

114TH CONGRESS  
2D SESSION

# H. R. 5189

To address the opioid abuse crisis.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2016

Ms. KUSTER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, Education and the Workforce, Ways and Means, Armed Services, and Natural Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To address the opioid abuse crisis.

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

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

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Opioid Abuse Crisis Act of 2016”.

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

Sec. 1. Short title; table of contents.

### TITLE I—PUBLIC HEALTH PROVISIONS

Sec. 101. Funding for opioid and heroin abuse prevention and treatment.

Sec. 102. Opioid overdose reversal drugs prescribing grant program.

- Sec. 103. Partial fills of schedule II controlled substances.
- Sec. 104. Opioid use disorder treatment modernization.
- Sec. 105. Nurturing and supporting healthy babies.
- Sec. 106. Improving treatment for pregnant and postpartum women.
- Sec. 107. Assisting veterans with military emergency medical training to meet requirements for becoming civilian emergency medical technicians.
- Sec. 108. Information materials and resources to prevent addiction related to youth sports injuries.
- Sec. 109. Lali's Law.
- Sec. 110. Opioid review modernization.
- Sec. 111. Study on treatment infrastructure.
- Sec. 112. National youth recovery initiative.
- Sec. 113. Building communities of recovery.

#### TITLE II—COMPREHENSIVE OPIOID ABUSE REDUCTION

- Sec. 201. Comprehensive opioid abuse grant program.
- Sec. 202. Audit and accountability of grantees.
- Sec. 203. Veterans treatment courts.
- Sec. 204. Emergency Federal law enforcement assistance.
- Sec. 205. Opioid Program Evaluation Act.
- Sec. 206. Good Samaritan Assessment Act.

#### TITLE III—PROMOTING RESPONSIBLE OPIOID MANAGEMENT AND INCORPORATING SCIENTIFIC EXPERTISE

- Sec. 301. Short title.

##### Subtitle A—Opioid Therapy and Pain Management

- Sec. 311. Guidelines on management of opioid therapy by Department of Veterans Affairs and Department of Defense and implementation of such guidelines by Department of Veterans Affairs.
- Sec. 312. Improvement of opioid safety measures by Department of Veterans Affairs.
- Sec. 313. Strengthening of joint working group on pain management of the Department of Veterans Affairs and the Department of Defense.
- Sec. 314. Review, investigation, and report on use of opioids in treatment by Department of Veterans Affairs.

##### Subtitle B—Patient Advocacy

- Sec. 321. Community meetings on improving care furnished by Department of Veterans Affairs.
- Sec. 322. Improvement of awareness of patient advocacy program and patient bill of rights of Department of Veterans Affairs.
- Sec. 323. Comptroller general report on patient advocacy program of Department of Veterans Affairs.

##### Subtitle C—Complementary and Integrative Health

- Sec. 331. Expansion of research and education on and delivery of complementary and integrative health to veterans.
- Sec. 332. Pilot program on integration of complementary alternative medicines and related issues for veterans and family members of veterans.

Subtitle D—Fitness of Health Care Providers

- Sec. 341. Additional requirements for hiring of health care providers by Department of Veterans Affairs.
- Sec. 342. Provision of information on health care providers of Department of Veterans Affairs to State Medical Boards.
- Sec. 343. Report on compliance by Department of Veterans Affairs with reviews of health care providers leaving the Department or transferring to other facilities.

Subtitle E—Other Veterans Matters

- Sec. 351. Audit of Veterans Health Administration programs of Department of Veterans Affairs.

TITLE IV—IMPROVING SAFE CARE FOR PREVENTING INFANT ABUSE AND NEGLECT

- Sec. 401. Short title.
- Sec. 402. Best practices for development of plans of safe care.
- Sec. 403. State plans.
- Sec. 404. Data reports.
- Sec. 405. Monitoring and oversight.
- Sec. 406. Rule of construction.

TITLE V—OTHER PROVISIONS

- Sec. 501. Programs to prevent prescription drug abuse under Medicare parts C and D.
- Sec. 502. Exclusion of authorized generic drugs from calculation of average manufacturer price for brand name drugs.

1 **TITLE I—PUBLIC HEALTH**  
 2 **PROVISIONS**

3 **SEC. 101. FUNDING FOR OPIOID AND HEROIN ABUSE PRE-**  
 4 **VENTION AND TREATMENT.**

5 (a) FUNDING.—There are authorized to be appro-  
 6 priated, and are appropriated, out of monies in the Treas-  
 7 ury not otherwise obligated, \$600,000,000 for fiscal year  
 8 2017, to improve opioid prescribing practices and expand  
 9 access to substance use treatments to reduce opioid use  
 10 disorders and overdose, to be made available in accordance  
 11 with this Act.

1 (b) STATE TARGETED RESPONSE COOPERATIVE  
2 AGREEMENTS.—Subpart 1 of part B of title V of the Pub-  
3 lic Health Service Act (42 U.S.C. 290bb et seq.) is amend-  
4 ed by inserting after section 509 the following:

5 **“SEC. 510. STATE TARGETED RESPONSE COOPERATIVE**  
6 **AGREEMENTS.**

7 “(a) IN GENERAL.—The Secretary shall enter into  
8 additional targeted response cooperative agreements with  
9 States under this title to expand opioid treatment capacity  
10 and make services more affordable to those who cannot  
11 afford such services.

12 “(b) AWARDING OF FUNDING.—The Secretary shall  
13 allocate funding to States under this section based on—

14 “(1) the severity of the opioid epidemic in the  
15 State; and

16 “(2) the strength of the strategy of the State  
17 to respond to such epidemic.

18 “(c) USE OF FUNDS.—Amounts received by a State  
19 under this section shall be used to expand treatment ca-  
20 pacity and make services more affordable to those who  
21 cannot afford such services and to help individuals seek  
22 treatment, successfully complete treatment, and sustain  
23 recovery.

24 “(d) FUNDING.—Of the amounts appropriated under  
25 section 101(a) of the Opioid Use Disorder Treatment Ex-

1 pansion and Modernization Act for fiscal year 2017,  
2 \$460,000,000 shall be made available to carry out this  
3 section, to remain available until expended.”.

4 (c) TREATMENT FOR PRESCRIPTION DRUG ABUSE  
5 AND HEROIN USE.—Section 331(b) of the Public Health  
6 Service Act (42 U.S.C. 254d(b)) is amended by adding  
7 at the end the following:

8 “(3)(A) The Secretary shall use amounts made  
9 available under subparagraph (B) to support en-  
10 hanced loan repayment awards to increase the num-  
11 ber of clinicians in the Corps with medication as-  
12 sisted treatment training to treat individuals with  
13 opioid use disorders through loan repayments to cli-  
14 nicians.

15 “(B) Of the amounts appropriated under sec-  
16 tion 101(a) of the Opioid Use Disorder Treatment  
17 Expansion and Modernization Act for fiscal year  
18 2017, \$25,000,000 shall be made available to carry  
19 out this section, to remain available until ex-  
20 pended.”.

21 (d) EVALUATION OF MEDICATION-ASSISTED TREAT-  
22 MENT.—Subpart 1 of part B of title V of the Public  
23 Health Service Act (42 U.S.C. 290bb et seq.) is amended  
24 by inserting after section 510, as added by subsection (b),  
25 the following:

1 **“SEC. 511. EVALUATION OF MEDICATION-ASSISTED TREAT-**  
2 **MENT.**

3 “(a) IN GENERAL.—In order to assess the treatment  
4 outcomes of patients with opioid addiction receiving medi-  
5 cation-assisted treatment, the Secretary shall evaluate the  
6 short, medium, and long-term outcomes of such substance  
7 abuse treatment programs in order to increase effective-  
8 ness in reducing opioid use disorders, overdose, and death.

9 “(b) FUNDING.—Of the amounts appropriated under  
10 section 101(a) of the Opioid Use Disorder Treatment Ex-  
11 pansion and Modernization Act for fiscal year 2017,  
12 \$15,000,000 shall be made available to carry out this sec-  
13 tion, to remain available until expended.”.

14 **SEC. 102. OPIOID OVERDOSE REVERSAL DRUGS PRE-**  
15 **SCRIBING GRANT PROGRAM.**

16 (a) ESTABLISHMENT.—

17 (1) IN GENERAL.—Not later than six months  
18 after the date of the enactment of this Act, the Sec-  
19 retary of Health and Human Services may establish,  
20 in accordance with this section, a five-year opioid  
21 overdose reversal drugs prescribing grant program  
22 (in this section referred to as the “grant program”).

23 (2) MAXIMUM GRANT AMOUNT.—A grant made  
24 under this section may not be for more than  
25 \$200,000 per grant year.

1           (3) ELIGIBLE ENTITY.—For purposes of this  
2 section, the term “eligible entity” means a federally  
3 qualified health center (as defined in section  
4 1861(aa) of the Social Security Act (42 U.S.C.  
5 1395x(aa))), an opioid treatment program under  
6 part 8 of title 42, Code of Federal Regulations, any  
7 practitioner dispensing narcotic drugs pursuant to  
8 section 303(g) of the Controlled Substances Act (21  
9 U.S.C. 823(g)), or any other entity that the Sec-  
10 retary deems appropriate.

11           (4) PRESCRIBING.—For purposes of this sec-  
12 tion, the term “prescribing” means, with respect to  
13 an opioid overdose reversal drug, such as naloxone,  
14 the practice of prescribing such drug—

15                   (A) in conjunction with an opioid prescrip-  
16 tion for patients at an elevated risk of overdose;

17                   (B) in conjunction with an opioid agonist  
18 approved under section 505 of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 355)  
20 for the treatment of opioid abuse disorder;

21                   (C) to the caregiver or a close relative of  
22 patients at an elevated risk of overdose from  
23 opioids; or

24                   (D) in other circumstances, as identified  
25 by the Secretary, in which a provider identifies

1 a patient is at an elevated risk for an inten-  
2 tional or unintentional drug overdose from her-  
3 oin or prescription opioid therapies.

4 (b) APPLICATION.—To be eligible to receive a grant  
5 under this section, an eligible entity shall submit to the  
6 Secretary of Health and Human Services, in such form  
7 and manner as specified by the Secretary, an application  
8 that describes—

9 (1) the extent to which the area to which the  
10 entity will furnish services through use of the grant  
11 is experiencing significant morbidity and mortality  
12 caused by opioid abuse;

13 (2) the criteria that will be used to identify eli-  
14 gible patients to participate in such program; and

15 (3) how such program will work to try to iden-  
16 tify State, local, or private funding to continue the  
17 program after expiration of the grant.

18 (c) USE OF FUNDS.—An eligible entity receiving a  
19 grant under this section may use the grant for any of the  
20 following activities, but may use not more than 20 percent  
21 of the grant funds for activities described in paragraphs  
22 (4) and (5):

23 (1) To establish a program for prescribing  
24 opioid overdose reversal drugs, such as naloxone.



1           (2) To train and provide resources for health  
2           care providers and pharmacists on the prescribing of  
3           opioid overdose reversal drugs, such as naloxone.

4           (3) To establish mechanisms and processes for  
5           tracking patients participating in the program de-  
6           scribed in paragraph (1) and the health outcomes of  
7           such patients.

8           (4) To purchase opioid overdose reversal drugs,  
9           such as naloxone, for distribution under the program  
10          described in paragraph (1).

11          (5) To offset the co-pays and other cost sharing  
12          associated with opioid overdose reversal drugs, such  
13          as naloxone, to ensure that cost is not a limiting fac-  
14          tor for eligible patients.

15          (6) To conduct community outreach, in con-  
16          junction with community-based organizations, de-  
17          signed to raise awareness of prescribing practices,  
18          and the availability of opioid overdose reversal  
19          drugs, such as naloxone.

20          (7) To establish protocols to connect patients  
21          who have experienced a drug overdose with appro-  
22          priate treatment, including medication assisted  
23          treatment and appropriate counseling and behavioral  
24          therapies.

1 (d) EVALUATIONS BY RECIPIENTS.—As a condition  
2 of receipt of a grant under this section, an eligible entity  
3 shall, for each year for which the grant is received, submit  
4 to the Secretary of Health and Human Services informa-  
5 tion on appropriate outcome measures specified by the  
6 Secretary to assess the outcomes of the program funded  
7 by the grant, including—

- 8 (1) the number of prescribers trained;
- 9 (2) the number of prescribers who have co-pre-  
10 scribed an opioid overdose reversal drug, such as  
11 naloxone, to at least one patient;
- 12 (3) the total number of prescriptions written for  
13 opioid overdose reversal drugs, such as naloxone;
- 14 (4) the percentage of patients at elevated risk  
15 who received a prescription for an opioid overdose  
16 reversal drug, such as naloxone;
- 17 (5) the number of patients reporting use of an  
18 opioid overdose reversal drug, such as naloxone; and
- 19 (6) any other outcome measures that the Sec-  
20 retary deems appropriate.

21 (e) REPORTS BY SECRETARY.—For each year of the  
22 grant program under this section, the Secretary of Health  
23 and Human Services shall submit to the appropriate com-  
24 mittees of the House of Representatives and the Senate  
25 a report aggregating the information received from the

1 grant recipients for such year under subsection (d) and  
2 evaluating the outcomes achieved by the programs funded  
3 by grants made under this section.

4 (f) PROVIDING INFORMATION TO PRESCRIBERS IN  
5 CERTAIN FEDERAL HEALTH CARE AND MEDICAL FACILI-  
6 TIES ON BEST PRACTICES FOR PRESCRIBING OPIOID  
7 OVERDOSE REVERSAL DRUGS.—

8 (1) IN GENERAL.—Not later than 180 days  
9 after the date of enactment of this Act, the Sec-  
10 retary of Health and Human Services (in this sub-  
11 section referred to as the “Secretary”) may, as ap-  
12 propriate, provide information to prescribers within  
13 Federally qualified health centers (as defined in  
14 paragraph (4) of section 1861(aa) of the Social Se-  
15 curity Act (42 U.S.C. 1395x(aa))), and the health  
16 care facilities of the Indian Health Service, on best  
17 practices for prescribing opioid overdose reversal  
18 drugs, such as naloxone, for patients receiving  
19 chronic opioid therapy, patients being treated for  
20 opioid use disorders, and other patients that a pro-  
21 vider identifies as having an elevated risk of over-  
22 dose from heroin or prescription opioid therapies.

23 (2) NOT ESTABLISHING A MEDICAL STANDARD  
24 OF CARE.—The information on best practices pro-  
25 vided under this section shall not be construed as

1 constituting or establishing a medical standard of  
2 care for prescribing opioid overdose reversal drugs,  
3 such as naloxone, for patients described in para-  
4 graph (1).

5 (3) NO AUTHORIZATION OF ANY ADDITIONAL  
6 APPROPRIATIONS.—The Secretary shall carry out  
7 this subsection through funds otherwise appro-  
8 priated and nothing in this subsection shall be con-  
9 strued as authorizing the appropriations of addi-  
10 tional funds to carry out this subsection.

11 (4) ELEVATED RISK OF OVERDOSE DEFINED.—  
12 In this subsection, the term “elevated risk of over-  
13 dose” has the meaning given such term by the Sec-  
14 retary, which—

15 (A) may be based on the criteria provided  
16 in the Opioid Overdose Toolkit published by the  
17 Substance Abuse and Mental Health Services  
18 Administration (SAMHSA); and

19 (B) may include patients on a first course  
20 opioid treatment, patients using extended-re-  
21 lease and long-acting opioid analgesics, and pa-  
22 tients with a respiratory disease or other co-  
23 morbidities.

24 (g) FUNDING.—There is authorized to be appro-  
25 priated \$5,000,000 to carry out this section (other than

1 subsection (f)) for the period of fiscal years 2017 through  
2 2021, of which \$5,000,000 shall be made available from  
3 amounts appropriated under section 101(a) of the Opioid  
4 Use Disorder Treatment Expansion and Modernization  
5 Act for fiscal year 2017, to remain available until ex-  
6 pended.

7 **SEC. 103. PARTIAL FILLS OF SCHEDULE II CONTROLLED**  
8 **SUBSTANCES.**

9 (a) IN GENERAL.—Section 309 of the Controlled  
10 Substances Act (21 U.S.C. 829) is amended by adding at  
11 the end the following:

12 “(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED  
13 SUBSTANCES.—

14 “(1) PARTIAL FILLS.—

15 “(A) IN GENERAL.—A prescription for a  
16 controlled substance in schedule II may be par-  
17 tially filled if—

18 “(i) it is not prohibited by State law;

19 “(ii) the prescription is written and  
20 filled in accordance with this Act, regula-  
21 tions prescribed by the Attorney General,  
22 and State law;

23 “(iii) the partial fill is requested by  
24 the patient or the practitioner that wrote  
25 the prescription; and

1           “(iv) the total quantity dispensed in  
2           all partial fillings does not exceed the total  
3           quantity prescribed.

4           “(B) OTHER CIRCUMSTANCES.—A pre-  
5           scription for a controlled substance in schedule  
6           II may be partially filled in accordance with  
7           section 1306.13 of title 21, Code of Federal  
8           Regulations (as in effect on the date of enact-  
9           ment of the Opioid Abuse Crisis Act of 2016).

10          “(2) REMAINING PORTIONS.—

11           “(A) IN GENERAL.—Except as provided in  
12           subparagraph (B), remaining portions of a par-  
13           tially filled prescription for a controlled sub-  
14           stance in schedule II—

15                   “(i) may be filled; and

16                   “(ii) shall be filled not later than 30  
17           days after the date on which the prescrip-  
18           tion is written.

19           “(B) EMERGENCY SITUATIONS.—In emer-  
20           gency situations, as described in subsection (a),  
21           the remaining portions of a partially filled pre-  
22           scription for a controlled substance in schedule  
23           II—

24                   “(i) may be filled; and

1                   “(ii) shall be filled not later than 72  
2                   hours after the prescription is issued.”.

3           (b) **RULE OF CONSTRUCTION.**—Nothing in this sec-  
4 tion shall be construed to affect the authority of the Attor-  
5 ney General to allow a prescription for a controlled sub-  
6 stance in schedule III, IV, or V of section 202(c) of the  
7 Controlled Substances Act (21 U.S.C. 812(c)) to be par-  
8 tially filled.

9   **SEC. 104. OPIOID USE DISORDER TREATMENT MODERNIZA-**  
10   **TION.**

11           (a) **IN GENERAL.**—Section 303(g)(2) of the Con-  
12 trolled Substances Act (21 U.S.C. 823(g)(2)) is amend-  
13 ed—

14                   (1) in subparagraph (B), by striking clauses (i),  
15                   (ii), and (iii) and inserting the following:

16                           “(i) The practitioner is a qualifying practitioner  
17                           (as defined in subparagraph (G)).

18                           “(ii) With respect to patients to whom the prac-  
19                           titioner will provide such drugs or combinations of  
20                           drugs, the practitioner has the capacity to provide  
21                           directly, by referral, or in such other manner as de-  
22                           termined by the Secretary—

23                                   “(I) all schedule III, IV, and V drugs, as  
24                                   well as unscheduled medications approved by  
25                                   the Food and Drug Administration, for the

1 treatment of opioid use disorder, including such  
2 drugs and medications for maintenance, detoxi-  
3 fication, overdose reversal, and relapse preven-  
4 tion, as available; and

5 “(II) appropriate counseling and other ap-  
6 propriate ancillary services.

7 “(iii)(I) The total number of such patients of  
8 the practitioner at any one time will not exceed the  
9 applicable number. Except as provided in subclauses  
10 (II) and (III), the applicable number is 30.

11 “(II) The applicable number is 100 if, not soon-  
12 er than 1 year after the date on which the practi-  
13 tioner submitted the initial notification, the practi-  
14 tioner submits a second notification to the Secretary  
15 of the need and intent of the practitioner to treat up  
16 to 100 patients.

17 “(III) The applicable number is 300 if the prac-  
18 titioner is a qualifying physician meeting the re-  
19 quirement of subclause (VI) and, not sooner than 1  
20 year after the date on which the physician submitted  
21 a second notification under subclause (II), the prac-  
22 titioner submits a third notification to the Secretary  
23 of the need and intent of the physician to treat up  
24 to 300 patients.



