
17 import in violation of section 301(cc), then such ar-
18 ticle shall be refused admission”.

19 (3) DEFINITION OF ARTICLE OF CONCERN.—
20 Section 801 of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 381), as amended, is further
22 amended by adding at the end the following:

23 “(u) ARTICLE OF CONCERN DEFINED.—For pur-
24 poses of subsection (a), the term ‘article of concern’ means
25 an article that is or contains a drug or other substance—

1 “(1) for which, during the 24-month period
2 prior to the article being imported or offered for im-
3 port, the Secretary of Health and Human Services—

4 “(A) has requested that, based on a deter-
5 mination that the drug or other substance ap-
6 pears to meet the requirements for temporary
7 or permanent scheduling pursuant to section
8 201 of the Controlled Substances Act, the At-
9 torney General initiate the process to control
10 the drug or other substance in accordance with
11 such Act; or

12 “(B) has, following the publication by the
13 Attorney General of a notice in the Federal
14 Register of the intention to issue an order tem-
15 porarily scheduling such drug or substance in
16 schedule I of section 202 of the Controlled Sub-
17 stances Act pursuant to section 201(h) of such
18 Act, made a determination that such article
19 presents an imminent hazard to public safety;
20 and

21 “(2) with respect to which the Attorney General
22 has not—

23 “(A) scheduled the drug or other substance
24 under such Act; or

1 “(B) notified the Secretary of Health and
2 Human Services that the Attorney General has
3 made a determination not to schedule the drug
4 or other substance under such Act.”.

5 **SEC. 7193. SEIZURE.**

6 Section 304(b) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 334(b)) is amended by striking the
8 first sentence and inserting the following: “The article,
9 equipment, or other thing proceeded against shall be liable
10 to seizure by process pursuant to the libel, and the proce-
11 dure in cases under this section shall conform, as nearly
12 as may be, to the procedure in admiralty rather than the
13 procedure used for civil asset forfeiture proceedings set
14 forth in section 983 of title 18, United States Code. On
15 demand of either party any issue of fact joined in any such
16 a case brought under this section shall be tried by jury.
17 A seizure brought under this section is not governed by
18 Rule G of the Supplemental Rules of Admiralty or Mari-
19 time Claims and Asset Forfeiture Actions. Exigent cir-
20 cumstances shall be deemed to exist for all seizures
21 brought under this section, and in such cases, the sum-
22 mons and arrest warrant shall be issued by the clerk of
23 the court without court review.”.

1 **SEC. 7194. DEBARRING VIOLATIVE INDIVIDUALS OR COM-**
2 **PANIES.**

3 (a) PROHIBITED ACT.—Section 301(cc) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331(cc))
5 is amended—

6 (1) by inserting after “an article of food” the
7 following: “or a drug”; and

8 (2) by inserting after “a person debarred” the
9 following: “from such activity”.

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

13 (1) in paragraph (1)—

14 (A) in the matter preceding subparagraph
15 (A), by striking “paragraph (2)” and inserting
16 “paragraph (2) or (3)”;

17 (B) in subparagraph (B), by striking “or”
18 at the end;

19 (C) in subparagraph (C), by striking the
20 period at the end and inserting “, or”; and

21 (D) by adding at the end the following:

22 “(D) a person from importing or offering
23 to import into the United States—

24 “(i) a controlled substance as defined
25 in section 102(6) of the Controlled Sub-
26 stances Act; or

1 “(ii) any drug, if such drug is de-
2 clared to be valued at an amount that is
3 \$2,500 or less (or such higher amount as
4 the Secretary of the Treasury may set by
5 regulation pursuant to section 498(a)(1) of
6 the Tariff Act of 1930), or if such drug is
7 entering the United States by mail.”; and

8 (2) in paragraph (3)—

9 (A) in the paragraph heading after
10 “FOOD” by inserting “OR DRUG”;

11 (B) by redesignating subparagraphs (A)
12 and (B) as clauses (i) and (ii), respectively, and
13 moving the indentation of each such clause 2
14 ems to the right;

15 (C) after making the amendments required
16 by subparagraph (B), by striking “A person is
17 subject” and inserting the following:

18 “(A) FOOD.—A person is subject”; and

19 (D) by adding at the end the following:

20 “(B) IMPORTATION OF DRUGS.—A person
21 is subject to debarment under paragraph (1)(D)
22 if—

23 “(i) the person has been convicted of
24 a felony for conduct relating to the impor-
25 tation into the United States of any drug

1 or controlled substance (as defined in sec-
2 tion 102 of the Controlled Substances
3 Act); or

4 “(ii) the person has engaged in a pat-
5 tern of importing or offering for import ar-
6 ticles of drug that are—

7 “(I)(aa) adulterated, misbranded,
8 or in violation of section 505; and

9 “(bb) present a threat of serious
10 adverse health consequences or death
11 to humans or animals; or

12 “(II) controlled substances whose
13 importation is prohibited pursuant to
14 section 401(m) of the Tariff Act of
15 1930.