1           “(IV) The Secretary may by regulation change  
2 such total number.

3           “(V) The Secretary may exclude from the appli-  
4 cable number patients to whom such drugs or com-  
5 binations of drugs are directly administered by the  
6 qualifying practitioner in the office setting.

7           “(VI) For purposes of subclause (III), a quali-  
8 fying physician meets the requirement of this sub-  
9 clause if the physician—

10                   “(aa) holds a special certification in addic-  
11 tion psychiatry or addiction medicine as de-  
12 scribed in clause (ii) from the American Board  
13 of Medical Specialties, the American Board of  
14 Addiction Medicine, the American Osteopathic  
15 Association, the American Society of Addiction  
16 Medicine, or such other organization as the Sec-  
17 retary determines to be appropriate for pur-  
18 poses of this subclause; or

19                   “(bb) has completed not fewer than 24  
20 hours of training, with respect to the treatment  
21 and management of opiate-dependent patients,  
22 addressing the topics listed in subparagraph  
23 (G)(ii)(IV).

24           The Secretary may review and update the require-  
25 ments of this subclause.

1           “(iv) In the case of a third notification under  
2           clause (iii)(III), the qualifying physician maintains  
3           and implements a diversion control plan that con-  
4           tains specific measures to reduce the likelihood of  
5           the diversion of controlled substances prescribed by  
6           the physician for the treatment of opioid use dis-  
7           order.

8           “(v) In the case of a third notification under  
9           clause (iii)(III), the qualifying physician obtains a  
10          written agreement from each patient, including the  
11          patient’s signature, that the patient—

12                 “(I) will receive an initial assessment and  
13                 treatment plan and periodic assessments and  
14                 treatment plans thereafter;

15                 “(II) will be subject to medication adher-  
16                 ence and substance use monitoring;

17                 “(III) understands available treatment op-  
18                 tions, including all drugs approved by the Food  
19                 and Drug Administration for the treatment of  
20                 opioid use disorder, including their potential  
21                 risks and benefits; and

22                 “(IV) understands that receiving regular  
23                 counseling services is critical to recovery.

24           “(vi) The practitioner will comply with the re-  
25          porting requirements of subparagraph (D)(i)(IV).”;

1 (2) in subparagraph (D)—

2 (A) in clause (i), by adding at the end the  
3 following:

4 “(IV) The practitioner reports to the Secretary,  
5 at such times and in such manner as specified by  
6 the Secretary, such information and assurances as  
7 the Secretary determines necessary to assess wheth-  
8 er the practitioner continues to meet the require-  
9 ments for a waiver under this paragraph.”;

10 (B) in clause (ii), by striking “Upon re-  
11 ceiving a notification under subparagraph (B)”  
12 and inserting “Upon receiving a determination  
13 from the Secretary under clause (iii) finding  
14 that a practitioner meets all requirements for a  
15 waiver under subparagraph (B)”;

16 (C) in clause (iii)—

17 (i) by inserting “and shall forward  
18 such determination to the Attorney Gen-  
19 eral” before the period at the end of the  
20 first sentence; and

21 (ii) by striking “physician” and in-  
22 serting “practitioner”;

23 (3) in subparagraph (G)—

24 (A) by amending clause (ii)(IV) to read as  
25 follows:

1           “(IV) The physician has, with respect to  
2           the treatment and management of opiate-de-  
3           pendent patients, completed not less than eight  
4           hours of training (through classroom situations,  
5           seminars at professional society meetings, elec-  
6           tronic communications, or otherwise) that is  
7           provided by the American Society of Addiction  
8           Medicine, the American Academy of Addiction  
9           Psychiatry, the American Medical Association,  
10          the American Osteopathic Association, the  
11          American Psychiatric Association, or any other  
12          organization that the Secretary determines is  
13          appropriate for purposes of this subclause. Such  
14          training shall address—

15                 “(aa) opioid maintenance and detoxi-  
16                 fication;

17                 “(bb) appropriate clinical use of all  
18                 drugs approved by the Food and Drug Ad-  
19                 ministration for the treatment of opioid  
20                 use disorder;

21                 “(cc) initial and periodic patient as-  
22                 sessments (including substance use moni-  
23                 toring);

24                 “(dd) individualized treatment plan-  
25                 ning; overdose reversal; relapse prevention;

1 “(ee) counseling and recovery support  
2 services;

3 “(ff) staffing roles and considerations;

4 “(gg) diversion control; and

5 “(hh) other best practices, as identi-  
6 fied by the Secretary.”; and

7 (B) by adding at the end the following:

8 “(iii) The term ‘qualifying practitioner’  
9 means—

10 “(I) a qualifying physician, as defined in  
11 clause (ii); or

12 “(II) a qualifying other practitioner, as de-  
13 fined in clause (iv).

14 “(iv) The term ‘qualifying other practitioner’  
15 means a nurse practitioner or physician assistant  
16 who satisfies each of the following:

17 “(I) The nurse practitioner or physician  
18 assistant is licensed under State law to pre-  
19 scribe schedule III, IV, or V medications for the  
20 treatment of pain.

21 “(II) The nurse practitioner or physician  
22 assistant satisfies 1 or more of the following:

23 “(aa) Has completed not fewer than  
24 24 hours of initial training addressing each  
25 of the topics listed in clause (ii)(IV)

1 (through classroom situations, seminars at  
2 professional society meetings, electronic  
3 communications, or otherwise) provided by  
4 the American Society of Addiction Medi-  
5 cine, the American Academy of Addiction  
6 Psychiatry, the American Medical Associa-  
7 tion, the American Osteopathic Associa-  
8 tion, the American Nurses Credentialing  
9 Center, the American Psychiatric Associa-  
10 tion, the American Association of Nurse  
11 Practitioners, the American Academy of  
12 Physician Assistants, or any other organi-  
13 zation that the Secretary determines is ap-  
14 propriate for purposes of this subclause.

15 “(bb) Has such other training or ex-  
16 perience as the Secretary determines will  
17 demonstrate the ability of the nurse practi-  
18 tioner or physician assistant to treat and  
19 manage opiate-dependent patients.

20 “(III) The nurse practitioner or physician  
21 assistant is supervised by or works in collabora-  
22 tion with a qualifying physician, if the nurse  
23 practitioner or physician assistant is required  
24 by State law to prescribe medications for the

1 treatment of opioid use disorder in collaboration  
2 with or under the supervision of a physician.

3 The Secretary may review and update the require-  
4 ments for being a qualifying other practitioner under  
5 this clause.”; and

6 (4) in subparagraph (H)—

7 (A) in clause (i), by inserting after sub-  
8 clause (II) the following:

9 “(III) Such other elements of the requirements  
10 under this paragraph as the Secretary determines  
11 necessary for purposes of implementing such re-  
12 quirements.”; and

13 (B) by amending clause (ii) to read as fol-  
14 lows:

15 “(ii) Not later than one year after the date of enact-  
16 ment of the Opioid Use Disorder Treatment Expansion  
17 and Modernization Act, the Secretary shall update the  
18 treatment improvement protocol containing best practice  
19 guidelines for the treatment of opioid-dependent patients  
20 in office-based settings. The Secretary shall update such  
21 protocol in consultation with experts in opioid use disorder  
22 research and treatment.”.

23 (b) RECOMMENDATION OF REVOCATION OR SUSPEN-  
24 SION OF REGISTRATION IN CASE OF SUBSTANTIAL NON-  
25 COMPLIANCE.—The Secretary of Health and Human

1 Services may recommend to the Attorney General that the  
2 registration of a practitioner be revoked or suspended if  
3 the Secretary determines, according to such criteria as the  
4 Secretary establishes by regulation, that a practitioner  
5 who is registered under section 303(g)(2) of the Controlled  
6 Substances Act (21 U.S.C. 823(g)(2)) is not in substantial  
7 compliance with the requirements of such section, as  
8 amended by this Act.

9 (c) OPIOID DEFINED.—Section 102(18) of the Con-  
10 trolled Substances Act (21 U.S.C. 802(18)) is amended  
11 by inserting “or ‘opioid’” after “The term ‘opiate’”.

12 (d) REPORTS TO CONGRESS.—

13 (1) IN GENERAL.—Not later than 2 years after  
14 the date of enactment of this Act and not less than  
15 over every 5 years thereafter, the Secretary of  
16 Health and Human Services, in consultation with  
17 the Drug Enforcement Administration and experts  
18 in opioid use disorder research and treatment,  
19 shall—

20 (A) perform a thorough review of the pro-  
21 vision of opioid use disorder treatment services  
22 in the United States, including services pro-  
23 vided in opioid treatment programs and other  
24 specialty and nonspecialty settings; and



1 (B) submit a report to the Congress on the  
2 findings and conclusions of such review.

3 (2) CONTENTS.—Each report under paragraph  
4 (1) shall include an assessment of—

5 (A) compliance with the requirements of  
6 section 303(g)(2) of the Controlled Substances  
7 Act (21 U.S.C. 823(g)(2)), as amended by this  
8 Act;

9 (B) the measures taken by the Secretary of  
10 Health and Human Services to ensure such  
11 compliance;

12 (C) whether there is further need to in-  
13 crease or decrease the number of patients a  
14 waived practitioner is permitted to treat, as  
15 provided for by the amendment made by sub-  
16 section (a)(1);

17 (D) the extent to which, and proportions  
18 with which, the full range of Food and Drug  
19 Administration-approved treatments for opioid  
20 use disorder are used in routine health care set-  
21 tings and specialty substance use disorder treat-  
22 ment settings;

23 (E) access to, and use of, counseling and  
24 recovery support services, including the percent-  
25 age of patients receiving such services;

1 (F) changes in State or local policies and  
2 legislation relating to opioid use disorder treat-  
3 ment;

4 (G) the use of prescription drug moni-  
5 toring programs by practitioners who are per-  
6 mitted to dispense narcotic drugs to individuals  
7 pursuant to a waiver under section 303(g)(2) of  
8 the Controlled Substances Act (21 U.S.C.  
9 823(g)(2));

10 (H) the findings resulting from inspections  
11 by the Drug Enforcement Administration of  
12 practitioners described in subparagraph (G);  
13 and

14 (I) the effectiveness of cross-agency col-  
15 laboration between the Department of Health  
16 and Human Services and the Drug Enforce-  
17 ment Administration for expanding effective  
18 opioid use disorder treatment.

19 **SEC. 105. NURTURING AND SUPPORTING HEALTHY BABIES.**

20 (a) GAO REPORT ON NEONATAL ABSTINENCE SYN-  
21 DROME (NAS).—

22 (1) IN GENERAL.—Not later than one year  
23 after the date of the enactment of this Act, the  
24 Comptroller General of the United States shall sub-  
25 mit to the Committee on Energy and Commerce of

1 the House of Representatives and the Committee on  
2 Finance and the Committee on Health, Education,  
3 Labor, and Pensions of the Senate a report on neo-  
4 natal abstinence syndrome (in this section referred  
5 to as “NAS”) in the United States.

6 (2) INFORMATION TO BE INCLUDED IN RE-  
7 PORT.—Such report shall include information on the  
8 following:

9 (A) The prevalence of NAS in the United  
10 States, including the proportion of children  
11 born in the United States with NAS who are el-  
12 igible for medical assistance under State Med-  
13 icaid programs under title XIX of the Social  
14 Security Act at birth and the costs associated  
15 with NAS through such programs.

16 (B) The services for which coverage is  
17 available under State Medicaid programs for  
18 treatment of infants with NAS.

19 (C) The settings (including inpatient, out-  
20 patient, hospital-based, and other settings) for  
21 the treatment of infants with NAS and the re-  
22 imbursement methodologies and costs associ-  
23 ated with such treatment in such settings.

24 (D) The prevalence of utilization of various  
25 care settings under State Medicaid programs

1           for treatment of infants with NAS and any  
2           Federal barriers to treating such infants under  
3           such programs, particularly in non-hospital-  
4           based settings.

5           (3) RECOMMENDATIONS.—Such report also  
6           shall include such recommendations as the Comp-  
7           troller General determines appropriate for improve-  
8           ments that will ensure access to treatment for in-  
9           fants with NAS under State Medicaid programs.

10          (b) EXCLUDING ABUSE-DETERRENT FORMULATIONS  
11 OF PRESCRIPTION DRUGS FROM THE MEDICAID ADDI-  
12 TIONAL REBATE REQUIREMENT FOR NEW FORMULA-  
13 TIONS OF PRESCRIPTION DRUGS.—

14           (1) IN GENERAL.—The last sentence of section  
15           1927(c)(2)(C) of the Social Security Act (42 U.S.C.  
16           1396r–8(c)(2)(C)) is amended by inserting before  
17           the period at the end the following: “, but does not  
18           include an abuse-deterrent formulation of the drug  
19           (as determined by the Secretary), regardless of  
20           whether such abuse-deterrent formulation is an ex-  
21           tended release formulation”.

22           (2) EFFECTIVE DATE.—The amendment made  
23           by paragraph (1) shall apply to drugs that are paid  
24           for by a State in calendar quarters beginning on or  
25           after the date of the enactment of this Act.

1 (c) LIMITING DISCLOSURE OF PREDICTIVE MOD-  
2 ELING AND OTHER ANALYTICS TECHNOLOGIES TO IDEN-  
3 TIFY AND PREVENT WASTE, FRAUD, AND ABUSE.—

4 (1) IN GENERAL.—Title XI of the Social Secu-  
5 rity Act is amended by inserting after section 1128J  
6 (42 U.S.C. 1320a–7k) the following new section:

7 **“SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND**  
8 **OTHER ANALYTICS TECHNOLOGIES TO IDEN-**  
9 **TIFY AND PREVENT WASTE, FRAUD, AND**  
10 **ABUSE.**

11 “(a) REFERENCE TO PREDICTIVE MODELING TECH-  
12 NOLOGIES REQUIREMENTS.—For provisions relating to  
13 the use of predictive modeling and other analytics tech-  
14 nologies to identify and prevent waste, fraud, and abuse  
15 with respect to the Medicare program under title XVIII,  
16 the Medicaid program under title XIX, and the Children’s  
17 Health Insurance Program under title XXI, see section  
18 4241 of the Small Business Jobs Act of 2010 (42 U.S.C.  
19 1320a–7m).

20 “(b) LIMITING DISCLOSURE OF PREDICTIVE MOD-  
21 ELING TECHNOLOGIES.—In implementing such provisions  
22 under such section 4241 with respect to covered algo-  
23 rithms (as defined in subsection (c)), the following shall  
24 apply:

1           “(1) NONAPPLICATION OF FOIA.—The covered  
2 algorithms used or developed for purposes of such  
3 section (including by the Secretary or a State (or an  
4 entity operating under a contract with a State))  
5 shall be exempt from disclosure under section  
6 552(b)(3) of title 5, United States Code.

7           “(2) LIMITATION WITH RESPECT TO USE AND  
8 DISCLOSURE OF INFORMATION BY STATE AGEN-  
9 CIES.—

10           “(A) IN GENERAL.—A State agency may  
11 not use or disclose covered algorithms used or  
12 developed for purposes of such section except  
13 for purposes of administering the State plan (or  
14 a waiver of the plan) under the Medicaid pro-  
15 gram under title XIX or the State child health  
16 plan (or a waiver of the plan) under the Chil-  
17 dren’s Health Insurance Program under title  
18 XXI, including by enabling an entity operating  
19 under a contract with a State to assist the  
20 State to identify or prevent waste, fraud and  
21 abuse with respect to such programs.

22           “(B) INFORMATION SECURITY.—A State  
23 agency shall have in effect data security and  
24 control policies that the Secretary finds ade-  
25 quate to ensure the security of covered algo-

1           rithms used or developed for purposes of such  
2           section 4241 and to ensure that access to such  
3           information is restricted to authorized persons  
4           for purposes of authorized uses and disclosures  
5           described in subparagraph (A).

6           “(C) PROCEDURAL REQUIREMENTS.—  
7           State agencies to which information is disclosed  
8           pursuant to such section 4241 shall adhere to  
9           uniform procedures established by the Sec-  
10          retary.

11          “(c) COVERED ALGORITHM DEFINED.—In this sec-  
12          tion, the term ‘covered algorithm’—

13                 “(1) means a predictive modeling or other ana-  
14                 lytics technology, as used for purposes of section  
15                 4241(a) of the Small Business Jobs Act of 2010 (42  
16                 U.S.C. 1320a–7m(a)) to identify and prevent waste,  
17                 fraud, and abuse with respect to the Medicare pro-  
18                 gram under title XVIII, the Medicaid program  
19                 under title XIX, and the Children’s Health Insur-  
20                 ance Program under title XXI; and

21                 “(2) includes the mathematical expressions uti-  
22                 lized in the application of such technology and the  
23                 means by which such technology is developed.”.

24                 (2) CONFORMING AMENDMENTS.—

1 (A) MEDICAID STATE PLAN REQUIRE-  
2 MENT.—Section 1902(a) of the Social Security  
3 Act (42 U.S.C. 1396a(a)) is amended—

4 (i) in paragraph (80), by striking  
5 “and” at the end;

6 (ii) in paragraph (81), by striking the  
7 period at the end and inserting “; and”;  
8 and

9 (iii) by inserting after paragraph (81)  
10 the following new paragraph:

11 “(82) provide that the State agency responsible  
12 for administering the State plan under this title pro-  
13 vides assurances to the Secretary that the State  
14 agency is in compliance with subparagraphs (A),  
15 (B), and (C) of section 1128K(b)(2).”.

16 (B) STATE CHILD HEALTH PLAN REQUIRE-  
17 MENT.—Section 2102(a)(7) of the Social Secu-  
18 rity Act (42 U.S.C. 1397bb(a)(7)) is amend-  
19 ed—

20 (i) in subparagraph (A), by striking “,  
21 and” at the end and inserting a semicolon;

22 (ii) in subparagraph (B), by striking  
23 the period at the end and inserting “;  
24 and”; and



1 (iii) by adding at the end the fol-  
2 lowing new subparagraph:

3 “(C) to ensure that the State agency in-  
4 volved is in compliance with subparagraphs (A),  
5 (B), and (C) of section 1128K(b)(2).”.

6 (d) MEDICAID IMPROVEMENT FUND.—Section  
7 1941(b)(1) of the Social Security Act (42 U.S.C. 1396w-  
8 1(b)(1)) is amended to read as follows:

9 “(1) IN GENERAL.—There shall be available to  
10 the Fund, for expenditures from the Fund for fiscal  
11 year 2021 and thereafter, \$5,000,000.”.

12 **SEC. 106. IMPROVING TREATMENT FOR PREGNANT AND**  
13 **POSTPARTUM WOMEN.**

14 (a) REAUTHORIZATION OF RESIDENTIAL TREAT-  
15 MENT PROGRAMS FOR PREGNANT AND POSTPARTUM  
16 WOMEN.—Section 508 of the Public Health Service Act  
17 (42 U.S.C. 290bb-1) is amended—

18 (1) in subsection (p), in the first sentence, by  
19 inserting “(other than subsection (r))” after “sec-  
20 tion”; and

21 (2) in subsection (r), by striking “such sums”  
22 and all that follows through “2003” and inserting  
23 “\$16,900,000 for each of fiscal years 2017 through  
24 2021”.

1 (b) PILOT PROGRAM GRANTS FOR STATE SUB-  
2 STANCE ABUSE AGENCIES.—

3 (1) IN GENERAL.—Section 508 of the Public  
4 Health Service Act (42 U.S.C. 290bb–1) is amend-  
5 ed—

6 (A) by redesignating subsection (r), as  
7 amended by subsection (a), as subsection (s);  
8 and

9 (B) by inserting after subsection (q) the  
10 following new subsection:

11 “(r) PILOT PROGRAM FOR STATE SUBSTANCE  
12 ABUSE AGENCIES.—

13 “(1) IN GENERAL.—From amounts made avail-  
14 able under subsection (s), the Director of the Center  
15 for Substance Abuse Treatment shall carry out a  
16 pilot program under which competitive grants are  
17 made by the Director to State substance abuse agen-  
18 cies to—

19 “(A) enhance flexibility in the use of funds  
20 designed to support family-based services for  
21 pregnant and postpartum women with a pri-  
22 mary diagnosis of a substance use disorder, in-  
23 cluding opioid use disorders;

24 “(B) help State substance abuse agencies  
25 address identified gaps in services furnished to

1 such women along the continuum of care, in-  
2 cluding services provided to women in nonresi-  
3 dential based settings; and

4 “(C) promote a coordinated, effective, and  
5 efficient State system managed by State sub-  
6 stance abuse agencies by encouraging new ap-  
7 proaches and models of service delivery.

8 “(2) REQUIREMENTS.—In carrying out the  
9 pilot program under this subsection, the Director  
10 shall—

11 “(A) require State substance abuse agen-  
12 cies to submit to the Director applications, in  
13 such form and manner and containing such in-  
14 formation as specified by the Director, to be eli-  
15 gible to receive a grant under the program;

16 “(B) identify, based on such submitted ap-  
17 plications, State substance abuse agencies that  
18 are eligible for such grants;

19 “(C) require services proposed to be fur-  
20 nished through such a grant to support family-  
21 based treatment and other services for pregnant  
22 and postpartum women with a primary diag-  
23 nosis of a substance use disorder, including  
24 opioid use disorders;

1           “(D) not require that services furnished  
2 through such a grant be provided solely to  
3 women that reside in facilities;

4           “(E) not require that grant recipients  
5 under the program make available through use  
6 of the grant all services described in subsection  
7 (d); and

8           “(F) consider not applying requirements  
9 described in paragraphs (1) and (2) of sub-  
10 section (f) to applicants, depending on the cir-  
11 cumstances of the applicant.

12           “(3) REQUIRED SERVICES.—

13           “(A) IN GENERAL.—The Director shall  
14 specify a minimum set of services required to be  
15 made available to eligible women through a  
16 grant awarded under the pilot program under  
17 this subsection. Such minimum set—

18           “(i) shall include requirements de-  
19 scribed in subsection (c) and be based on  
20 the recommendations submitted under sub-  
21 paragraph (B); and

22           “(ii) may be selected from among the  
23 services described in subsection (d) and in-  
24 clude other services as appropriate.

1           “(B) STAKEHOLDER INPUT.—The Director  
2           shall convene and solicit recommendations from  
3           stakeholders, including State substance abuse  
4           agencies, health care providers, persons in re-  
5           covery from substance abuse, and other appro-  
6           priate individuals, for the minimum set of serv-  
7           ices described in subparagraph (A).

8           “(4) DURATION.—The pilot program under this  
9           subsection shall not exceed 5 years.

10           “(5) EVALUATION AND REPORT TO CON-  
11           GRESS.—The Director of the Center for Behavioral  
12           Health Statistics and Quality shall fund an evalua-  
13           tion of the pilot program at the conclusion of the  
14           first grant cycle funded by the pilot program. The  
15           Director of the Center for Behavioral Health Statis-  
16           tics and Quality, in coordination with the Director of  
17           the Center for Substance Abuse Treatment shall  
18           submit to the relevant committees of jurisdiction of  
19           the House of Representatives and the Senate a re-  
20           port on such evaluation. The report shall include at  
21           a minimum outcomes information from the pilot pro-  
22           gram, including any resulting reductions in the use  
23           of alcohol and other drugs; engagement in treatment  
24           services; retention in the appropriate level and dura-  
25           tion of services; increased access to the use of medi-

1 cations approved by the Food and Drug Administra-  
2 tion for the treatment of substance use disorders in  
3 combination with counseling; and other appropriate  
4 measures.

5 “(6) STATE SUBSTANCE ABUSE AGENCIES DE-  
6 FINED.—For purposes of this subsection, the term  
7 ‘State substance abuse agency’ means, with respect  
8 to a State, the agency in such State that manages  
9 the Substance Abuse Prevention and Treatment  
10 Block Grant under part B of title XIX.”.

11 (2) FUNDING.—Subsection (s) of section 508 of  
12 the Public Health Service Act (42 U.S.C. 290bb–1),  
13 as amended by subsection (a) and redesignated by  
14 paragraph (1), is further amended by adding at the  
15 end the following new sentence: “Of the amounts  
16 made available for a year pursuant to the previous  
17 sentence to carry out this section, not more than 25  
18 percent of such amounts shall be made available for  
19 such year to carry out subsection (r), other than  
20 paragraph (5) of such subsection. Notwithstanding  
21 the preceding sentence, no funds shall be made  
22 available to carry out subsection (r) for a fiscal year  
23 unless the amount made available to carry out this  
24 section for such fiscal year is more than the amount

1 made available to carry out this section for fiscal  
2 year 2016.”.

3 (c) CUT-GO COMPLIANCE.—Subsection (f) of section  
4 319D of the Public Health Service Act (42 U.S.C. 247d–  
5 4) is amended by striking “through 2018” and inserting  
6 “through 2016, \$133,300,000 for fiscal year 2017, and  
7 \$138,300,000 for fiscal year 2018”.

8 **SEC. 107. ASSISTING VETERANS WITH MILITARY EMER-**  
9 **GENCY MEDICAL TRAINING TO MEET RE-**  
10 **QUIREMENTS FOR BECOMING CIVILIAN**  
11 **EMERGENCY MEDICAL TECHNICIANS.**

12 Part B of title III of the Public Health Service Act  
13 (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
14 tion 314 the following:

15 **“SEC. 315. ASSISTING VETERANS WITH MILITARY EMER-**  
16 **GENCY MEDICAL TRAINING TO MEET RE-**  
17 **QUIREMENTS FOR BECOMING CIVILIAN**  
18 **EMERGENCY MEDICAL TECHNICIANS.**

19 “(a) PROGRAM.—The Secretary shall establish a pro-  
20 gram consisting of awarding demonstration grants to  
21 States to streamline State requirements and procedures  
22 in order to assist veterans who completed military emer-  
23 gency medical technician training while serving in the  
24 Armed Forces of the United States to meet certification,

1 licensure, and other requirements applicable to becoming  
2 an emergency medical technician in the State.

3       “(b) USE OF FUNDS.—Amounts received as a dem-  
4 onstration grant under this section shall be used to pre-  
5 pare and implement a plan to streamline State require-  
6 ments and procedures as described in subsection (a), in-  
7 cluding by—

8               “(1) determining the extent to which the re-  
9 quirements for the education, training, and skill level  
10 of emergency medical technicians in the State are  
11 equivalent to requirements for the education, train-  
12 ing, and skill level of military emergency medical  
13 technicians; and

14               “(2) identifying methods, such as waivers, for  
15 military emergency medical technicians to forgo or  
16 meet any such equivalent State requirements.

17       “(c) ELIGIBILITY.—To be eligible for a grant under  
18 this section, a State shall demonstrate that the State has  
19 a shortage of emergency medical technicians.

20       “(d) REPORT.—The Secretary shall submit to the  
21 Congress an annual report on the program under this sec-  
22 tion.

23       “(e) FUNDING.—No additional funds are authorized  
24 to be appropriated for the purpose of carrying out this



1 section. This section shall be carried out using amounts  
2 otherwise available for such purpose.”.

3 **SEC. 108. INFORMATION MATERIALS AND RESOURCES TO**  
4 **PREVENT ADDICTION RELATED TO YOUTH**  
5 **SPORTS INJURIES.**

6 (a) TECHNICAL CLARIFICATION.—Effective as if in-  
7 cluded in the enactment of the Children’s Health Act of  
8 2000 (Public Law 106–310), section 3405(a) of such Act  
9 (114 Stat. 1221) is amended by striking “Part E of title  
10 III” and inserting “Part E of title III of the Public Health  
11 Service Act”.

12 (b) AMENDMENT.—Title III of the Public Health  
13 Service Act is amended by inserting after part D of such  
14 title (42 U.S.C. 254b et seq.) the following new part E:

15 **“PART E—OPIOID USE DISORDER**  
16 **“SEC. 341. INFORMATION MATERIALS AND RESOURCES TO**  
17 **PREVENT ADDICTION RELATED TO YOUTH**  
18 **SPORTS INJURIES.**

19 “(a) REPORT.—The Secretary shall—

20 “(1) not later than 24 months after the date of  
21 the enactment of this section, make publicly avail-  
22 able a report determining the extent to which infor-  
23 mational materials and resources described in sub-  
24 section (b) are available to teenagers and adolescents  
25 who play youth sports, families of such teenagers

1 and adolescents, nurses, youth sports groups, and  
2 relevant health care provider groups; and

3 “(2) for purposes of educating and preventing  
4 addiction in teenagers and adolescents who are in-  
5 jured playing youth sports and are subsequently pre-  
6 scribed an opioid, not later than 12 months after  
7 such report is made publicly available and taking  
8 into consideration the findings of such report, de-  
9 velop and, in coordination with youth sports groups,  
10 disseminate informational materials and resources  
11 described in subsection (b) for teenagers and adoles-  
12 cents who play youth sports, families of such teen-  
13 agers and adolescents, nurses, youth sports groups,  
14 and relevant health care provider groups.

15 “(b) MATERIALS AND RESOURCES DESCRIBED.—For  
16 purposes of this section, the informational materials and  
17 resources described in this subsection are informational  
18 materials and resources with respect to youth sports inju-  
19 ries for which opioids are potentially prescribed and subse-  
20 quently potentially lead to addiction, including materials  
21 and resources focused on the dangers of opioid use and  
22 misuse, treatment options for such injuries that do not  
23 involve the use of opioids, and how to seek treatment for  
24 addiction.

1       “(c) NO ADDITIONAL FUNDS.—No additional funds  
2 are authorized to be appropriated for the purpose of car-  
3 rying out this section. This section shall be carried out  
4 using amounts otherwise available for such purpose.”.

5 **SEC. 109. LALP'S LAW.**

6       (a) OPIOID OVERDOSE REVERSAL MEDICATION AC-  
7 CESS AND EDUCATION GRANT PROGRAM.—Part E of title  
8 III of the Public Health Service Act, as added by section  
9 109, is amended by adding at the end the following

10 **“SEC. 342. OPIOID OVERDOSE REVERSAL MEDICATION AC-**  
11 **CESS AND EDUCATION GRANT PROGRAMS.**

12       “(a) GRANTS TO STATES.—The Secretary may make  
13 grants to States for—

14               “(1) developing standing orders for pharmacies  
15 regarding opioid overdose reversal medication;

16               “(2) encouraging pharmacies to dispense opioid  
17 overdose reversal medication pursuant to a standing  
18 order;

19               “(3) implementing best practices for persons  
20 authorized to prescribe medication regarding—

21                       “(A) prescribing opioids for the treatment  
22 of chronic pain;

23                       “(B) co-prescribing opioid overdose rever-  
24 sal medication with opioids; and

1           “(C) discussing the purpose and adminis-  
2           tration of opioid overdose reversal medication  
3           with patients;

4           “(4) developing or adapting training materials  
5           and methods for persons authorized to prescribe or  
6           dispense medication to use in educating the public  
7           regarding—

8           “(A) when and how to administer opioid  
9           overdose reversal medication; and

10          “(B) steps to be taken after administering  
11          opioid overdose reversal medication; and

12          “(5) educating the public regarding—

13          “(A) the public health benefits of opioid  
14          overdose reversal medication; and

15          “(B) the availability of opioid overdose re-  
16          versal medication without a person-specific pre-  
17          scription.

18          “(b) CERTAIN REQUIREMENT.—A grant may be  
19          made under this section only if the State involved has au-  
20          thorized standing orders regarding opioid overdose rever-  
21          sal medication.

22          “(c) PREFERENCE IN MAKING GRANTS.—In making  
23          grants under this section, the Secretary shall give pref-  
24          erence to States that—

1           “(1) have not issued standing orders regarding  
2 opioid overdose reversal medication;

3           “(2) authorize standing orders that permit com-  
4 munity-based organizations, substance abuse pro-  
5 grams, or other nonprofit entities to acquire, dis-  
6 pense, or administer opioid overdose reversal medica-  
7 tion;

8           “(3) authorize standing orders that permit po-  
9 lice, fire, or emergency medical services agencies to  
10 acquire and administer opioid overdose reversal  
11 medication;

12           “(4) have a higher per capita rate of opioid  
13 overdoses than other applicant States; or

14           “(5) meet any other criteria deemed appro-  
15 priate by the Secretary.

16           “(d) GRANT TERMS.—

17           “(1) NUMBER.—A State may not receive more  
18 than 1 grant under this section.

19           “(2) PERIOD.—A grant under this section shall  
20 be for a period of 3 years.

21           “(3) AMOUNT.—A grant under this section may  
22 not exceed \$500,000.

23           “(4) LIMITATION.—A State may use not more  
24 than 20 percent of a grant under this section for  
25 educating the public pursuant to subsection (a)(5).

1       “(e) APPLICATIONS.—To be eligible to receive a grant  
2 under this section, a State shall submit an application to  
3 the Secretary in such form and manner and containing  
4 such information as the Secretary may require, including  
5 detailed proposed expenditures of grant funds.

6       “(f) REPORTING.—Not later than 3 months after the  
7 Secretary disburses the first grant payment to any State  
8 under this section and every 6 months thereafter for 3  
9 years, such State shall submit a report to the Secretary  
10 that includes the following:

11           “(1) The name and ZIP Code of each pharmacy  
12 in the State that dispenses opioid overdose reversal  
13 medication under a standing order.

14           “(2) The total number of opioid overdose rever-  
15 sal medication doses dispensed by each such phar-  
16 macy, specifying how many were dispensed with or  
17 without a person-specific prescription.

18           “(3) The number of pharmacists in the State  
19 who have participated in training pursuant to sub-  
20 section (a)(4).

21       “(g) DEFINITIONS.—In this section:

22           “(1) OPIOID OVERDOSE REVERSAL MEDICA-  
23 TION.—The term ‘opioid overdose reversal medica-  
24 tion’ means any drug, including naloxone, that—

1           “(A) blocks opioids from attaching to, but  
2           does not itself activate, opioid receptors; or

3           “(B) inhibits the effects of opioids on  
4           opioid receptors.

5           “(2) STANDING ORDER.—The term ‘standing  
6           order’ means a document prepared by a person au-  
7           thorized to prescribe medication that permits an-  
8           other person to acquire, dispense, or administer  
9           medication without a person-specific prescription.

10          “(h) AUTHORIZATION OF APPROPRIATIONS.—

11           “(1) IN GENERAL.—To carry out this section,  
12           there is authorized to be appropriated \$5,000,000  
13           for the period of fiscal years 2017 through 2019.

14           “(2) ADMINISTRATIVE COSTS.—Not more than  
15           3 percent of the amounts made available to carry  
16           out this section may be used by the Secretary for  
17           administrative expenses of carrying out this sec-  
18           tion.”.

19          (b) CUT-GO COMPLIANCE.—Subsection (f) of section  
20          319D of the Public Health Service Act (42 U.S.C. 247d-  
21          4) is amended by inserting before the period at the end  
22          the following: “(except such dollar amount shall be re-  
23          duced by \$5,000,000 for fiscal year 2017)”.

1 **SEC. 110. OPIOID REVIEW MODERNIZATION.**

2 (a) FDA OPIOID ACTION PLAN.—Chapter V of the  
3 Federal Food, Drug, and Cosmetic Act is amended by in-  
4 serting after section 569 of such Act (21 U.S.C. 350bbb-  
5 8) the following:

6 **“SEC. 569–1. OPIOID ACTION PLAN.**

7 “(a) NEW DRUG APPLICATION.—

8 “(1) IN GENERAL.—Subject to paragraph (2),  
9 prior to the approval pursuant to an application  
10 under section 505(b) of a new drug that is an opioid  
11 and does not have abuse-deterrent properties, the  
12 Secretary shall refer the application to an advisory  
13 committee of the Food and Drug Administration to  
14 seek recommendations from such advisory com-  
15 mittee.

16 “(2) PUBLIC HEALTH EXEMPTION.—A referral  
17 to an advisory committee under paragraph (1) is not  
18 required with respect to a new drug if the Sec-  
19 retary—

20 “(A) finds that such a referral is not in  
21 the interest of protecting and promoting public  
22 health;

23 “(B) finds that such a referral is not nec-  
24 essary based on a review of the relevant sci-  
25 entific information; and



1           “(C) submits a notice containing the ra-  
2           tionale for such findings to the Committee on  
3           Health, Education, Labor, and Pensions of the  
4           Senate and the Committee on Energy and Com-  
5           merce of the House of Representatives.

6           “(b) PEDIATRIC OPIOID LABELING.—The Secretary  
7           shall convene the Pediatric Advisory Committee of the  
8           Food and Drug Administration to seek recommendations  
9           from such Committee regarding a framework for the inclu-  
10          sion of information in the labeling of drugs that are  
11          opioids relating to the use of such drugs in pediatric popu-  
12          lations before the Secretary approves any labeling or  
13          change to labeling for any drug that is an opioid intended  
14          for use in a pediatric population.

15          “(c) SUNSET.—The requirements of subsections (a)  
16          and (b) shall cease to be effective on October 1, 2022.”.

17          (b) PRESCRIBER EDUCATION.—Not later than 1 year  
18          after the date of the enactment of this Act, the Secretary  
19          of Health and Human Services, acting through the Com-  
20          missioner of Food and Drugs, as part of the Food and  
21          Drug Administration’s evaluation of the Extended-Re-  
22          lease/Long-Acting Opioid Analgesics Risk Evaluation and  
23          Mitigation Strategy, and in consultation with relevant  
24          stakeholders, shall develop recommendations regarding  
25          education programs for prescribers of opioids pursuant to

1 section 505–1 of the Federal Food, Drug, and Cosmetic  
2 Act (21 U.S.C. 355–1), including recommendations on—

3 (1) which prescribers should participate in such  
4 programs; and

5 (2) how often participation in such programs is  
6 necessary.

7 (c) GUIDANCE ON EVALUATING THE ABUSE DETER-  
8 RENCE OF GENERIC SOLID ORAL OPIOID DRUG PROD-  
9 UCTS.—Not later than 2 years after the end of the period  
10 for public comment on the draft guidance entitled “Gen-  
11 eral Principles for Evaluating the Abuse Deterrence of Ge-  
12 neric Solid Oral Opioid Drug Products” issued by the  
13 Center for Drug Evaluation and Research of the Food and  
14 Drug Administration in March 2016, the Commissioner  
15 of Food and Drugs shall publish in the Federal Register  
16 a final version of such guidance.

17 **SEC. 111. STUDY ON TREATMENT INFRASTRUCTURE.**

18 Not later than 24 months after the date of enactment  
19 of this Act, the Comptroller General of the United States  
20 shall initiate an evaluation, and submit to Congress a re-  
21 port, of the inpatient and outpatient treatment capacity,  
22 availability, and needs of the United States, which shall  
23 include, to the extent data are available—

24 (1) the capacity of acute residential or inpatient  
25 detoxification programs;

1           (2) the capacity of inpatient clinical stabiliza-  
2           tion programs, transitional residential support serv-  
3           ices, and residential rehabilitation programs;

4           (3) the capacity of demographic specific resi-  
5           dential or inpatient treatment programs, such as  
6           those designed for pregnant women or adolescents;

7           (4) geographical differences of the availability  
8           of residential and outpatient treatment and recovery  
9           options for substance use disorders across the con-  
10          tinuum of care;

11          (5) the availability of residential and outpatient  
12          treatment programs that offer treatment options  
13          based on reliable scientific evidence of efficacy for  
14          the treatment of substance use disorders, including  
15          the use of Food and Drug Administration-approved  
16          medicines and evidence-based nonpharmacological  
17          therapies;

18          (6) the number of patients in residential and  
19          specialty outpatient treatment services for substance  
20          use disorders;

21          (7) an assessment of the need for residential  
22          and outpatient treatment for substance use disorders  
23          across the continuum of care;

24          (8) the availability of residential and outpatient  
25          treatment programs to American Indians and Alaska

1 Natives through an Indian health program (as de-  
2 fined by section 4 of the Indian Health Care Im-  
3 provement Act (25 U.S.C. 1603)); and

4 (9) the barriers (including technological bar-  
5 riers) at the Federal, State, and local levels to real-  
6 time reporting of de-identified information on drug  
7 overdoses and ways to overcome such barriers.