16 “(C) DEFINITION.—For purposes of sub-
17 paragraph (B), the term ‘pattern of importing
18 or offering for import articles of drug’ means
19 importing or offering for import articles of drug
20 described in subclause (I) or (II) of subpara-
21 graph (B)(ii) in an amount, frequency, or dos-
22 age that is inconsistent with personal or house-
23 hold use by the importer.”.

1 **Subtitle U—Creating Opportunities**
2 **That Necessitate New and En-**
3 **hanced Connections That Im-**
4 **prove Opioid Navigation Strate-**
5 **gies**

6 **SEC. 7201. SHORT TITLE.**

7 This subtitle may be cited as the “Creating Opportu-
8 nities that Necessitate New and Enhanced Connections
9 That Improve Opioid Navigation Strategies Act of 2018”
10 or the “CONNECTIONS Act”.

11 **SEC. 7202. PREVENTING OVERDOSES OF CONTROLLED SUB-**
12 **STANCES.**

13 Part P of title III of the Public Health Service Act
14 (42 U.S.C. 280g et seq.) is amended by adding at the end
15 the following new section:

16 **“SEC. 399V-7. PREVENTING OVERDOSES OF CONTROLLED**
17 **SUBSTANCES.**

18 “(a) EVIDENCE-BASED PREVENTION GRANTS.—

19 “(1) IN GENERAL.—The Director of the Cen-
20 ters for Disease Control and Prevention may—

21 “(A) to the extent practicable, carry out
22 any evidence-based prevention activity described
23 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 sede 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 one year after the date
12 of 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 congres-
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 congres-
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 one 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) 4 of the members shall be individuals
23 representative of employers or other organiza-
24 tions representing employers.

1 (B) 4 of the members shall be individuals
2 representative of workers or other organizations
3 representing workers, of which at least 2 must
4 be representatives designated by labor organiza-
5 tions.

6 (C) 3 of the members shall be individuals
7 representative of health benefit plans, employee
8 assistance plan providers, workers' compensa-
9 tion program administrators, and workplace
10 safety and health professionals.

11 (D) 8 of the members shall be individuals
12 representative of substance abuse treatment
13 and recovery experts, including medical doctors,
14 licensed addiction therapists, and scientific and
15 academic researchers, of which 1 individual may
16 be a representative of a local or State govern-
17 ment agency that oversees or coordinates pro-
18 grams that address substance use disorder.

19 (2) CHAIR.—From the members appointed
20 under paragraph (1), the Secretary of Labor shall
21 appoint a chairperson.

22 (3) TERMS.—Each member of the Advisory
23 Committee shall serve for a term of three years. A
24 member appointed to fill a vacancy shall be ap-
25 pointed only for the remainder of such term.

1 (4) QUORUM.—A majority of members of the
2 Advisory Committee shall constitute a quorum and
3 action shall be taken only by a majority vote of the
4 members.

5 (5) VOTING.—The Advisory Committee shall es-
6 tablish voting procedures.

7 (6) NO COMPENSATION.—Members of the Advi-
8 sory Committee shall serve without compensation.

9 (7) DISCLOSURE.—Every member of the Advi-
10 sory Committee must disclose the entity, if applica-
11 ble, that he or she is representing.

12 (c) DUTIES.—

13 (1) ADVISEMENT.—

14 (A) IN GENERAL.—The Advisory Com-
15 mittee established under subsection (a) shall
16 advise the Secretary of Labor on actions the
17 Department of Labor can take to provide infor-
18 mational resources and best practices on how to
19 appropriately address the impact of opioid
20 abuse on the workplace and support workers
21 abusing opioids.