8 **SEC. 112. NATIONAL YOUTH RECOVERY INITIATIVE.**

9 Part II of title I of the Omnibus Crime Control and  
10 Safe Streets Act of 1968 (42 U.S.C. 3797cc et seq.) is  
11 amended by adding at the end the following:

12 **“SEC. 2999A. NATIONAL YOUTH RECOVERY INITIATIVE.**

13 “(a) DEFINITIONS.—In this section:

14 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-  
15 tity’ means—

16 “(A) a high school that has been accred-  
17 ited as a recovery high school by the Associa-  
18 tion of Recovery Schools;

19 “(B) an accredited high school that is  
20 seeking to establish or expand recovery support  
21 services;

22 “(C) an institution of higher education;

23 “(D) a recovery program at a nonprofit  
24 collegiate institution; or

25 “(E) a nonprofit organization.

1           “(2) INSTITUTION OF HIGHER EDUCATION.—  
2           The term ‘institution of higher education’ has the  
3           meaning given the term in section 101 of the Higher  
4           Education Act of 1965 (20 U.S.C. 1001).

5           “(3) RECOVERY PROGRAM.—The term ‘recovery  
6           program’—

7                   “(A) means a program to help individuals  
8                   who are recovering from substance use dis-  
9                   orders to initiate, stabilize, and maintain  
10                  healthy and productive lives in the community;  
11                  and

12                   “(B) includes peer-to-peer support and  
13                   communal activities to build recovery skills and  
14                   supportive social networks.

15           “(b) GRANTS AUTHORIZED.—The Secretary of  
16           Health and Human Services, in coordination with the Sec-  
17           retary of Education, may award grants to eligible entities  
18           to enable the entities to—

19                   “(1) provide substance use disorder recovery  
20                   support services to young people in high school and  
21                   enrolled in institutions of higher education;

22                   “(2) help build communities of support for  
23                   young people in recovery through a spectrum of ac-  
24                   tivities such as counseling and health- and wellness-  
25                   oriented social activities; and

1           “(3) encourage initiatives designed to help  
2           young people achieve and sustain recovery from sub-  
3           stance use disorders.

4           “(c) USE OF FUNDS.—Grants awarded under sub-  
5           section (b) may be used for activities to develop, support,  
6           and maintain youth recovery support services, including—

7           “(1) the development and maintenance of a  
8           dedicated physical space for recovery programs;

9           “(2) dedicated staff for the provision of recov-  
10          ery programs;

11          “(3) health- and wellness-oriented social activi-  
12          ties and community engagement;

13          “(4) establishment of recovery high schools;

14          “(5) coordination of recovery programs with—

15               “(A) substance use disorder treatment pro-  
16               grams and systems;

17               “(B) providers of mental health services;

18               “(C) primary care providers and physi-  
19               cians;

20               “(D) the criminal justice system, including  
21               the juvenile justice system;

22               “(E) employers;

23               “(F) housing services;

24               “(G) child welfare services;

1           “(H) high schools and institutions of high-  
2           er education; and

3           “(I) other programs or services related to  
4           the welfare of an individual in recovery from a  
5           substance use disorder;

6           “(6) the development of peer-to-peer support  
7           programs or services; and

8           “(7) additional activities that help youths and  
9           young adults to achieve recovery from substance use  
10          disorders.

11          “(d) FUNDING.—There is authorized to be appro-  
12          priated \$5,000,000 to carry out this section for each of  
13          fiscal years 2017 through 2021, of which \$5,000,000 shall  
14          be made available from amounts appropriated under sec-  
15          tion 101(a) of the Opioid Use Disorder Treatment Expan-  
16          sion and Modernization Act for fiscal year 2017, to remain  
17          available until expended.”.

18          **SEC. 113. BUILDING COMMUNITIES OF RECOVERY.**

19          Part II of title I of the Omnibus Crime Control and  
20          Safe Streets Act of 1968 (42 U.S.C. 3797*cc* et seq.), as  
21          amended by section 113, is amended by adding at the end  
22          the following:

1 **“SEC. 2999B. BUILDING COMMUNITIES OF RECOVERY.**

2 “(a) DEFINITION.—In this section, the term ‘recov-  
3 ery community organization’ means an independent non-  
4 profit organization that—

5 “(1) mobilizes resources within and outside of  
6 the recovery community to increase the prevalence  
7 and quality of long-term recovery from substance  
8 use disorders; and

9 “(2) is wholly or principally governed by people  
10 in recovery for substance use disorders who reflect  
11 the community served.

12 “(b) GRANTS AUTHORIZED.—The Secretary of  
13 Health and Human Services may award grants to recovery  
14 community organizations to enable such organizations to  
15 develop, expand, and enhance recovery services.

16 “(c) FEDERAL SHARE.—The Federal share of the  
17 costs of a program funded by a grant under this section  
18 may not exceed 50 percent.

19 “(d) USE OF FUNDS.—Grants awarded under sub-  
20 section (b)—

21 “(1) shall be used to develop, expand, and en-  
22 hance community and statewide recovery support  
23 services; and

24 “(2) may be used to—

25 “(A) advocate for individuals in recovery  
26 from substance use disorders;



1           “(B) build connections between recovery  
2 networks, between recovery community organi-  
3 zations, and with other recovery support serv-  
4 ices, including—

5                   “(i) substance use disorder treatment  
6 programs and systems;

7                   “(ii) providers of mental health serv-  
8 ices;

9                   “(iii) primary care providers and phy-  
10 sicians;

11                   “(iv) the criminal justice system;

12                   “(v) employers;

13                   “(vi) housing services;

14                   “(vii) child welfare agencies; and

15                   “(viii) other recovery support services  
16 that facilitate recovery from substance use  
17 disorders;

18           “(C) reduce the stigma associated with  
19 substance use disorders;

20           “(D) conduct public education and out-  
21 reach on issues relating to substance use dis-  
22 orders and recovery, including—

23                   “(i) how to identify the signs of addic-  
24 tion;

1           “(ii) the resources that are available  
2           to individuals struggling with addiction  
3           and families who have a family member  
4           struggling with or being treated for addic-  
5           tion, including programs that mentor and  
6           provide support services to children;

7           “(iii) the resources that are available  
8           to help support individuals in recovery; and

9           “(iv) information on the medical con-  
10          sequences of substance use disorders, in-  
11          cluding neonatal abstinence syndrome and  
12          potential infection with human immuno-  
13          deficiency virus and viral hepatitis; and

14          “(E) carry out other activities that  
15          strengthen the network of community support  
16          for individuals in recovery.

17          “(e) FUNDING.—Of the amounts appropriated under  
18          section 101(a) of the Opioid Use Disorder Treatment Ex-  
19          pansion and Modernization Act for fiscal year 2017,  
20          \$25,000,000 shall be made available to carry out this sec-  
21          tion, to remain available until expended”.

1       **TITLE II—COMPREHENSIVE**  
2       **OPIOID ABUSE REDUCTION**

3       **SEC. 201. COMPREHENSIVE OPIOID ABUSE GRANT PRO-**  
4               **GRAM.**

5           (a) IN GENERAL.—Title I of the Omnibus Crime  
6 Control and Safe Streets Act of 1968 (42 U.S.C. 3711  
7 et seq.) is amended by adding at the end the following:

8       **“PART LL—COMPREHENSIVE OPIOID ABUSE**  
9               **GRANT PROGRAM**

10       **“SEC. 3021. DESCRIPTION.**

11           “(a) GRANTS AUTHORIZED.—From amounts made  
12 available to carry out this part, the Attorney General may  
13 make grants to States, units of local government, and In-  
14 dian tribes, for use by the State, unit of local government,  
15 or Indian tribe to provide services primarily relating to  
16 opioid abuse, including for any one or more of the fol-  
17 lowing:

18               “(1) Developing, implementing, or expanding a  
19 treatment alternative to incarceration program,  
20 which may include—

21                   “(A) pre-booking or post-booking compo-  
22 nents, which may include the activities de-  
23 scribed in part HH of this title;

24                   “(B) training for criminal justice agency  
25 personnel on substance use disorders and co-oc-

1 curring mental illness and substance use dis-  
2 orders;

3 “(C) a mental health court, including the  
4 activities described in part V of this title;

5 “(D) a drug court, including the activities  
6 described in part EE of this title; and

7 “(E) a veterans treatment court program,  
8 including the activities described in subsection  
9 (i) of section 2991 of this title.

10 “(2) In the case of a State, facilitating or en-  
11 hancing planning and collaboration between State  
12 criminal justice agencies and State substance abuse  
13 systems in order to more efficiently and effectively  
14 carry out programs described in paragraph (1) that  
15 address problems related to opioid abuse.

16 “(3) Providing training and resources for first  
17 responders on carrying and administering an opioid  
18 overdose reversal drug or device approved by the  
19 Food and Drug Administration, and purchasing  
20 such a drug or device for first responders who have  
21 received such training to carry and administer.

22 “(4) Investigative purposes to locate or inves-  
23 tigate illicit activities related to the unlawful dis-  
24 tribution of opioids.

1           “(5) Developing, implementing, or expanding a  
2 medication-assisted treatment program used or oper-  
3 ated by a criminal justice agency, which may include  
4 training criminal justice agency personnel on medi-  
5 cation-assisted treatment, and carrying out the ac-  
6 tivities described in part S of this title.

7           “(6) In the case of a State, developing, imple-  
8 menting, or expanding a prescription drug moni-  
9 toring program to collect and analyze data related to  
10 the prescribing of schedule II, III, and IV controlled  
11 substances through a centralized database adminis-  
12 tered by an authorized State agency, which includes  
13 tracking the dispensation of such substances, and  
14 providing for data sharing with other States.

15           “(7) Developing, implementing, or expanding a  
16 program to prevent and address opioid abuse by ju-  
17 veniles.

18           “(8) Developing, implementing, or expanding an  
19 integrated and comprehensive opioid abuse response  
20 program.

21           “(b) CONTRACTS AND SUBAWARDS.—A State, unit of  
22 local government, or Indian tribe may, in using a grant  
23 under this subpart for purposes authorized by subsection  
24 (a), use all or a portion of that grant to contract with  
25 or make one or more subawards to one or more—

1           “(1) local or regional organizations that are pri-  
2           vate and nonprofit, including faith-based organiza-  
3           tions;

4           “(2) units of local government; or

5           “(3) tribal organizations.

6           “(c) PROGRAM ASSESSMENT COMPONENT; WAIV-  
7           ER.—

8           “(1) PROGRAM ASSESSMENT COMPONENT.—

9           Each program funded under this subpart shall con-  
10          tain a program assessment component, developed  
11          pursuant to guidelines established by the Attorney  
12          General, in coordination with the National Institute  
13          of Justice.

14          “(2) WAIVER.—The Attorney General may  
15          waive the requirement of paragraph (1) with respect  
16          to a program if, in the opinion of the Attorney Gen-  
17          eral, the program is not of sufficient size to justify  
18          a full program assessment.

19          “(d) ADMINISTRATIVE COSTS.—Not more than 10  
20          percent of a grant made under this subpart may be used  
21          for costs incurred to administer such grant.

22          “(e) PERIOD.—The period of a grant made under  
23          this part may not be longer than 4 years, except that re-  
24          newals and extensions beyond that period may be granted  
25          at the discretion of the Attorney General.

1 **“SEC. 3022. APPLICATIONS.**

2 “To request a grant under this part, the chief execu-  
3 tive officer of a State, unit of local government, or Indian  
4 tribe shall submit an application to the Attorney General  
5 at such time and in such form as the Attorney General  
6 may require. Such application shall include the following:

7 “(1) A certification that Federal funds made  
8 available under this subpart will not be used to sup-  
9 plant State, local, or tribal funds, but will be used  
10 to increase the amounts of such funds that would,  
11 in the absence of Federal funds, be made available  
12 for the activities described in section 3021(a).

13 “(2) An assurance that, for each fiscal year  
14 covered by an application, the applicant shall main-  
15 tain and report such data, records, and information  
16 (programmatic and financial) as the Attorney Gen-  
17 eral may reasonably require.

18 “(3) A certification, made in a form acceptable  
19 to the Attorney General and executed by the chief  
20 executive officer of the applicant (or by another offi-  
21 cer of the applicant, if qualified under regulations  
22 promulgated by the Attorney General), that—

23 “(A) the programs to be funded by the  
24 grant meet all the requirements of this part;

25 “(B) all the information contained in the  
26 application is correct;

1           “(C) there has been appropriate coordina-  
2           tion with affected agencies; and

3           “(D) the applicant will comply with all  
4           provisions of this part and all other applicable  
5           Federal laws.

6           “(4) An assurance that the applicant will work  
7           with the Drug Enforcement Administration to de-  
8           velop an integrated and comprehensive strategy to  
9           address opioid abuse.

10 **“SEC. 3023. REVIEW OF APPLICATIONS.**

11           “The Attorney General shall not finally disapprove  
12 any application (or any amendment to that application)  
13 submitted under this part without first affording the ap-  
14 plicant reasonable notice of any deficiencies in the applica-  
15 tion and opportunity for correction and reconsideration.

16 **“SEC. 3024. GEOGRAPHIC DIVERSITY.**

17           “The Attorney General shall ensure equitable geo-  
18 graphic distribution of grants under this part and take  
19 into consideration the needs of underserved populations,  
20 including rural and tribal communities.

21 **“SEC. 3025. DEFINITIONS.**

22           “In this part:

23           “(1) The term ‘first responder’ includes a fire-  
24 fighter, law enforcement officer, paramedic, emer-  
25 gency medical technician, or other individual (includ-



1       ing an employee of a legally organized and recog-  
2       nized volunteer organization, whether compensated  
3       or not), who, in the course of professional duties, re-  
4       sponds to fire, medical, hazardous material, or other  
5       similar emergencies.

6               “(2) The term ‘medication-assisted treatment’  
7       means the use of medications approved by the Food  
8       and Drug Administration for the treatment of opioid  
9       abuse.

10              “(3) The term ‘opioid’ means any drug, includ-  
11       ing heroin, having an addiction-forming or addiction-  
12       sustaining liability similar to morphine or being ca-  
13       pable of conversion into a drug having such addic-  
14       tion-forming or addiction-sustaining liability.

15              “(4) The term ‘schedule II, III, or IV controlled  
16       substance’ means a controlled substance that is list-  
17       ed on schedule II, schedule III, or schedule IV of  
18       section 202(c) of the Controlled Substances Act (21  
19       U.S.C. 812(c)).

20              “(5) The terms ‘drug’ and ‘device’ have the  
21       meanings given those terms in section 201 of the  
22       Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
23       321).

24              “(6) The term ‘criminal justice agency’ means  
25       a State, local, or tribal—

1           “(A) court;  
2           “(B) prison;  
3           “(C) jail;  
4           “(D) law enforcement agency; or  
5           “(E) other agency that performs the ad-  
6           ministration of criminal justice, including pros-  
7           ecution, pretrial services, and community super-  
8           vision.

9           “(7) The term ‘tribal organization’ has the  
10          meaning given that term in section 4 of the Indian  
11          Self-Determination and Education Assistance Act  
12          (25 U.S.C. 450b).”.

13          (b) FUNDING.—There is authorized to be appro-  
14          priated \$65,000,000 to carry out this section, section 203,  
15          and section 204 (including the amendments made by such  
16          sections) for the period of fiscal years 2017 through 2021,  
17          of which \$65,000,000 shall be made available from  
18          amounts appropriated under section 101(a) of the Opioid  
19          Use Disorder Treatment Expansion and Modernization  
20          Act for fiscal year 2017, to remain available until ex-  
21          pended.

22          **SEC. 202. AUDIT AND ACCOUNTABILITY OF GRANTEES.**

23          (a) DEFINITIONS.—In this section—

1           (1) the term “covered grant program” means a  
2 grant program operated by the Department of Jus-  
3 tice;

4           (2) the term “covered grantee” means a recipi-  
5 ent of a grant from a covered grant program;

6           (3) the term “nonprofit”, when used with re-  
7 spect to an organization, means an organization that  
8 is described in section 501(c)(3) of the Internal Rev-  
9 enue Code of 1986, and is exempt from taxation  
10 under section 501(a) of such Code; and

11           (4) the term “unresolved audit finding” means  
12 an audit report finding in a final audit report of the  
13 Inspector General of the Department of Justice that  
14 a covered grantee has used grant funds awarded to  
15 that grantee under a covered grant program for an  
16 unauthorized expenditure or otherwise unallowable  
17 cost that is not closed or resolved during a 12-month  
18 period prior to the date on which the final audit re-  
19 port is issued.

20           (b) AUDIT REQUIREMENT.—Beginning in fiscal year  
21 2016, and annually thereafter, the Inspector General of  
22 the Department of Justice shall conduct audits of covered  
23 grantees to prevent waste, fraud, and abuse of funds  
24 awarded under covered grant programs. The Inspector

1 General shall determine the appropriate number of cov-  
2 ered grantees to be audited each year.

3 (c) MANDATORY EXCLUSION.—A grantee that is  
4 found to have an unresolved audit finding under an audit  
5 conducted under subsection (b) may not receive grant  
6 funds under a covered grant program in the fiscal year  
7 following the fiscal year to which the finding relates.

8 (d) REIMBURSEMENT.—If a covered grantee is  
9 awarded funds under the covered grant program from  
10 which it received a grant award during the 1-fiscal-year  
11 period during which the covered grantee is ineligible for  
12 an allocation of grant funds under subsection (c), the At-  
13 torney General shall—

14 (1) deposit into the General Fund of the Treas-  
15 ury an amount that is equal to the amount of the  
16 grant funds that were improperly awarded to the  
17 covered grantee; and

18 (2) seek to recoup the costs of the repayment  
19 to the Fund from the covered grantee that was im-  
20 properly awarded the grant funds.

21 (e) PRIORITY OF GRANT AWARDS.—The Attorney  
22 General, in awarding grants under a covered grant pro-  
23 gram shall give priority to eligible entities that during the  
24 2-year period preceding the application for a grant have  
25 not been found to have an unresolved audit finding.

1 (f) NONPROFIT REQUIREMENTS.—

2 (1) PROHIBITION.—A nonprofit organization  
3 that holds money in offshore accounts for the pur-  
4 pose of avoiding the tax described in section 511(a)  
5 of the Internal Revenue Code of 1986, shall not be  
6 eligible to receive, directly or indirectly, any funds  
7 from a covered grant program.

8 (2) DISCLOSURE.—Each nonprofit organization  
9 that is a covered grantee shall disclose in its applica-  
10 tion for such a grant, as a condition of receipt of  
11 such a grant, the compensation of its officers, direc-  
12 tors, and trustees. Such disclosure shall include a  
13 description of the criteria relied on to determine  
14 such compensation.

15 **SEC. 203. VETERANS TREATMENT COURTS.**

16 Section 2991 of the Omnibus Crime Control and Safe  
17 Streets Act of 1968 (42 U.S.C. 3797aa) is amended—

18 (1) by redesignating subsection (i) as subsection  
19 (j); and

20 (2) by inserting after subsection (h) the fol-  
21 lowing:

22 “(i) ASSISTING VETERANS.—

23 “(1) DEFINITIONS.—In this subsection:

24 “(A) PEER TO PEER SERVICES OR PRO-  
25 GRAMS.—The term ‘peer to peer services or

1 programs’ means services or programs that con-  
2 nect qualified veterans with other veterans for  
3 the purpose of providing support and  
4 mentorship to assist qualified veterans in ob-  
5 taining treatment, recovery, stabilization, or re-  
6 habilitation.

7 “(B) QUALIFIED VETERAN.—The term  
8 ‘qualified veteran’ means a preliminarily quali-  
9 fied offender who—

10 “(i) served on active duty in any  
11 branch of the Armed Forces, including the  
12 National Guard or Reserves; and

13 “(ii) was discharged or released from  
14 such service under conditions other than  
15 dishonorable.

16 “(C) VETERANS TREATMENT COURT PRO-  
17 GRAM.—The term ‘veterans treatment court  
18 program’ means a court program involving col-  
19 laboration among criminal justice, veterans, and  
20 mental health and substance abuse agencies  
21 that provides qualified veterans with—

22 “(i) intensive judicial supervision and  
23 case management, which may include ran-  
24 dom and frequent drug testing where ap-  
25 propriate;

1           “(ii) a full continuum of treatment  
2           services, including mental health services,  
3           substance abuse services, medical services,  
4           and services to address trauma;

5           “(iii) alternatives to incarceration; or

6           “(iv) other appropriate services, in-  
7           cluding housing, transportation, mentoring,  
8           employment, job training, education, or as-  
9           sistance in applying for and obtaining  
10          available benefits.

11          “(2) VETERANS ASSISTANCE PROGRAM.—

12           “(A) IN GENERAL.—The Attorney General,  
13          in consultation with the Secretary of Veterans  
14          Affairs, may award grants under this sub-  
15          section to applicants to establish or expand—

16           “(i) veterans treatment court pro-  
17          grams;

18           “(ii) peer to peer services or programs  
19          for qualified veterans;

20           “(iii) practices that identify and pro-  
21          vide treatment, rehabilitation, legal, transi-  
22          tional, and other appropriate services to  
23          qualified veterans who have been incarcer-  
24          ated; or

1           “(iv) training programs to teach  
2 criminal justice, law enforcement, correc-  
3 tions, mental health, and substance abuse  
4 personnel how to identify and appro-  
5 priately respond to incidents involving  
6 qualified veterans.

7           “(B) PRIORITY.—In awarding grants  
8 under this subsection, the Attorney General  
9 shall give priority to applications that—

10           “(i) demonstrate collaboration be-  
11 tween and joint investments by criminal  
12 justice, mental health, substance abuse,  
13 and veterans service agencies;

14           “(ii) promote effective strategies to  
15 identify and reduce the risk of harm to  
16 qualified veterans and public safety; and

17           “(iii) propose interventions with em-  
18 pirical support to improve outcomes for  
19 qualified veterans.”.

20 **SEC. 204. EMERGENCY FEDERAL LAW ENFORCEMENT AS-**  
21 **SISTANCE.**

22           Section 609Y(a) of the Justice Assistance Act of  
23 1984 (42 U.S.C. 10513(a)) is amended by striking “Sep-  
24 tember 30, 1984” and inserting “September 30, 2021”.



1 **SEC. 205. OPIOID PROGRAM EVALUATION ACT.**

2 (a) SHORT TITLE.—This section may be cited as the  
3 “Opioid Program Evaluation Act” or the “OPEN Act”.

4 (b) EVALUATION OF PERFORMANCE OF DEPART-  
5 MENT OF JUSTICE PROGRAM.—

6 (1) EVALUATION OF JUSTICE DEPARTMENT  
7 COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.—

8 Not later than 5 years after the date of enactment  
9 of this Act, the Attorney General shall complete an  
10 evaluation of the effectiveness of the Comprehensive  
11 Opioid Abuse Grant Program under part LL of the  
12 Omnibus Crime Control and Safe Streets Act of  
13 1968 administered by the Department of Justice  
14 based upon the information reported under para-  
15 graph (4) of this subsection.

16 (2) INTERIM EVALUATION.—Not later than 3  
17 years after the date of enactment of this Act, the  
18 Attorney General shall complete an interim evalua-  
19 tion assessing the nature and extent of the incidence  
20 of opioid abuse and illegal opioid distribution in the  
21 United States.

22 (3) METRICS AND OUTCOMES FOR EVALUA-  
23 TION.—Not later than 180 days after the date of en-  
24 actment of this Act, the Attorney General shall iden-  
25 tify outcomes that are to be achieved by activities  
26 funded by the Comprehensive Opioid Grant Abuse

1 Program and the metrics by which the achievement  
2 of such outcomes shall be determined.

3 (4) METRICS DATA COLLECTION.—The Attor-  
4 ney General shall require grantees under the Com-  
5 prehensive Opioid Abuse Grant Program (and those  
6 receiving subawards under section 3021(b) of part  
7 LL of the Omnibus Crime Control and Safe Streets  
8 Act of 1968) to collect and annually report to the  
9 Department of Justice data based upon the metrics  
10 identified under paragraph (3).

11 (5) PUBLICATION OF DATA AND FINDINGS.—

12 (A) PUBLICATION OF OUTCOMES AND  
13 METRICS.—The Attorney General shall, not  
14 later than 30 days after completion of the re-  
15 quirement under paragraph (3), publish the  
16 outcomes and metrics identified under that  
17 paragraph.

18 (B) PUBLICATION OF EVALUATION.—In  
19 the case of the interim evaluation under para-  
20 graph (2), and the final evaluation under para-  
21 graph (1), the Secretary shall arrange for an  
22 independent, external evaluator to, not later  
23 than 90 days after such an evaluation is com-  
24 pleted, publish the results of such evaluation  
25 and issue a report on such evaluation to the

1           Committee on the Judiciary of the House of  
2           Representatives and the Committee on the Ju-  
3           diary of the Senate. Such report shall also be  
4           published along with the data used to make  
5           such evaluation.

6           (6) ARRANGEMENT WITH THE NATIONAL ACAD-  
7           EMY OF SCIENCES.—For purposes of paragraphs  
8           (1), (2), and (3), the Attorney General shall enter  
9           into an arrangement with the National Academy of  
10          Sciences.

11          (c) EVALUATION OF PERFORMANCE OF DEPART-  
12          MENT OF HEALTH AND HUMAN SERVICES PROGRAM.—

13           (1) EVALUATION OF JUSTICE DEPARTMENT  
14           COMPREHENSIVE OPIOID ABUSE GRANT PROGRAM.—  
15           Not later than 5 years after the date of enactment  
16           of this Act, the Secretary of Health and Human  
17           Services shall complete an evaluation of any pro-  
18           gram administered by the Secretary that provides  
19           grants for the primary purpose of providing assist-  
20           ance in addressing problems pertaining to opioid  
21           abuse based upon the information reported under  
22           paragraph (4) of this subsection.

23           (2) INTERIM EVALUATION.—Not later than 3  
24           years after the date of enactment of this Act, the  
25           Secretary shall complete an interim evaluation as-

1       sessing the nature and extent of the incidence of  
2       opioid abuse and illegal opioid distribution in the  
3       United States.

4               (3) METRICS AND OUTCOMES FOR EVALUA-  
5       TION.—Not later than 180 days after the date of en-  
6       actment of this Act, the Secretary shall identify out-  
7       comes that are to be achieved by activities funded by  
8       the programs described in paragraph (1) and the  
9       metrics by which the achievement of such outcomes  
10      shall be determined.

11              (4) METRICS DATA COLLECTION.—The Sec-  
12      retary shall require grantees under the programs de-  
13      scribed in paragraph (1) to collect and annually re-  
14      port to the Department of Health and Human Serv-  
15      ices data based upon the metrics identified under  
16      paragraph (3).

17              (5) PUBLICATION OF DATA AND FINDINGS.—

18                      (A) PUBLICATION OF OUTCOMES AND  
19                      METRICS.—The Secretary shall, not later than  
20                      30 days after completion of the requirement  
21                      under paragraph (3), publish the outcomes and  
22                      metrics identified under that paragraph.

23                      (B) PUBLICATION OF EVALUATION.—In  
24                      the case of the interim evaluation under sub-  
25                      paragraph (B), and each final evaluation under

1 paragraph (1), the Secretary shall arrange for  
2 an independent, external evaluator to, not later  
3 than 90 days after such an evaluation is com-  
4 pleted, publish the results of such evaluation  
5 and issue a report on such evaluation to the  
6 Committee on Energy and Commerce of the  
7 House of Representatives and the Committee  
8 on Health, Education, Labor, and Pensions of  
9 the Senate. Such report shall also be published  
10 along with the data used to make such evalua-  
11 tion.

12 (6) ARRANGEMENT WITH AN INDEPENDENT,  
13 EXTERNAL EVALUATOR.—For purposes of para-  
14 graphs (1), (2), (3), and (5), the Secretary shall  
15 enter into an arrangement with an independent, ex-  
16 ternal evaluator.

17 (d) DEFINITION.—In this section, the term “opioid”  
18 has the meaning given the term “opiate” in section 102  
19 of the Controlled Substances Act (21 U.S.C. 802).

20 (e) NO ADDITIONAL FUNDS AUTHORIZED.—No addi-  
21 tional funds are authorized to be appropriated to carry  
22 out this Act.

23 **SEC. 206. GOOD SAMARITAN ASSESSMENT ACT.**

24 (a) GAO STUDY ON GOOD SAMARITAN LAWS PER-  
25 TAINING TO TREATMENT OF OPIOID OVERDOSES.—The

1 Comptroller General of the United States shall submit to  
2 the Committee on the Judiciary of the House of Rep-  
3 resentatives, the Committee on Oversight and Government  
4 Reform of the House of Representatives, the Committee  
5 on the Judiciary of the Senate, and the Committee on  
6 Homeland Security and Governmental Affairs of the Sen-  
7 ate a report on—

8           (1) the extent to which the Director of National  
9       Drug Control Policy has reviewed Good Samaritan  
10      laws, and any findings from such a review, including  
11      findings related to the potential effects of such laws,  
12      if available;

13           (2) efforts by the Director to encourage the en-  
14      actment of Good Samaritan laws; and

15           (3) a compilation of Good Samaritan laws in ef-  
16      fect in the States, the territories, and the District of  
17      Columbia.

18      (b) DEFINITIONS.—In this section—

19           (1) the term “Good Samaritan law” means a  
20      law of a State or unit of local government that ex-  
21      empts from criminal or civil liability any individual  
22      who administers an opioid overdose reversal drug or  
23      device, or who contacts emergency services providers  
24      in response to an overdose; and

1           (2) the term “opioid” means any drug, includ-  
2           ing heroin, having an addiction-forming or addiction-  
3           sustaining liability similar to morphine or being ca-  
4           pable of conversion into a drug having such addic-  
5           tion-forming or addiction-sustaining liability.

6   **TITLE III—PROMOTING RESPON-**  
7   **SIBLE OPIOID MANAGEMENT**  
8   **AND INCORPORATING SCI-**  
9   **ENTIFIC EXPERTISE**

10 **SEC. 301. SHORT TITLE.**

11           This title may be cited as the “Promoting Respon-  
12           sible Opioid Management and Incorporating Scientific Ex-  
13           pertise Act” or the “Jason Simeakoski PROMISE Act”.

14   **Subtitle A—Opioid Therapy and**  
15   **Pain Management**

16 **SEC. 311. GUIDELINES ON MANAGEMENT OF OPIOID THER-**  
17           **APY BY DEPARTMENT OF VETERANS AFFAIRS**  
18           **AND DEPARTMENT OF DEFENSE AND IMPLE-**  
19           **MENTATION OF SUCH GUIDELINES BY DE-**  
20           **PARTMENT OF VETERANS AFFAIRS.**

21           (a) **IN GENERAL.**—Not later than one year after the  
22           date of the enactment of this Act, the Secretary of Vet-  
23           erans Affairs and the Secretary of Defense shall jointly  
24           update the VA/DOD Clinical Practice Guideline for Man-

1 agement of Opioid Therapy for Chronic Pain to include  
2 the following:

3 (1) In accordance with subsection (b), common  
4 recommended guidelines for safely prescribing  
5 opioids for the treatment of chronic, non-cancer pain  
6 in outpatient settings as compiled by the Director of  
7 the Centers for Disease Control and Prevention.

8 (2) Enhanced guidance with respect to—

9 (A) the administration of two or more  
10 drugs that may result in a life-limiting drug-to-  
11 drug interaction, including benzodiazepines;

12 (B) the treatment of patients with current  
13 acute psychiatric instability or substance use  
14 disorder or patients at risk of suicide; and

15 (C) the use of opioid therapy to treat men-  
16 tal health disorders other than opioid use dis-  
17 order.

18 (3) Enhanced guidance with respect to the  
19 treatment of patients with behaviors or  
20 comorbidities, such as post-traumatic stress dis-  
21 order, psychiatric disorders, or a history of sub-  
22 stance abuse or addiction, that requires a consulta-  
23 tion or comanagement of opioid therapy with one or  
24 more specialists in pain management, mental health,  
25 or addictions.



1           (4) Enhanced guidance with respect to the con-  
2           duct by health care providers of an effective assess-  
3           ment for patients receiving opioid therapy, including  
4           patients on long-term opioid therapy, to determine—

5                   (A) whether opioid therapy is meeting the  
6                   expected goals of the patient and health care  
7                   provider of relieving pain, improving function,  
8                   and providing patient satisfaction; and

9                   (B) whether opioid therapy should be con-  
10                  tinued.

11           (5) Guidance that each health care provider of  
12           the Department of Veterans Affairs and the Depart-  
13           ment of Defense, before initiating opioid therapy to  
14           treat a patient as part of the comprehensive assess-  
15           ment conducted by the health care provider, use the  
16           Opioid Therapy Risk Report tool of the Department  
17           of Veterans Affairs (or successor tool), which shall  
18           include the ability to access the most recent patient  
19           information from the prescription drug monitoring  
20           program of each State that has such a program to  
21           assess the risk for adverse outcomes of opioid ther-  
22           apy for the patient, including with respect to the  
23           concurrent use of controlled substances, including  
24           benzodiazepines.

1           (6) Guidelines to govern the methodologies used  
2           by health care providers of the Department of Vet-  
3           erans Affairs and the Department of Defense to  
4           safely titrate and taper opioid therapy when adjust-  
5           ing or discriminating the use of opioid therapy, in-  
6           cluding with respect to—

7                   (A) prescription of the lowest effective dose  
8                   based on patient need;

9                   (B) use of opioid only for a limited period  
10                  of time; and

11                  (C) augmentation of opioid therapy with  
12                  other pain management therapies and modali-  
13                  ties.

14           (7) Guidelines with respect to appropriate case  
15           management for patients receiving opioid therapy  
16           who transition between inpatient and outpatient  
17           health care settings, which may include the use of  
18           care transition plans.

19           (8) Guidelines with respect to appropriate  
20           transfer of case management responsibility for pa-  
21           tients receiving opioid therapy who transition from  
22           receiving care furnished by the Secretary of Defense  
23           to receiving care furnished by other health care pro-  
24           viders after the patient has been discharged or sepa-  
25           rated from the Armed Forces.

1           (9) Enhanced standards with respect to the use  
2 of routine and random urine drug tests for all pa-  
3 tients before and during opioid therapy to help pre-  
4 vent substance abuse, dependence, and diversion, in-  
5 cluding—

6                   (A) that such tests occur not less fre-  
7 quently than once each year; and

8                   (B) that health care providers appro-  
9 priately interpret and respond to the results  
10 from such tests to tailor pain therapy, safe-  
11 guards, and risk management strategies to each  
12 patient.

13           (10) Guidance that health care providers dis-  
14 cuss with patients, before initiating opioid therapy,  
15 options for pain management therapies without the  
16 use of opioids and options to augment opioid therapy  
17 with other clinical and complementary and integra-  
18 tive health services to minimize opioid dependence.

19           (b) TREATMENT OF CERTAIN GUIDELINES DEVEL-  
20 OPED AFTER DEADLINE.—If the Director of the Centers  
21 for Disease Control and Prevention issues the guidelines  
22 described in paragraph (1) of subsection (a) after the date  
23 on which the Secretary of Veterans Affairs and the Sec-  
24 retary of Defense jointly update the VA/DOD Clinical  
25 Practice Guideline for Management of Opioid Therapy for

1 Chronic Pain pursuant to such subsection, the Secretaries  
2 shall jointly modify the VA/DOD Clinical Practice Guide-  
3 line for Management of Opioid Therapy for Chronic Pain  
4 to incorporate such guidelines of the Director.

5 (c) CONSULTATION BEFORE UPDATE.—Before up-  
6 dating the guideline under subsection (a), the Secretary  
7 of Veterans Affairs and the Secretary of Defense shall  
8 jointly consult with the Pain Management Working Group  
9 of the Department of Veterans Affairs–Department of De-  
10 fense Joint Executive Committee established by section  
11 320 of title 38, United States Code.

12 (d) DEFINITIONS.—In this section:

13 (1) The term “controlled substance” has the  
14 meaning given that term in section 102 of the Con-  
15 trolled Substances Act (21 U.S.C. 802).

16 (2) The term “State” means each of the several  
17 States, territories, and possessions of the United  
18 States, the District of Columbia, and the Common-  
19 wealth of Puerto Rico.

20 **SEC. 312. IMPROVEMENT OF OPIOID SAFETY MEASURES BY**  
21 **DEPARTMENT OF VETERANS AFFAIRS.**

22 (a) EXPANSION OF OPIOID SAFETY INITIATIVE.—  
23 Not later than 180 days after the date of the enactment  
24 of this Act, the Secretary of Veterans Affairs shall expand

1 the Opioid Safety Initiative of the Department of Veterans  
2 Affairs to include all medical facilities of the Department.

3 (b) PAIN MANAGEMENT EDUCATION AND TRAIN-  
4 ING.—

5 (1) IN GENERAL.—In carrying out the Opioid  
6 Safety Initiative of the Department, the Secretary  
7 shall require all employees of the Department re-  
8 sponsible for prescribing opioids to receive education  
9 and training described in paragraph (2).

10 (2) EDUCATION AND TRAINING.—Education  
11 and training described in this paragraph is edu-  
12 cation and training on pain management and safe  
13 opioid prescribing practices for purposes of safely  
14 and effectively managing patients with chronic pain,  
15 including education and training on the following:

16 (A) The implementation of and full compli-  
17 ance with the VA/DOD Clinical Practice Guide-  
18 line for Management of Opioid Therapy for  
19 Chronic Pain, including any update to such  
20 guideline.

21 (B) The use of evidence-based pain man-  
22 agement therapies, including cognitive-behav-  
23 ioral therapy, non-opioid alternatives, and non-  
24 drug methods and procedures to managing pain

1 and related health conditions including com-  
2plementary alternative medicines.

3 (C) Screening and identification of patients  
4 with substance use disorder, including drug-  
5 seeking behavior, before prescribing opioids, as-  
6 sessment of risk potential for patients devel-  
7 oping an addiction, and referral of patients to  
8 appropriate addiction treatment professionals if  
9 addiction is identified or strongly suspected.

10 (D) Communication with patients on the  
11 potential harm associated with the use of  
12 opioids and other controlled substances, includ-  
13 ing the need to safely store and dispose of sup-  
14 plies relating to the use of opioids and other  
15 controlled substances.

16 (E) Such other education and training as  
17 the Secretary considers appropriate to ensure  
18 that veterans receive safe and high-quality pain  
19 management care from the Department.

20 (3) USE OF EXISTING PROGRAM.—In providing  
21 education and training described in paragraph (2),  
22 the Secretary shall use the Interdisciplinary Chronic  
23 Pain Management Training Team Program of the  
24 Department (or success program).

25 (c) PAIN MANAGEMENT TEAMS.—

1           (1) IN GENERAL.—In carrying out the Opioid  
2       Safety Initiative of the Department, the director of  
3       each medical facility of the Department shall iden-  
4       tify and designate a pain management team of  
5       health care professionals, which may include board  
6       certified pain medicine specialists, responsible for co-  
7       ordinating and overseeing pain management therapy  
8       at such facility for patients experiencing acute and  
9       chronic pain that is non-cancer related.

10           (2) ESTABLISHMENT OF PROTOCOLS.—

11           (A) IN GENERAL.—In consultation with  
12       the Directors of each Veterans Integrated Serv-  
13       ice Network, the Secretary shall establish  
14       standard protocols for the designation of pain  
15       management teams at each medical facility  
16       within the Department.

17           (B) CONSULTATION ON PRESCRIPTION OF  
18       OPIOIDS.—Each protocol established under sub-  
19       paragraph (A) shall ensure that any health care  
20       provider without expertise in prescribing anal-  
21       gesics or who has not completed the education  
22       and training under subsection (b), including a  
23       mental health care provider, does not prescribe  
24       opioids to a patient unless that health care pro-  
25       vider—

1 (i) consults with a health care pro-  
2 vider with pain management expertise or  
3 who is on the pain management team of  
4 the medical facility; and

5 (ii) refers the patient to the pain man-  
6 agement team for any subsequent prescrip-  
7 tions and related therapy.