22 (B) CONSIDERATIONS.—In providing such
23 advice, the Advisory Committee shall take into
24 account—

1 (i) evidence-based and other employer
2 substance abuse policies and best practices
3 regarding opioid use or abuse, including
4 benefits provided by employee assistance
5 programs or other employer-provided bene-
6 fits, programs, or resources;

7 (ii) the effect of opioid use or abuse
8 on the safety of the workplace as well as
9 policies and procedures addressing work-
10 place safety and health;

11 (iii) the impact of opioid abuse on
12 productivity and absenteeism, and assess-
13 ments of model human resources policies
14 that support workers abusing opioids, such
15 as policies that facilitate seeking and re-
16 ceiving treatment and returning to work;

17 (iv) the extent to which alternative
18 pain management treatments other than
19 opioids are or should be covered by em-
20 ployer-sponsored health plans;

21 (v) the legal requirements protecting
22 employee privacy and health information in
23 the workplace, as well as the legal require-
24 ments related to nondiscrimination;

1 (vi) potential interactions of opioid
2 abuse with other substance use disorders;

3 (vii) any additional benefits or re-
4 sources available to an employee abusing
5 opioids that promote retaining employment
6 or reentering the workforce;

7 (viii) evidence-based initiatives that
8 engage employers, employees, and commu-
9 nity leaders to promote early identification
10 of opioid abuse, intervention, treatment,
11 and recovery;

12 (ix) workplace policies regarding
13 opioid abuse that reduce stigmatization
14 among fellow employees and management;
15 and

16 (x) the legal requirements of the Men-
17 tal Health Parity and Addiction Equity
18 Act and other laws related to health cov-
19 erage of substance abuse and mental
20 health services and medications.

21 (2) REPORT.—Prior to its termination as pro-
22 vided in subsection (j), the Advisory Committee shall
23 issue a report to the Secretary of Labor and to the
24 Committee on Education and the Workforce of the
25 House of Representatives and the Committee on

1 Health, Education, Labor, and Pensions of the Sen-
2 ate, detailing successful programs and policies in-
3 volving workplace resources and benefits, including
4 recommendations or examples of best practices for
5 how employers can support and respond to employ-
6 ees impacted by opioid abuse.

7 (d) MEETINGS.—The Advisory Committee shall meet
8 at least twice a year at the call of the chairperson.

9 (e) STAFF SUPPORT.—The Secretary of Labor shall
10 make available staff necessary for the Advisory Committee
11 to carry out its responsibilities.

12 (f) FEDERAL ADVISORY COMMITTEE ACT.—The
13 Federal Advisory Committee Act shall apply to the Advi-
14 sory Committee established under this subtitle.

15 (g) NO APPROPRIATED FUNDS.—No additional
16 funds are authorized to be appropriated to carry out this
17 subtitle. Expenses of the Advisory Committee shall be paid
18 with funds otherwise appropriated to Departmental Man-
19 agement within the Department of Labor.

20 (h) EX OFFICIO.—Three nonvoting representatives
21 from agencies within the Department of Health and
22 Human Services whose responsibilities include opioid pre-
23 scribing guidelines, workplace safety, and monitoring of
24 substance abuse and prevention programs shall be ap-

1 pointed by the Secretary of Labor and designated as ex
2 officio members.

3 (i) AGENDA.—The Secretary of Labor or a represent-
4 ative of the Secretary shall consult with the Chair in es-
5 tablishing the agenda for Committee meetings.

6 (j) TERMINATION.—The Advisory Committee estab-
7 lished under this subtitle shall terminate three years after
8 the date of enactment of this Act.

9 **Subtitle F—Veterans Treatment** 10 **Court Improvement**

11 **SEC. 8051. SHORT TITLE.**

12 This subtitle may be cited as the “Veterans Treat-
13 ment Court Improvement Act of 2018”.

14 **SEC. 8052. HIRING BY DEPARTMENT OF VETERANS AFFAIRS** 15 **OF ADDITIONAL VETERANS JUSTICE OUT-** 16 **REACH SPECIALISTS.**

17 (a) HIRING OF ADDITIONAL VETERANS JUSTICE
18 OUTREACH SPECIALISTS.—

19 (1) IN GENERAL.—Not later than one year
20 after the date of the enactment of this Act, the Sec-
21 retary of Veterans Affairs shall hire not fewer than
22 50 Veterans Justice Outreach Specialists and place
23 each such Veterans Justice Outreach Specialist at
24 an eligible Department of Veterans Affairs medical
25 center in accordance with this section.

1 (2) REQUIREMENTS.—The Secretary shall en-
2 sure that each Veterans Justice Outreach Specialist
3 employed under paragraph (1)—

4 (A) serves, either exclusively or in addition
5 to other duties, as part of a justice team in a
6 veterans treatment court or other veteran-fo-
7 cused court; and

8 (B) otherwise meets Department hiring
9 guidelines for Veterans Justice Outreach Spe-
10 cialists.