8 (3) REPORT.—

9 (A) IN GENERAL.—Not later than one year  
10 after the date of enactment of this Act, the di-  
11 rector of each medical facility of the Depart-  
12 ment shall submit to the Under Secretary for  
13 Health and the director of the Veterans Inte-  
14 grated Service Network in which the medical fa-  
15 cility is located a report identifying the health  
16 care professionals that have been designated as  
17 members of the pain management team at the  
18 medical facility pursuant to paragraph (1).

19 (B) ELEMENTS.—Each report submitted  
20 under subparagraph (A) with respect to a med-  
21 ical facility of the Department shall include—

22 (i) a certification as to whether all  
23 members of the pain management team at  
24 the medical facility have completed the



1 education and training required under sub-  
2 section (b); and

3 (ii) a plan for the management and  
4 referral of patients to such pain manage-  
5 ment team if health care providers without  
6 expertise in prescribing analgesics pre-  
7 scribe opioid medications to treat acute  
8 and chronic pain that is non-cancer re-  
9 lated.

10 (d) TRACKING AND MONITORING OF OPIOID USE.—

11 (1) PRESCRIPTION DRUG MONITORING PRO-  
12 GRAMS OF STATES.—In carrying out the Opioid  
13 Safety Initiative and the Opioid Therapy Risk Re-  
14 port tool of the Department, the Secretary shall—

15 (A) ensure access by health care providers  
16 of the Department to information on controlled  
17 substances, including opioids and  
18 benzodiazepines, prescribed to veterans who re-  
19 ceive care outside the Department through the  
20 prescription drug monitoring program of each  
21 State with such a program, including by seek-  
22 ing to enter into memoranda of understanding  
23 with States to allow shared access of such infor-  
24 mation between States and the Department;

1 (B) include such information in the Opioid  
2 Therapy Risk Report; and

3 (C) require health care providers of the  
4 Department to submit to the prescription drug  
5 monitoring program of each State information  
6 on prescriptions of controlled substances re-  
7 ceived by veterans in that State under the laws  
8 administered by the Secretary.

9 (2) REPORT ON TRACKING OF DATA ON OPIOID  
10 USE.—Not later than 18 months after the date of  
11 the enactment of this Act, the Secretary shall submit  
12 to the Committee on Veterans' Affairs of the Senate  
13 and the Committee on Veterans' Affairs of the  
14 House of Representatives a report on the feasibility  
15 and advisability of improving the Opioid Therapy  
16 Risk Report tool of the Department to allow for  
17 more advanced real-time tracking of and access to  
18 data on—

19 (A) the key clinical indicators with respect  
20 to the totality of opioid use by veterans;

21 (B) concurrent prescribing by health care  
22 providers of the Department of opioids in dif-  
23 ferent health care settings, including data on  
24 concurrent prescribing of opioids to treat men-

1           tal health disorders other than opioid use dis-  
2           order; and

3                   (C) mail-order prescriptions of opioid pre-  
4           scribed to veterans under the laws administered  
5           by the Secretary.

6           (e) AVAILABILITY OF OPIOID RECEPTOR ANTAGO-  
7           NISTS.—

8                   (1) INCREASED AVAILABILITY AND USE.—

9                           (A) IN GENERAL.—The Secretary shall  
10           maximize the availability of opioid receptor an-  
11           tagonists approved by the Food and Drug Ad-  
12           ministration, including naloxone, to veterans.

13                           (B) AVAILABILITY, TRAINING, AND DIS-  
14           TRIBUTING.—In carrying out subparagraph  
15           (A), not later than 90 days after the date of the  
16           enactment of this Act, the Secretary shall—

17                                   (i) equip each pharmacy of the De-  
18           partment with opioid receptor antagonists  
19           approved by the Food and Drug Adminis-  
20           tration to be dispensed to outpatients as  
21           needed; and

22                                   (ii) expand the Overdose Education  
23           and Naloxone Distribution program of the  
24           Department to ensure that all veterans in  
25           receipt of health care under laws adminis-

1           tered by the Secretary who are at risk of  
2           opioid overdose may access such opioid re-  
3           ceptor antagonists and training on the  
4           proper administration of such opioid recep-  
5           tor antagonists.

6           (C) VETERANS WHO ARE AT RISK.—For  
7           purposes of subparagraph (B), veterans who are  
8           at risk of opioid overdose include—

9                   (i) veterans receiving long-term opioid  
10                  therapy;

11                   (ii) veterans receiving opioid therapy  
12                  who have a history of substance use dis-  
13                  order or prior instances of overdose; and

14                   (iii) veterans who are at risk as deter-  
15                  mined by a health care provider who is  
16                  treating the veteran.

17           (2) REPORT.—Not later than 120 days after  
18           the date of the enactment of this Act, the Secretary  
19           shall submit to the Committee on Veterans' Affairs  
20           of the Senate and the Committee on Veterans' Af-  
21           fairs of the House of Representatives a report on  
22           carrying out paragraph (1), including an assessment  
23           of any remaining steps to be carried out by the Sec-  
24           retary to carry out such paragraph.

1 (f) INCLUSION OF CERTAIN INFORMATION AND CA-  
2 PABILITIES IN OPIOID THERAPY RISK REPORT TOOL OF  
3 THE DEPARTMENT.—

4 (1) INFORMATION.—The Secretary shall include  
5 in the Opioid Therapy Risk Report tool of the De-  
6 partment—

7 (A) information on the most recent time  
8 the tool was accessed by a health care provider  
9 of the Department with respect to each veteran;  
10 and

11 (B) information on the results of the most  
12 recent urine drug test for each veteran.

13 (2) CAPABILITIES.—The Secretary shall include  
14 in the Opioid Therapy Risk Report tool the ability  
15 of the health care providers of the Department to  
16 determine whether a health care provider of the De-  
17 partment prescribed opioids to a veteran without  
18 checking the information in the tool with respect to  
19 the veteran.

20 (g) NOTIFICATIONS OF RISK IN COMPUTERIZED  
21 HEALTH RECORD.—The Secretary shall modify the com-  
22 puterized patient record system of the Department to en-  
23 sure that any health care provider that accesses the record  
24 of a veteran, regardless of the reason the veteran seeks

1 care from the health care provider, will be immediately no-  
2 tified whether the veteran—

3 (1) is receiving opioid therapy and has a history  
4 of substance use disorder or prior instances of over-  
5 dose;

6 (2) has a history of opioid abuse; or

7 (3) is at risk of becoming an opioid abuser as  
8 determined by a health care provider who is treating  
9 the veteran.

10 (h) DEFINITIONS.—In this section:

11 (1) The term “controlled substance” has the  
12 meaning given that term in section 102 of the Con-  
13 trolled Substances Act (21 U.S.C. 802).

14 (2) The term “State” means each of the several  
15 States, territories, and possessions of the United  
16 States, the District of Columbia, and the Common-  
17 wealth of Puerto Rico.

18 **SEC. 313. STRENGTHENING OF JOINT WORKING GROUP ON**  
19 **PAIN MANAGEMENT OF THE DEPARTMENT**  
20 **OF VETERANS AFFAIRS AND THE DEPART-**  
21 **MENT OF DEFENSE.**

22 (a) IN GENERAL.—Not later than 90 days after the  
23 date of enactment of this Act, the Secretary of Veterans  
24 Affairs and the Secretary of Defense shall ensure that the  
25 Pain Management Working Group of the Health Execu-

1 tive Committee of the Department of Veterans Affairs—  
2 Department of Defense Joint Executive Committee estab-  
3 lished under section 320 of title 38, United States Code,  
4 includes a focus on the following:

5 (1) The opioid prescribing practices of health  
6 care providers of each Department.

7 (2) The ability of each Department to manage  
8 acute and chronic pain among individuals receiving  
9 health care from the Department, including training  
10 health care providers with respect to pain manage-  
11 ment.

12 (3) The use by each Department of complemen-  
13 tary and integrative health and complementary alter-  
14 native medicines in treating such individuals.

15 (4) The concurrent use by health care providers  
16 of each Department of opioids and prescription  
17 drugs to treat mental health disorders, including  
18 benzodiazepines.

19 (5) The practice by health care providers of  
20 each Department of prescribing opioids to treat  
21 mental health disorders.

22 (6) The coordination in coverage of and con-  
23 sistent access to medications prescribed for patients  
24 transitioning from receiving health care from the

1 Department of Defense to receiving health care from  
2 the Department of Veterans Affairs.

3 (7) The ability of each Department to identify  
4 and treat substance use disorders among individuals  
5 receiving health care from that Department.

6 (b) COORDINATION AND CONSULTATION.—The Sec-  
7 retary of Veterans Affairs and the Secretary of Defense  
8 shall ensure that the working group described in sub-  
9 section (a)—

10 (1) coordinates the activities of the working  
11 group with other relevant working groups estab-  
12 lished under section 320 of title 38, United States  
13 Code, including the working groups on evidence-  
14 based practice, patient safety, pharmacy, psycho-  
15 logical health, and psychological health;

16 (2) consults with other relevant Federal agen-  
17 cies, including the Centers for Disease Control and  
18 Prevention, with respect to the activities of the  
19 working group; and

20 (3) consults with the Department of Veterans  
21 Affairs and the Department of Defense with respect  
22 to, reviews, and comments on the VA/DOD Clinical  
23 Practice Guideline for Management of Opioid Ther-  
24 apy for Chronic Pain, or any successor guideline, be-  
25 fore any update to the guideline is released.



1 (c) CONSULTATIONS.—The Secretary of Veterans Af-  
2 fairs and the Secretary of Defense shall ensure that the  
3 working group described in subsection (a) is able to mean-  
4 ingfully consult with respect to the updated guideline re-  
5 quired under subsection (a) of section 311, as required  
6 by subsection (b) of such section, not later than 1 year  
7 after the date of enactment of this Act.

8 **SEC. 314. REVIEW, INVESTIGATION, AND REPORT ON USE**  
9 **OF OPIOIDS IN TREATMENT BY DEPARTMENT**  
10 **OF VETERANS AFFAIRS.**

11 (a) COMPTROLLER GENERAL REPORT.—

12 (1) IN GENERAL.—Not later than two years  
13 after the date of the enactment of this Act, the  
14 Comptroller General of the United States shall sub-  
15 mit to the Committee on Veterans' Affairs of the  
16 Senate and the Committee on Veterans' Affairs of  
17 the House of Representatives a report on the Opioid  
18 Safety Initiative of the Department of Veterans Af-  
19 fairs and the opioid prescribing practices of health  
20 care providers of the Department.

21 (2) ELEMENTS.—The report submitted under  
22 paragraph (1) shall include the following:

23 (A) Recommendations on such improve-  
24 ments to the Opioid Safety Initiative of the De-

1           partment as the Comptroller General considers  
2           appropriate.

3           (B) Information with respect to—

4           (i) deaths resulting from sentinel  
5           events involving veterans prescribed opioids  
6           by a health care provider of the Depart-  
7           ment;

8           (ii) overall prescription rates and pre-  
9           scriptions indications of opioids to treat  
10          non-cancer, non-palliative, and non-hospice  
11          care patients;

12          (iii) the prescription rates and pre-  
13          scriptions indications of benzodiazepines  
14          and opioids concomitantly by health care  
15          providers of the Department;

16          (iv) the practice by health care pro-  
17          viders of the Department of prescribing  
18          opioids to treat patients without any pain,  
19          including to treat patients with mental  
20          health disorders other than opioid use dis-  
21          order; and

22          (v) the effectiveness of opioid therapy  
23          for patients receiving such therapy, includ-  
24          ing the effectiveness of long-term opioid  
25          therapy.

1           (C) An evaluation of processes of the De-  
2           partment in place to oversee opioid use among  
3           veterans, including procedures to identify and  
4           remedy potential over-prescribing of opioids by  
5           health care providers of the Department.

6           (D) An assessment of the implementation  
7           by the Secretary of the VA/DOD Clinical Prac-  
8           tice Guideline for Management of Opioid Ther-  
9           apy for Chronic Pain.

10       (b) QUARTERLY PROGRESS REPORT ON IMPLEMEN-  
11       TATION OF COMPTROLLER GENERAL RECOMMENDA-  
12       TIONS.—Not later than two years after the date of the  
13       enactment of this Act, and not later than 30 days after  
14       the end of each quarter thereafter, the Secretary of Vet-  
15       erans Affairs shall submit to the Committee on Veterans'  
16       Affairs of the Senate and the Committee on Veterans' Af-  
17       fairs of the House of Representatives a progress report  
18       detailing the actions by the Secretary during the period  
19       covered by the report to address any outstanding findings  
20       and recommendations by the Comptroller General of the  
21       United States under subsection (a) with respect to the  
22       Veterans Health Administration.

23       (c) ANNUAL REVIEW OF PRESCRIPTION RATES.—  
24       Not later than one year after the date of the enactment  
25       of this Act, and not less frequently than annually for the

1 following five years, the Secretary shall submit to the  
2 Committee on Veterans' Affairs of the Senate and the  
3 Committee on Veterans' Affairs of the House of Rep-  
4 resentatives a report, with respect to each medical facility  
5 of the Department of Veterans Affairs, to collect and re-  
6 view information on opioids prescribed by health care pro-  
7 viders at the facility to treat non-cancer, non-palliative,  
8 and non-hospice care patients that contains, for the one-  
9 year period preceding the submission of the report, the  
10 following:

11           (1) The number of patients and the percentage  
12           of the patient population of the Department who  
13           were prescribed benzodiazepines and opioids concur-  
14           rently by a health care provider of the Department.

15           (2) The number of patients and the percentage  
16           of the patient population of the Department without  
17           any pain who were prescribed opioids by a health  
18           care provider of the Department, including those  
19           who were prescribed benzodiazepines and opioids  
20           concurrently.

21           (3) The number of non-cancer, non-palliative,  
22           and non-hospice care patients and the percentage of  
23           such patients who were treated with opioids by a  
24           health care provider of the Department on an inpa-  
25           tient-basis and who also received prescription opioids

1 by mail from the Department while being treated on  
2 an inpatient-basis.

3 (4) The number of non-cancer, non-palliative,  
4 and non-hospice care patients and the percentage of  
5 such patients who were prescribed opioids concu-  
6 rently by a health care provider of the Department  
7 and a health care provider that is not health care  
8 provider of the Department.

9 (5) With respect to each medical facility of the  
10 Department, information on opioids prescribed by  
11 health care providers at the facility to treat non-can-  
12 cer, non-palliative, and non-hospice care patients, in-  
13 cluding information on—

14 (A) the prescription rate at which each  
15 health care provider at the facility prescribed  
16 benzodiazepines and opioids concurrently to  
17 such patients and the aggregate such prescrip-  
18 tion rate for all health care providers at the fa-  
19 cility;

20 (B) the prescription rate at which each  
21 health care provider at the facility prescribed  
22 benzodiazepines or opioids to such patients to  
23 treat conditions for which benzodiazepines or  
24 opioids are not approved treatment and the ag-

1            aggregate such prescription rate for all health  
2            care providers at the facility;

3            (C) the prescription rate at which each  
4            health care provider at the facility prescribed or  
5            dispensed mail-order prescriptions of opioids to  
6            such patients while such patients were being  
7            treated with opioids on an inpatient-basis and  
8            the aggregate of such prescription rate for all  
9            health care providers at the facility; and

10           (D) the prescription rate at which each  
11           health care provider at the facility prescribed  
12           opioids to such patients who were also concur-  
13           rently prescribed opioids by a health care pro-  
14           vider that is not a health care provider of the  
15           Department and the aggregate of such prescrip-  
16           tion rates for all health care providers at the fa-  
17           cility.

18           (6) With respect to each medical facility of the  
19           Department, the number of times a pharmacist at  
20           the facility overrode a critical drug interaction warn-  
21           ing with respect to an interaction between opioids  
22           and another medication before dispensing such medi-  
23           cation to a veteran.

24           (d) INVESTIGATION OF PRESCRIPTION RATES.—If  
25           the Secretary determines that a prescription rate with re-

1 spect to a health care provider or medical facility of the  
2 Department conflicts with or is otherwise inconsistent  
3 with the standards of appropriate and safe care, the Sec-  
4 retary shall—

5           (1) immediately notify the Committee on Vet-  
6 erans' Affairs of the Senate and the Committee on  
7 Veterans' Affairs of the House of Representatives of  
8 such determination, including information relating to  
9 such determination, prescription rate, and health  
10 care provider or medical facility, as the case may be;  
11 and

12           (2) through the Office of the Medical Inspector  
13 of the Veterans Health Administration, conduct a  
14 full investigation of the health care provider or med-  
15 ical facility, as the case may be.

16       (e) PRESCRIPTION RATE DEFINED.—In this section,  
17 the term “prescription rate” means, with respect to a  
18 health care provider or medical facility of the Department,  
19 each of the following:

20           (1) The number of patients treated with opioids  
21 by the health care provider or at the medical facility,  
22 as the case may be, divided by the total number of  
23 pharmacy users of that health care provider or med-  
24 ical facility.

1           (2) The average number of morphine equiva-  
2           lents per day prescribed by the health care provider  
3           or at the medical facility, as the case may be, to pa-  
4           tients being treated with opioids.

5           (3) Of the patients being treated with opioids  
6           by the health care provider or at the medical facility,  
7           as the case may be, the average number of prescrip-  
8           tions of opioids per patient.

## 9           **Subtitle B—Patient Advocacy**

### 10   **SEC. 321. COMMUNITY MEETINGS ON IMPROVING CARE**

#### 11                           **FURNISHED BY DEPARTMENT OF VETERANS**

#### 12                           **AFFAIRS.**

13           (a) COMMUNITY MEETINGS.—

14                   (1) MEDICAL CENTERS.—Not later than 90  
15           days after the date of the enactment of this Act, and  
16           not less frequently than once every 90 days there-  
17           after, the Secretary shall ensure that each medical  
18           facility of the Department of Veterans Affairs hosts  
19           a community meeting open to the public on improv-  
20           ing health care furnished by the Secretary.

21                   (2) COMMUNITY BASED OUTPATIENT CLIN-  
22           ICS.—Not later than one year after the date of the  
23           enactment of this Act, and not less frequently than  
24           annually thereafter, the Secretary shall ensure that  
25           each community based outpatient clinic of the De-



1       partment hosts a community meeting open to the  
2       public on improving health care furnished by the  
3       Secretary.

4       (b) ATTENDANCE BY DIRECTOR OF VETERANS INTE-  
5       GRATED SERVICE NETWORK OR DESIGNEE.—

6           (1) IN GENERAL.—Each community meeting  
7       hosted by a medical facility or community based out-  
8       patient clinic under subsection (a) shall be attended  
9       by the Director of the Veterans Integrated Service  
10      Network in which the medical facility or community  
11      based outpatient clinic, as the case may be, is lo-  
12      cated. Subject to paragraph (2), the Director may  
13      delegate such attendance only to an employee who  
14      works in the Office of the Director.

15          (2) ATTENDANCE BY DIRECTOR.—Each Direc-  
16      tor of a Veterans Integrated Service Network shall  
17      personally attend not less than one community meet-  
18      ing under subsection (a) hosted by each medical fa-  
19      cility located in the Veterans Integrated Service Net-  
20      work each year.

21      (c) NOTICE.—The Secretary shall notify the Com-  
22      mittee on Veterans' Affairs of the Senate, the Committee  
23      on Veterans' Affairs of the House of Representatives, and  
24      each Member of Congress (as defined in section 314) who  
25      represents the area in which the medical facility is located

1 of a community meeting under subsection (a) by not later  
2 than 10 days before such community meeting occurs.

3 **SEC. 322. IMPROVEMENT OF AWARENESS OF PATIENT AD-**  
4 **VOCACY PROGRAM AND PATIENT BILL OF**  
5 **RIGHTS OF DEPARTMENT OF VETERANS AF-**  
6 **FAIRS.**

7 Not later than 90 days after the date of the enact-  
8 ment of this Act, the Secretary of Veterans Affairs shall,  
9 in as many prominent locations as the Secretary deter-  
10 mines appropriate to be seen by the largest percentage of  
11 patients and family members of patients at each medical  
12 facility of the Department of Veterans Affairs—

13 (1) display the purposes of the Patient Advoca-  
14 cacy Program of the Department and the contact in-  
15 formation for the patient advocate at such medical  
16 facility; and

17 (2) display the rights and responsibilities of—

18 (A) patients and family members and pa-  
19 tients at such medical facility; and

20 (B) with respect to community living cen-  
21 ters and other residential facilities of the De-  
22 partment, residents and family members of resi-  
23 dents at such medical facility.