11 (b) ELIGIBLE DEPARTMENT OF VETERANS AFFAIRS
12 MEDICAL CENTERS.—For purposes of this section, an eli-
13 gible Department of Veterans Affairs medical center is
14 any Department of Veterans Affairs medical center that—

15 (1) complies with all Department guidelines and
16 regulations for placement of a Veterans Justice Out-
17 reach Specialist;

18 (2) works within a local criminal justice system
19 with justice-involved veterans;

20 (3) maintains an affiliation with one or more
21 veterans treatment courts or other veteran-focused
22 courts; and

23 (4) either—

24 (A) routinely provides Veterans Justice
25 Outreach Specialists to serve as part of a jus-

1 tice team in a veterans treatment court or other
2 veteran-focused court; or

3 (B) establishes a plan that is approved by
4 the Secretary to provide Veterans Justice Out-
5 reach Specialists employed under subsection
6 (a)(1) to serve as part of a justice team in a
7 veterans treatment court or other veteran-fo-
8 cused court.

9 (c) PLACEMENT PRIORITY.—The Secretary shall
10 prioritize the placement of Veterans Justice Outreach Spe-
11 cialists employed under subsection (a)(1) at eligible De-
12 partment of Veterans Affairs medical centers that have
13 or intend to establish an affiliation, for the purpose of car-
14 rying out the Veterans Justice Outreach Program, with
15 a veterans treatment court, or other veteran-focused court,
16 that—

17 (1) was established on or after the date of the
18 enactment of this Act; or

19 (2)(A) was established before the date of the
20 enactment of this Act; and

21 (B) is not fully staffed with Veterans Justice
22 Outreach Specialists.

23 (d) REPORTS.—

24 (1) REPORT BY SECRETARY OF VETERANS AF-
25 FAIRS.—

1 (A) IN GENERAL.—Not later than one year
2 after the date of the enactment of this Act, the
3 Secretary of Veterans Affairs shall submit to
4 Congress a report on the implementation of this
5 section and its effect on the Veterans Justice
6 Outreach Program.

7 (B) CONTENTS.—The report submitted
8 under paragraph (1) shall include the following:

9 (i) The status of the efforts of the
10 Secretary to hire Veterans Justice Out-
11 reach Specialists pursuant to subsection
12 (a)(1), including the total number of Vet-
13 erans Justice Outreach Specialists hired by
14 the Secretary pursuant to such subsection
15 and the number that the Secretary expects
16 to hire pursuant to such subsection.

17 (ii) The total number of Veterans
18 Justice Outreach Specialists assigned to
19 each Department of Veterans Affairs med-
20 ical center that participates in the Vet-
21 erans Justice Outreach Program, including
22 the number of Veterans Justice Outreach
23 Specialists hired under subsection (a)(1)
24 disaggregated by Department of Veterans
25 Affairs medical center.

1 (iii) The total number of eligible De-
2 partment of Veterans Affairs medical cen-
3 ters that sought placement of a Veterans
4 Justice Outreach Specialist under sub-
5 section (a)(1), how many Veterans Justice
6 Outreach Specialists each such center
7 sought, and how many of such medical
8 centers received no placement of a Vet-
9 erans Justice Outreach Specialist under
10 subsection (a)(1).

11 (iv) For each eligible Department of
12 Veterans Affairs medical center—

13 (I) the number of justice-involved
14 veterans who were served or are ex-
15 pected to be served by a Veterans
16 Justice Outreach Specialist hired
17 under subsection (a)(1); and

18 (II) the number of justice-in-
19 volved veterans who do not have ac-
20 cess to a Veterans Justice Outreach
21 Specialist.

22 (2) REPORT BY COMPTROLLER GENERAL OF
23 THE UNITED STATES.—

24 (A) IN GENERAL.—Not later than three
25 years after the date of the enactment of this

1 Act, the Comptroller General of the United
2 States shall submit to Congress a report on the
3 implementation of this section and the effective-
4 ness of the Veterans Justice Outreach Program.

5 (B) CONTENTS.—The report required by
6 subparagraph (A) shall include the following:

7 (i) An assessment of whether the Sec-
8 retary has fulfilled the Secretary's obliga-
9 tions under this section.

10 (ii) The number of veterans who are
11 served by Veterans Justice Outreach Spe-
12 cialists hired under subsection (a)(1),
13 disaggregated by demographics (including
14 discharge status).

15 (iii) An identification of any sub-
16 groups of veterans who underutilize serv-
17 ices provided under laws administered by
18 the Secretary, including an assessment of
19 whether these veterans have access to Vet-
20 erans Justice Outreach Specialists under
21 the Veterans Justice Outreach Program.