1 **SEC. 323. COMPTROLLER GENERAL REPORT ON PATIENT**  
2 **ADVOCACY PROGRAM OF DEPARTMENT OF**  
3 **VETERANS AFFAIRS.**

4 (a) IN GENERAL.—Not later than two years after the  
5 date of the enactment of this Act, the Comptroller General  
6 of the United States shall submit to the Committee on  
7 Veterans' Affairs of the Senate and the Committee on Vet-  
8 erans' Affairs of the House of Representatives a report  
9 on the Patient Advocacy Program of the Department of  
10 Veterans Affairs (in this section referred to as the "Pro-  
11 gram").

12 (b) ELEMENTS.—The report required by subsection  
13 (a) shall include the following:

14 (1) A description of the Program, including—

15 (A) the purpose of the Program;

16 (B) the activities carried out under the  
17 Program; and

18 (C) the sufficiency of the Program in  
19 achieving the purpose of the Program.

20 (2) An assessment of the sufficiency of staffing  
21 of employees of the Department responsible for car-  
22 rying out the Program.

23 (3) An assessment of the sufficiency of the  
24 training of such employees.

25 (4) An assessment of—

1 (A) the awareness of the Program among  
2 veterans and family members of veterans; and

3 (B) the use of the Program by veterans  
4 and family members of veterans.

5 (5) Such recommendations and proposals for  
6 improving or modifying the Program as the Comp-  
7 troller General considers appropriate.

8 (6) Such other information with respect to the  
9 Program as the Comptroller General considers ap-  
10 propriate.

11 **Subtitle C—Complementary and**  
12 **Integrative Health**

13 **SEC. 331. EXPANSION OF RESEARCH AND EDUCATION ON**  
14 **AND DELIVERY OF COMPLEMENTARY AND IN-**  
15 **TEGRATIVE HEALTH TO VETERANS.**

16 (a) ESTABLISHMENT.—There is established a com-  
17 mission to be known as the “Creating Options for Vet-  
18 erans’ Expedited Recovery” or the “COVER Commission”  
19 (in this Act referred to as the “Commission”). The Com-  
20 mission shall examine the evidence-based therapy treat-  
21 ment model used by the Secretary of Veterans Affairs for  
22 treating mental health conditions of veterans and the po-  
23 tential benefits of incorporating complementary alter-  
24 native treatments available in non-Department facilities

1 (as defined in section 1701 of title 38, United States  
2 Code).

3 (b) DUTIES.—The Commission shall perform the fol-  
4 lowing duties:

5 (1) Examine the efficacy of the evidence-based  
6 therapy model used by the Secretary for treating  
7 mental health illnesses of veterans and identify areas  
8 to improve wellness-based outcomes.

9 (2) Conduct a patient-centered survey within  
10 each of the Veterans Integrated Service Networks to  
11 examine—

12 (A) the experience of veterans with the De-  
13 partment of Veterans Affairs when seeking  
14 medical assistance for mental health issues  
15 through the health care system of the Depart-  
16 ment;

17 (B) the experience of veterans with non-  
18 Department facilities and health professionals  
19 for treating mental health issues;

20 (C) the preference of veterans regarding  
21 available treatment for mental health issues and  
22 which methods the veterans believe to be most  
23 effective;

1 (D) the experience, if any, of veterans with  
2 respect to the complementary alternative treat-  
3 ment therapies described in paragraph (3);

4 (E) the prevalence of prescribing prescrip-  
5 tion medication among veterans seeking treat-  
6 ment through the health care system of the De-  
7 partment as remedies for addressing mental  
8 health issues; and

9 (F) the outreach efforts of the Secretary  
10 regarding the availability of benefits and treat-  
11 ments for veterans for addressing mental health  
12 issues, including by identifying ways to reduce  
13 barriers to gaps in such benefits and treat-  
14 ments.

15 (3) Examine available research on complemen-  
16 tary alternative treatment therapies for mental  
17 health issues and identify what benefits could be  
18 made with the inclusion of such treatments for vet-  
19 erans, including with respect to—

20 (A) music therapy;

21 (B) equine therapy;

22 (C) training and caring for service dogs;

23 (D) yoga therapy;

24 (E) acupuncture therapy;

25 (F) meditation therapy;

- 1 (G) outdoor sports therapy;
- 2 (H) hyperbaric oxygen therapy;
- 3 (I) accelerated resolution therapy;
- 4 (J) art therapy;
- 5 (K) magnetic resonance therapy; and
- 6 (L) other therapies the Commission deter-
- 7 mines appropriate.

8 (4) Study the sufficiency of the resources of the  
9 Department to ensure the delivery of quality health  
10 care for mental health issues among veterans seek-  
11 ing treatment within the Department.

12 (5) Study the current treatments and resources  
13 available within the Department and assess—

14 (A) the effectiveness of such treatments  
15 and resources in decreasing the number of sui-  
16 cides per day by veterans;

17 (B) the number of veterans who have been  
18 diagnosed with mental health issues;

19 (C) the percentage of veterans using the  
20 resources of the Department who have been di-  
21 agnosed with mental health issues;

22 (D) the percentage of veterans who have  
23 completed counseling sessions offered by the  
24 Department; and

1 (E) the efforts of the Department to ex-  
2 pand complementary alternative treatments via-  
3 ble to the recovery of veterans with mental  
4 health issues as determined by the Secretary to  
5 improve the effectiveness of treatments offered  
6 with the Department.

7 (c) MEMBERSHIP.—

8 (1) IN GENERAL.—The Commission shall be  
9 composed of 10 members, appointed as follows:

10 (A) Two members appointed by the Speak-  
11 er of the House of Representatives, at least one  
12 of whom shall be a veteran.

13 (B) Two members appointed by the Minor-  
14 ity Leader of the House of Representatives, at  
15 least one of whom shall be a veteran.

16 (C) Two members appointed by the Major-  
17 ity Leader of the Senate, at least one of whom  
18 shall be a veteran.

19 (D) Two members appointed by the Minor-  
20 ity Leader of the Senate, at least one of whom  
21 shall be a veteran.

22 (E) Two members appointed by the Presi-  
23 dent, at least one of whom shall be a veteran.

24 (2) QUALIFICATIONS.—Members of the Com-  
25 mission shall be—



1 (A) individuals who are of recognized  
2 standing and distinction within the medical  
3 community with a background in treating men-  
4 tal health;

5 (B) individuals with experience working  
6 with the military and veteran population; and

7 (C) individuals who do not have a financial  
8 interest in any of the complementary alternative  
9 treatments reviewed by the Commission.

10 (3) CHAIRMAN.—The President shall designate  
11 a member of the Commission to be the Chairman.

12 (4) PERIOD OF APPOINTMENT.—Members of  
13 the Commission shall be appointed for the life of the  
14 Commission.

15 (5) VACANCY.—A vacancy in the Commission  
16 shall be filled in the manner in which the original  
17 appointment was made.

18 (6) APPOINTMENT DEADLINE.—The appoint-  
19 ment of members of the Commission in this section  
20 shall be made not later than 90 days after the date  
21 of the enactment of this Act.

22 (d) POWERS OF COMMISSION.—

23 (1) MEETINGS.—

24 (A) INITIAL MEETING.—The Commission  
25 shall hold its first meeting not later than 30

1 days after a majority of members are appointed  
2 to the Commission.

3 (B) MEETING.—The Commission shall reg-  
4 ularly meet at the call of the Chairman. Such  
5 meetings may be carried out through the use of  
6 telephonic or other appropriate telecommuni-  
7 cation technology if the Commission determines  
8 that such technology will allow the members to  
9 communicate simultaneously.

10 (2) HEARINGS.—The Commission may hold  
11 such hearings, sit and act at such times and places,  
12 take such testimony, and receive evidence as the  
13 Commission considers advisable to carry out the re-  
14 sponsibilities of the Commission.

15 (3) INFORMATION FROM FEDERAL AGENCIES.—  
16 The Commission may secure directly from any de-  
17 partment or agency of the Federal Government such  
18 information as the Commission considers necessary  
19 to carry out the duties of the Commission.

20 (4) INFORMATION FROM NONGOVERNMENTAL  
21 ORGANIZATIONS.—In carrying out its duties, the  
22 Commission may seek guidance through consultation  
23 with foundations, veteran service organizations, non-  
24 profit groups, faith-based organizations, private and  
25 public institutions of higher education, and other or-

1 organizations as the Commission determines appro-  
2 priate.

3 (5) COMMISSION RECORDS.—The Commission  
4 shall keep an accurate and complete record of the  
5 actions and meeting of the Commission. Such record  
6 shall be made available for public inspection and the  
7 Comptroller General of the United States may audit  
8 and examine such record.

9 (6) PERSONNEL RECORDS.—The Commission  
10 shall keep an accurate and complete record of the  
11 actions and meetings of the Commission. Such  
12 record shall be made available for public inspection  
13 and the Comptroller General of the United States  
14 may audit and examine such records.

15 (7) COMPENSATION OF MEMBERS; TRAVEL EX-  
16 PENSES.—Each member shall serve without pay but  
17 shall receive travel expenses to perform the duties of  
18 the Commission, including per diem in lieu of sub-  
19 stances, at rates authorized under subchapter I of  
20 chapter 57 of title 5, United States Code.

21 (8) STAFF.—The Chairman, in accordance with  
22 rules agreed upon the Commission, may appoint fix  
23 the compensation of a staff director and such other  
24 personnel as may be necessary to enable the Com-  
25 mission to carry out its functions, without regard to

1 the provisions of title 5, United States Code, gov-  
2 erning appointments in the competitive service, with-  
3 out regard to the provision of chapter 51 and sub-  
4 chapter III of chapter 53 of such title relating to  
5 classification and General Schedule pay rates, except  
6 that no rate of pay fixed under this paragraph may  
7 exceed the equivalent of that payable for a position  
8 at a level IV of the Executive Schedule under section  
9 5316 of title 5, United States Code.

10 (9) PERSONNEL AS FEDERAL EMPLOYEES.—

11 (A) IN GENERAL.—The executive director  
12 and any personnel of the Commission are em-  
13 ployees under section 2105 of title 5, United  
14 States Code, for purpose of chapters 63, 81, 83,  
15 84, 85, 87, 89, and 90 of such title.

16 (B) MEMBERS OF THE COMMISSION.—

17 Subparagraph (A) shall not be construed to  
18 apply to members of the Commission.

19 (10) CONTRACTING.—The Commission may, to  
20 such extent and in such amounts as are provided in  
21 appropriations Acts, enter into contracts to enable  
22 the Commission to discharge the duties of the Com-  
23 mission under this Act.

24 (11) EXPERT AND CONSULTANT SERVICE.—The  
25 Commission may procure the services of experts and

1 consultants in accordance with section 3109 or title  
2 5, United States Code, at rates not to exceed the  
3 daily rate paid to a person occupying a position at  
4 level IV of the Executive Schedule under section  
5 3109 of title 5, United States Code.

6 (12) POSTAL SERVICE.—The Commission may  
7 use the United States mails in the same manner and  
8 under the same conditions as departments and agen-  
9 cies of the United States.

10 (13) PHYSICAL FACILITIES AND EQUIPMENT.—  
11 Upon the request of the Commission, the Adminis-  
12 trator of General Services shall provide to the Com-  
13 mission, on a reimbursable basis, the administrative  
14 support services necessary for the Commission to  
15 carry out its responsibilities under this Act. These  
16 administrative services may include human resource  
17 management, budget, leasing accounting, and payroll  
18 services.

19 (e) REPORT.—

20 (1) INTERIM REPORTS.—

21 (A) IN GENERAL.—Not later than 60 days  
22 after the date on which the Commission first  
23 meets, and each 30-day period thereafter end-  
24 ing on the date on which the Commission sub-  
25 mits the final report under paragraph (2), the

1 Commission shall submit to the Committees on  
2 Veterans' Affairs of the House of Representa-  
3 tives and the Senate and the President a report  
4 detailing the level of cooperation the Secretary  
5 of Veterans Affairs (and the heads of other de-  
6 partments or agencies of the Federal Govern-  
7 ment) has provided to the Commission.

8 (B) OTHER REPORTS.—In carrying out its  
9 duties, at times that the Commission deter-  
10 mines appropriate, the Commission shall submit  
11 to the Committee on Veterans' Affairs of the  
12 House of Representatives and the Senate and  
13 any other appropriate entities an interim report  
14 with respect to the findings identified by the  
15 Commission.

16 (2) FINAL REPORT.—Not later than 18 months  
17 after the first meeting of the Commission, the Com-  
18 mission shall submit to the Committee on Veterans'  
19 Affairs of the House of Representatives and the Sen-  
20 ate, the President, and the Secretary of Veterans Af-  
21 fairs a final report on the findings of the Commis-  
22 sion. Such report shall include the following:

23 (A) Recommendations to implement in a  
24 feasible, timely, and cost efficient manner the  
25 solutions and remedies identified within the

1 findings of the Commission pursuant to sub-  
2 section (b).

3 (B) An analysis of the evidence-based ther-  
4 apy model used by the Secretary of Veterans  
5 Affairs for treating veterans with mental health  
6 care issues, and an examination of the preva-  
7 lence and efficacy of prescription drugs as a  
8 means for treatment.

9 (C) The findings of the patient-centered  
10 survey conducted within each of the Veterans  
11 Integrated Service Networks pursuant to sub-  
12 section (b)(2).

13 (D) An examination of complementary al-  
14 ternative treatments described in subsection  
15 (b)(3) and the potential benefits of incor-  
16 porating such treatments in the therapy models  
17 used by the Secretary for treating veterans with  
18 mental health issues.

19 (3) PLAN.—Not later than 90 days after the  
20 date on which the Commission submits the final re-  
21 port under paragraph (2), the Secretary of Veterans  
22 Affairs shall submit to the Committee on Veterans'  
23 Affairs of the House of Representatives and the Sen-  
24 ate a report on the following:

1           (A) An action plan for implementing the  
2           recommendations established by the Commis-  
3           sion on such solutions and remedies for improv-  
4           ing wellness-based outcomes for veterans with  
5           mental health care issues.

6           (B) A feasible timeframe on when the com-  
7           plementary alternative treatments described in  
8           subsection (b)(3) can be implemented Depart-  
9           ment-wide.

10          (C) With respect to each recommendation  
11          established by the Commission, including any  
12          complementary alternative treatment, that the  
13          Secretary determines is not appropriate or fea-  
14          sible to implement, a justification for such de-  
15          termination and an alternative solution to im-  
16          prove the efficacy of the therapy models used by  
17          the Secretary for treating veterans with mental  
18          health issues.

19          (f) TERMINATION OF COMMISSION.—The Commis-  
20          sion shall terminate 30 days after the Commission submits  
21          the final report under subsection (e)(2).



1 **SEC. 332. PILOT PROGRAM ON INTEGRATION OF COM-**  
2 **PLEMENTARY ALTERNATIVE MEDICINES AND**  
3 **RELATED ISSUES FOR VETERANS AND FAM-**  
4 **ILY MEMBERS OF VETERANS.**

5 (a) PILOT PROGRAM.—

6 (1) IN GENERAL.—Not later than 180 days  
7 after the date on which the Secretary of Veterans  
8 Affairs receives the final report under section  
9 331(e), the Secretary shall commence a pilot pro-  
10 gram to assess the feasibility and advisability of  
11 using wellness-based programs (as defined by the  
12 Secretary) to complement the provision of pain man-  
13 agement and related health care services, including  
14 mental health care services, to veterans.

15 (2) MATTERS ADDRESSED.—In carrying out the  
16 pilot program, the Secretary shall assess the fol-  
17 lowing:

18 (A) Means of improving coordination be-  
19 tween Federal, State, local, and community pro-  
20 viders of health care in the provision of pain  
21 management and related health care services to  
22 veterans.

23 (B) Means of enhancing outreach, and co-  
24 ordination of outreach, by and among providers  
25 of health care referred to in subparagraph (A)

1 on the pain management and related health  
2 care services available to veterans.

3 (C) Means of using wellness-based pro-  
4 grams of providers of health care referred to in  
5 subparagraph (A) as complements to the provi-  
6 sion by the Department of pain management  
7 and related health care services to veterans.

8 (D) Whether wellness-based programs de-  
9 scribed in subparagraph (C)—

10 (i) are effective in enhancing the qual-  
11 ity of life and well-being of veterans;

12 (ii) are effective in increasing the ad-  
13 herence of veterans to the primary pain  
14 management and related health care serv-  
15 ices provided such veterans by the Depart-  
16 ment;

17 (iii) have an effect on the sense of  
18 well-being of veterans who receive primary  
19 pain management and related health care  
20 services from the Department; and

21 (iv) are effective in encouraging vet-  
22 erans receiving health care from the De-  
23 partment to adopt a more healthy lifestyle.

1 (b) DURATION.—The Secretary shall carry out the  
2 pilot program under subsection (a)(1) for a period of three  
3 years.

4 (c) LOCATIONS.—

5 (1) FACILITIES.—The Secretary shall carry out  
6 the pilot program under subsection (a)(1) at facili-  
7 ties of the Department providing pain management  
8 and related health care services, including mental  
9 health care services, to veterans. In selecting such  
10 facilities to carry out the pilot program, the Sec-  
11 retary shall select not fewer than 15 medical centers  
12 of the Department, of which not fewer than two  
13 shall be polytrauma rehabilitation centers of the De-  
14 partment.

15 (2) MEDICAL CENTERS WITH PRESCRIPTION  
16 RATES OF OPIOIDS THAT CONFLICT WITH CARE  
17 STANDARDS.—In selecting the medical centers under  
18 paragraph (1), the Secretary shall give priority to  
19 medical centers of the Department at which there is  
20 a prescription rate of opioids that conflicts with or  
21 is otherwise inconsistent with the standards of ap-  
22 propriate and safe care.

23 (d) PROVISION OF SERVICES.—Under the pilot pro-  
24 gram under subsection (a)(1), the Secretary shall provide  
25 covered services to covered veterans by integrating com-

1 plementary and alternative medicines and integrative  
2 health services with other services provided by the Depart-  
3 ment at the medical centers selected under subsection (c).

4 (e) COVERED VETERANS.—For purposes of the pilot  
5 program under subsection (a)(1), a covered veteran is any  
6 veteran who—

7 (1) has a mental health condition diagnosed by  
8 a clinician of the Department;

9 (2) experiences chronic pain;

10 (3) has a chronic condition being treated by a  
11 clinician of the Department; or

12 (4) is not described in paragraph (1), (2), or  
13 (3) and requests to participate in the pilot program  
14 or is referred by a clinician of the Department who  
15 is treating the veteran.

16 (f) COVERED SERVICES.—

17 (1) IN GENERAL.—For purposes of the pilot  
18 program, covered services are services consisting of  
19 complementary and integrative health services as se-  
20 lected by the Secretary.

21 (2) ADMINISTRATION OF SERVICES.—Covered  
22 services shall be administered under the pilot pro-  
23 gram as follows:

24 (A) Covered services shall be administered  
25 by professionals or other instructors with ap-

1           appropriate training and expertise in complemen-  
2           tary and integrative health services who are em-  
3           ployees of the Department or with whom the  
4           Department enters into an agreement to pro-  
5           vide such services.

6           (B) Covered services shall be included as  
7           part of the Patient Aligned Care Teams initia-  
8           tive of the Office of Patient Care Services, Pri-  
9           mary Care Program Office, in coordination with  
10          the Office of Patient Centered Care and Cul-  
11          tural Transformation.

12          (C) Covered services shall be made avail-  
13          able to—

14               (i) covered veterans who have received  
15               conventional treatments from the Depart-  
16               ment for the conditions for which the cov-  
17               ered veteran seeks complementary and in-  
18               tegrative health services under the pilot  
19               program; and

20               (ii) covered veterans who have not re-  
21               ceived conventional treatments from the  
22               Department for such conditions.