22 (iv) Such recommendations as the
23 Comptroller General may have for the Sec-
24 retary to improve the effectiveness of the
25 Veterans Justice Outreach Program.

1 (e) DEFINITIONS.—In this section:

2 (1) JUSTICE TEAM.—The term “justice team”
3 means the group of individuals, which may include
4 a judge, court coordinator, prosecutor, public de-
5 fender, treatment provider, probation or other law
6 enforcement officer, program mentor, and Veterans
7 Justice Outreach Specialist, who assist justice-in-
8 volved veterans in a veterans treatment court or
9 other veteran-focused court.

10 (2) JUSTICE-INVOLVED VETERAN.—The term
11 “justice-involved veteran” means a veteran with ac-
12 tive, ongoing, or recent contact with some compo-
13 nent of a local criminal justice system.

14 (3) LOCAL CRIMINAL JUSTICE SYSTEM.—The
15 term “local criminal justice system” means law en-
16 forcement, jails, prisons, and Federal, State, and
17 local courts.

18 (4) VETERANS JUSTICE OUTREACH PRO-
19 GRAM.—The term “Veterans Justice Outreach Pro-
20 gram” means the program through which the De-
21 partment of Veterans Affairs identifies justice-in-
22 volved veterans and provides such veterans with ac-
23 cess to Department services.

24 (5) VETERANS JUSTICE OUTREACH SPE-
25 CIALIST.—The term “Veterans Justice Outreach

1 Specialist” means an employee of the Department of
2 Veterans Affairs who serves as a liaison between the
3 Department and the local criminal justice system on
4 behalf of a justice-involved veteran.

5 (6) VETERANS TREATMENT COURT.—The term
6 “veterans treatment court” means a State or local
7 court that is participating in the veterans treatment
8 court program (as defined in section 2991(i)(1) of
9 the Omnibus Crime Control and Safe Streets Act of
10 1968 (42 U.S.C. 3797aa(i)(1))).

11 **Subtitle G—Peer Support Coun-**
12 **seling Program for Women Vet-**
13 **erans**

14 **SEC. 8061. PEER SUPPORT COUNSELING PROGRAM FOR**
15 **WOMEN VETERANS.**

16 (a) IN GENERAL.—Section 1720F(j) of title 38,
17 United States Code, is amended by adding at the end the
18 following new paragraph:

19 “(4)(A) As part of the counseling program under this
20 subsection, the Secretary shall emphasize appointing peer
21 support counselors for women veterans. To the degree
22 practicable, the Secretary shall seek to recruit women peer
23 support counselors with expertise in—

24 “(i) female gender-specific issues and services;

1 “(ii) the provision of information about services
2 and benefits provided under laws administered by
3 the Secretary; or

4 “(iii) employment mentoring.

5 “(B) To the degree practicable, the Secretary shall
6 emphasize facilitating peer support counseling for women
7 veterans who are eligible for counseling and services under
8 section 1720D of this title, have post-traumatic stress dis-
9 order or suffer from another mental health condition, are
10 homeless or at risk of becoming homeless, or are otherwise
11 at increased risk of suicide, as determined by the Sec-
12 retary.

13 “(C) The Secretary shall conduct outreach to inform
14 women veterans about the program and the assistance
15 available under this paragraph.

16 “(D) In carrying out this paragraph, the Secretary
17 shall coordinate with such community organizations, State
18 and local governments, institutions of higher education,
19 chambers of commerce, local business organizations, orga-
20 nizations that provide legal assistance, and other organiza-
21 tions as the Secretary considers appropriate.

22 “(E) In carrying out this paragraph, the Secretary
23 shall provide adequate training for peer support coun-
24 selors, including training carried out under the national
25 program of training required by section 304(c) of the

1 Caregivers and Veterans Omnibus Health Services Act of
2 2010 (38 U.S.C. 1712A note).”.

3 (b) FUNDING.—The Secretary of Veterans Affairs
4 shall carry out paragraph (4) of section 1720F(j) of title
5 38, United States Code, as added by subsection (a), using
6 funds otherwise made available to the Secretary. No addi-
7 tional funds are authorized to be appropriated by reason
8 of such paragraph.

9 (c) REPORT TO CONGRESS.—Not later than two
10 years after the date of the enactment of this Act, the Sec-
11 retary of Veterans Affairs shall submit to the Committees
12 on Veterans’ Affairs of the Senate and House of Rep-
13 resentatives a report on the peer support counseling pro-
14 gram under section 1720F(j) of title 38, United States
15 Code, as amended by this section. Such report shall in-
16 clude—

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”.