23          (g) REPORTS.—

24               (1) IN GENERAL.—Not later than 30 months  
25          after the date on which the Secretary commences the

1 pilot program under subsection (a)(1), the Secretary  
2 shall submit to the Committee on Veterans' Affairs  
3 of the Senate and the Committee on Veterans' Af-  
4 fairs of the House of Representatives a report on the  
5 pilot program.

6 (2) ELEMENTS.—The report under paragraph  
7 (1) shall include the following:

8 (A) The findings and conclusions of the  
9 Secretary with respect to the pilot program  
10 under subsection (a)(1), including with respect  
11 to—

12 (i) the use and efficacy of the com-  
13 plementary and integrative health services  
14 established under the pilot program;

15 (ii) the outreach conducted by the  
16 Secretary to inform veterans and commu-  
17 nity organizations about the pilot program;  
18 and

19 (iii) an assessment of the benefit of  
20 the pilot program to covered veterans in  
21 mental health diagnoses, pain manage-  
22 ment, and treatment of chronic illness.

23 (B) Identification of any unresolved bar-  
24 riers that impede the ability of the Secretary to  
25 incorporate complementary and integrative

1 health services with other health care services  
2 provided by the Department.

3 (C) Such recommendations for the continu-  
4 ation or expansion of the pilot program as the  
5 Secretary considers appropriate.

6 (h) COMPLEMENTARY AND INTEGRATIVE HEALTH  
7 DEFINED.—In this section, the term “complementary and  
8 integrative health” shall have the meaning given that term  
9 by the National Institutes of Health.

## 10 **Subtitle D—Fitness of Health Care** 11 **Providers**

### 12 **SEC. 341. ADDITIONAL REQUIREMENTS FOR HIRING OF** 13 **HEALTH CARE PROVIDERS BY DEPARTMENT** 14 **OF VETERANS AFFAIRS.**

15 As part of the hiring process for each health care pro-  
16 vider considered for a position at the Department of Vet-  
17 erans Affairs after the date of the enactment of the Act,  
18 the Secretary of Veterans Affairs shall require from the  
19 medical board of each State in which the health care pro-  
20 vider has a medical license—

21 (1) information on any violation of the require-  
22 ments of the medical license of the health care pro-  
23 vider during the 20-year period preceding the con-  
24 sideration of the health care provider by the Depart-  
25 ment; and

1           (2) information on whether the health care pro-  
2           vider has entered into any settlement agreement for  
3           the disciplinary charge relating to the practice of  
4           medicine by the health care provider.

5 **SEC. 342. PROVISION OF INFORMATION ON HEALTH CARE**  
6                           **PROVIDERS OF DEPARTMENT OF VETERANS**  
7                           **AFFAIRS TO STATE MEDICAL BOARDS.**

8           Notwithstanding section 552a of title 5, United  
9           States Code, with respect to each health care provider of  
10          the Department of Veterans Affairs who has violated a  
11          requirement of the medical license of the health care pro-  
12          vider, the Secretary of Veterans Affairs shall provide to  
13          the medical board of each State in which the health care  
14          provider is licensed detailed information with respect to  
15          such violation, regardless of whether such board has for-  
16          mally requested such information.

17 **SEC. 343. REPORT ON COMPLIANCE BY DEPARTMENT OF**  
18                           **VETERANS AFFAIRS WITH REVIEWS OF**  
19                           **HEALTH CARE PROVIDERS LEAVING THE DE-**  
20                           **PARTMENT OR TRANSFERRING TO OTHER**  
21                           **FACILITIES.**

22          Not later than two years after the date of the enact-  
23          ment of this Act, the Secretary of Veterans Affairs shall  
24          submit to the Committee on Veterans' Affairs of the Sen-  
25          ate and the Committee on Veterans' Affairs of the House



1 of Representatives a report on the compliance by the De-  
2 partment of Veterans Affairs with the policy of the De-  
3 partment—

4 (1) to conduct a review of each health care pro-  
5 vider of the Department who transfers to another  
6 medical facility of the Department, retires, or is ter-  
7 minated to determine whether there are any con-  
8 cerns, complaints, or allegations of violations relat-  
9 ing to the medical practice of the health care pro-  
10 vider; and

11 (2) to take appropriate action with respect to  
12 any such concern, complaint, or allegation.

### 13 **Subtitle E—Other Veterans Matters**

#### 14 **SEC. 351. AUDIT OF VETERANS HEALTH ADMINISTRATION**

##### 15 **PROGRAMS OF DEPARTMENT OF VETERANS**

##### 16 **AFFAIRS.**

17 (a) AUDIT.—The Secretary of Veterans Affairs shall  
18 seek to enter into a contract with a nongovernmental enti-  
19 ty under which the entity shall conduct a audits of the  
20 programs of the Veterans Health Administration of the  
21 Department of Veterans Affairs to identify ways to im-  
22 prove the furnishing of benefits and health care adminis-  
23 tered by the Veterans Health Administration to veterans  
24 and families of veterans.

1 (b) AUDIT REQUIREMENTS.—In carrying out each  
2 audit under subsection (a), the entity shall perform the  
3 following:

4 (1) Five-year risk assessments to identify the  
5 functions, staff organizations, and staff offices of the  
6 Veterans Health Administration that would lead to-  
7 wards the greatest improvement in furnishing of  
8 benefits and health care to veterans and families of  
9 veterans.

10 (2) Development of plans that are informed by  
11 the risk assessment under paragraph (1) to conduct  
12 audits of the functions, staff organizations, and staff  
13 offices identified under paragraph (1).

14 (3) Conduct audits in accordance with the plans  
15 developed pursuant to paragraph (2).

16 (c) REPORTS.—Not later than 90 days after the date  
17 on which each audit is completed under subsection (a),  
18 the Secretary shall submit to the Committees on Veterans'  
19 Affairs of the House of Representatives and the Senate  
20 a report that includes—

21 (1) a summary of the audit;

22 (2) the findings of the entity that conducted the  
23 audit with respect to the audit; and

24 (3) such recommendations as the Secretary de-  
25 termines appropriate for legislative or administrative

1 action to improve the furnishing of benefits and  
2 health care to veterans and families of veterans.

3 **TITLE IV—IMPROVING SAFE**  
4 **CARE FOR PREVENTING IN-**  
5 **FANT ABUSE AND NEGLECT**

6 **SEC. 401. SHORT TITLE.**

7 This title may be cited as the “Improving Safe Care  
8 for the Prevention of Infant Abuse and Neglect Act”.

9 **SEC. 402. BEST PRACTICES FOR DEVELOPMENT OF PLANS**  
10 **OF SAFE CARE.**

11 Section 103(b) of the Child Abuse Prevention and  
12 Treatment Act (42 U.S.C. 5104(b)) is amended—

13 (1) by redesignating paragraphs (5) through  
14 (8) as paragraphs (6) through (9), respectively; and

15 (2) by inserting after paragraph (4), the fol-  
16 lowing:

17 “(5) maintain and disseminate information  
18 about the best practices relating to the development  
19 of plans of safe care as described in section  
20 106(b)(2)(B)(iii) for infants born and identified as  
21 being affected by illegal substance abuse or with-  
22 drawal symptoms, or a Fetal Alcohol Spectrum Dis-  
23 order;”.

1 **SEC. 403. STATE PLANS.**

2 Section 106(b)(2)(B)(iii) of the Child Abuse Preven-  
3 tion and Treatment Act (42 U.S.C. 5106a(b)(2)(B)(iii))  
4 is amended by inserting before the period at the end the  
5 following: “to ensure the safety and well-being of such in-  
6 fant following release from the care of healthcare pro-  
7 viders, including through addressing the health of the af-  
8 fected family or caregiver”.

9 **SEC. 404. DATA REPORTS.**

10 (a) IN GENERAL.—Section 106(d) of the Child Abuse  
11 Prevention and Treatment Act (42 U.S.C. 5106a(d)) is  
12 amended by adding at the end of the following:

13 “(17) The total number of infants—

14 “(A) identified under subsection  
15 (b)(2)(B)(ii);

16 “(B) for whom a plan of safe care was de-  
17 veloped under subsection (b)(2)(B)(iii); and

18 “(C) for whom referrals are made for ap-  
19 propriate services, including services for the af-  
20 fected family or caregiver, as may be necessary  
21 under subsection (b)(2)(B)(iii).”.

22 (b) REDESIGNATION.—Effective on May 29, 2017,  
23 section 106(d) of the Child Abuse Prevention and Treat-  
24 ment Act (42 U.S.C. 5106a(d)) is amended by redesi-  
25 gnating paragraph (17) (as added by subsection (a)) as  
26 paragraph (18).

1 **SEC. 405. MONITORING AND OVERSIGHT.**

2 (a) AMENDMENT.—Title I of the Child Abuse Preven-  
3 tion and Treatment Act (42 U.S.C. 5101 et seq.) is fur-  
4 ther amended by adding at the end the following:

5 **“SEC. 114. MONITORING AND OVERSIGHT.**

6 “The Secretary shall conduct monitoring to ensure  
7 that each State that receives a grant under section 106  
8 is in compliance with the requirements of section 106(b),  
9 which—

10 “(1) shall—

11 “(A) be in addition to the review of the  
12 State plan upon its submission under section  
13 106(b)(1)(A); and

14 “(B) include monitoring of State policies  
15 and procedures required under clauses (ii) and  
16 (iii) of section 106(b)(2)(B); and

17 “(2) may include—

18 “(A) a comparison of activities carried out  
19 by the State to comply with the requirements of  
20 section 106(b) with the State plan most re-  
21 cently approved under section 432 of the Social  
22 Security Act;

23 “(B) information available on the Website  
24 of the State relating to its compliance with the  
25 requirements of section 106(b);

1           “(C) site visits, as may be necessary to  
2           carry out such monitoring; and

3           “(D) information available in the State’s  
4           Annual Progress and Services Report most re-  
5           cently submitted under section 1357.16 of title  
6           45, Code of Federal Regulations (or successor  
7           regulations).”.

8           (b) TABLE OF CONTENTS.—The table of contents in  
9           section 1(b) of the Child Abuse Prevention and Treatment  
10          Act (42 U.S.C. 5101 note) is amended by inserting after  
11          the item relating to section 113, the following:

          “Sec. 114. Monitoring and oversight.”.

12          **SEC. 406. RULE OF CONSTRUCTION.**

13                 Nothing in this Act shall be construed to authorize  
14                 the Secretary of Health and Human Services or any other  
15                 officer of the Federal Government to add new require-  
16                 ments to section 106(b) of the Child Abuse Prevention and  
17                 Treatment Act (42 U.S.C. 5106a(b)), as amended by this  
18                 Act.

19          **TITLE V—OTHER PROVISIONS**

20          **SEC. 501. PROGRAMS TO PREVENT PRESCRIPTION DRUG**

21                         **ABUSE UNDER MEDICARE PARTS C AND D.**

22                 (a) DRUG MANAGEMENT PROGRAM FOR AT-RISK  
23                 BENEFICIARIES.—

1           (1) IN GENERAL.—Section 1860D–4(c) of the  
2 Social Security Act (42 U.S.C. 1395w–10(c)) is  
3 amended by adding at the end the following:

4           “(5) DRUG MANAGEMENT PROGRAM FOR AT-  
5 RISK BENEFICIARIES.—

6           “(A) AUTHORITY TO ESTABLISH.—A PDP  
7 sponsor may establish a drug management pro-  
8 gram for at-risk beneficiaries under which, sub-  
9 ject to subparagraph (B), the PDP sponsor  
10 may, in the case of an at-risk beneficiary for  
11 prescription drug abuse who is an enrollee in a  
12 prescription drug plan of such PDP sponsor,  
13 limit such beneficiary’s access to coverage for  
14 frequently abused drugs under such plan to fre-  
15 quently abused drugs that are prescribed for  
16 such beneficiary by one or more prescribers se-  
17 lected under subparagraph (D), and dispensed  
18 for such beneficiary by one or more pharmacies  
19 selected under such subparagraph.

20           “(B) REQUIREMENT FOR NOTICES.—

21           “(i) IN GENERAL.—A PDP sponsor  
22 may not limit the access of an at-risk ben-  
23 eficiary for prescription drug abuse to cov-  
24 erage for frequently abused drugs under a

1 prescription drug plan until such spon-  
2 sor—

3 “(I) provides to the beneficiary  
4 an initial notice described in clause  
5 (ii) and a second notice described in  
6 clause (iii); and

7 “(II) verifies with the providers  
8 of the beneficiary that the beneficiary  
9 is an at-risk beneficiary for prescrip-  
10 tion drug abuse.

11 “(ii) INITIAL NOTICE.—An initial no-  
12 tice described in this clause is a notice that  
13 provides to the beneficiary—

14 “(I) notice that the PDP sponsor  
15 has identified the beneficiary as po-  
16 tentially being an at-risk beneficiary  
17 for prescription drug abuse;

18 “(II) information describing all  
19 State and Federal public health re-  
20 sources that are designed to address  
21 prescription drug abuse to which the  
22 beneficiary has access, including men-  
23 tal health services and other coun-  
24 seling services;



1           “(III) notice of, and information  
2           about, the right of the beneficiary to  
3           appeal such identification under sub-  
4           section (h) and the option of an auto-  
5           matic escalation to external review;

6           “(IV) a request for the bene-  
7           ficiary to submit to the PDP sponsor  
8           preferences for which prescribers and  
9           pharmacies the beneficiary would pre-  
10          fer the PDP sponsor to select under  
11          subparagraph (D) in the case that the  
12          beneficiary is identified as an at-risk  
13          beneficiary for prescription drug  
14          abuse as described in clause (iii)(I);

15          “(V) an explanation of the mean-  
16          ing and consequences of the identi-  
17          fication of the beneficiary as poten-  
18          tially being an at-risk beneficiary for  
19          prescription drug abuse, including an  
20          explanation of the drug management  
21          program established by the PDP  
22          sponsor pursuant to subparagraph  
23          (A);

24          “(VI) clear instructions that ex-  
25          plain how the beneficiary can contact

1 the PDP sponsor in order to submit  
2 to the PDP sponsor the preferences  
3 described in subclause (IV) and any  
4 other communications relating to the  
5 drug management program for at-risk  
6 beneficiaries established by the PDP  
7 sponsor; and

8 “(VII) contact information for  
9 other organizations that can provide  
10 the beneficiary with assistance regard-  
11 ing such drug management program  
12 (similar to the information provided  
13 by the Secretary in other standardized  
14 notices provided to part D eligible in-  
15 dividuals enrolled in prescription drug  
16 plans under this part).

17 “(iii) SECOND NOTICE.—A second no-  
18 tice described in this clause is a notice that  
19 provides to the beneficiary notice—

20 “(I) that the PDP sponsor has  
21 identified the beneficiary as an at-risk  
22 beneficiary for prescription drug  
23 abuse;

24 “(II) that such beneficiary is  
25 subject to the requirements of the

1 drug management program for at-risk  
2 beneficiaries established by such PDP  
3 sponsor for such plan;

4 “(III) of the prescriber (or pre-  
5 scribers) and pharmacy (or phar-  
6 macies) selected for such individual  
7 under subparagraph (D);

8 “(IV) of, and information about,  
9 the beneficiary’s right to appeal such  
10 identification under subsection (h)  
11 and the option of an automatic esca-  
12 lation to external review;

13 “(V) that the beneficiary can, in  
14 the case that the beneficiary has not  
15 previously submitted to the PDP  
16 sponsor preferences for which pre-  
17 scribers and pharmacies the bene-  
18 ficiary would prefer the PDP sponsor  
19 select under subparagraph (D), sub-  
20 mit such preferences to the PDP  
21 sponsor; and

22 “(VI) that includes clear instruc-  
23 tions that explain how the beneficiary  
24 can contact the PDP sponsor.

25 “(iv) TIMING OF NOTICES.—

1           “(I) IN GENERAL.—Subject to  
2           subclause (II), a second notice de-  
3           scribed in clause (iii) shall be provided  
4           to the beneficiary on a date that is  
5           not less than 60 days after an initial  
6           notice described in clause (ii) is pro-  
7           vided to the beneficiary.

8           “(II) EXCEPTION.—In the case  
9           that the PDP sponsor, in conjunction  
10          with the Secretary, determines that  
11          concerns identified through rule-  
12          making by the Secretary regarding  
13          the health or safety of the beneficiary  
14          or regarding significant drug diversion  
15          activities require the PDP sponsor to  
16          provide a second notice described in  
17          clause (iii) to the beneficiary on a  
18          date that is earlier than the date de-  
19          scribed in subclause (I), the PDP  
20          sponsor may provide such second no-  
21          tice on such earlier date.

22                   “(C) AT-RISK BENEFICIARY FOR PRE-  
23          SCRIPTION DRUG ABUSE.—

24                   “(i) IN GENERAL.—For purposes of  
25          this paragraph, the term ‘at-risk bene-

1            beneficiary for prescription drug abuse’ means  
2            a part D eligible individual who is not an  
3            exempted individual described in clause (ii)  
4            and—

5                            “(I) who is identified as such an  
6                            at-risk beneficiary through the use of  
7                            clinical guidelines developed by the  
8                            Secretary in consultation with PDP  
9                            sponsors and other stakeholders de-  
10                            scribed in section 3141(f)(2)(A) of the  
11                            21st Century Cures Act; or

12                            “(II) with respect to whom the  
13                            PDP sponsor of a prescription drug  
14                            plan, upon enrolling such individual in  
15                            such plan, received notice from the  
16                            Secretary that such individual was  
17                            identified under this paragraph to be  
18                            an at-risk beneficiary for prescription  
19                            drug abuse under the prescription  
20                            drug plan in which such individual  
21                            was most recently previously enrolled  
22                            and such identification has not been  
23                            terminated under subparagraph (F).

24                            “(ii) EXEMPTED INDIVIDUAL DE-  
25                            SCRIBED.—An exempted individual de-

1 scribed in this clause is an individual  
2 who—

3 “(I) receives hospice care under  
4 this title;

5 “(II) is a resident of a long-term  
6 care facility, of an intermediate care  
7 facility for the mentally retarded, or  
8 of another facility for which fre-  
9 quently abused drugs are dispensed  
10 for residents through a contract with  
11 a single pharmacy; or

12 “(III) the Secretary elects to  
13 treat as an exempted individual for  
14 purposes of clause (i).

15 “(D) SELECTION OF PRESCRIBERS AND  
16 PHARMACIES.—

17 “(i) IN GENERAL.—With respect to  
18 each at-risk beneficiary for prescription  
19 drug abuse enrolled in a prescription drug  
20 plan offered by such sponsor, a PDP spon-  
21 sor shall, based on the preferences sub-  
22 mitted to the PDP sponsor by the bene-  
23 ficiary pursuant to clauses (ii)(IV) and  
24 (iii)(V) of subparagraph (B) (except as

1 otherwise provided in this subparagraph),  
2 select—

3 “(I) one or more individuals who  
4 are authorized to prescribe frequently  
5 abused drugs (referred to in this  
6 paragraph as ‘prescribers’) who may  
7 write prescriptions for such drugs for  
8 such beneficiary; and

9 “(II) one or more pharmacies  
10 that may dispense such drugs to such  
11 beneficiary.

12 “(ii) REASONABLE ACCESS.—In mak-  
13 ing the selections under this subpara-  
14 graph—

15 “(I) a PDP sponsor shall ensure  
16 that the beneficiary continues to have  
17 reasonable access to frequently abused  
18 drugs (as defined in subparagraph  
19 (G)), taking into account geographic  
20 location, beneficiary preference, im-  
21 pact on cost-sharing, and reasonable  
22 travel time; and

23 “(II) a PDP sponsor shall ensure  
24 such access (including access to pre-  
25 scribers and pharmacies with respect

1 to frequently abused drugs) in the  
2 case of individuals with multiple resi-  
3 dences and in the case of natural dis-  
4 asters and similar emergency situa-  
5 tions.

6 “(iii) BENEFICIARY PREFERENCES.—

7 If an at-risk beneficiary for prescription  
8 drug abuse submits preferences for which  
9 in-network prescribers and pharmacies the  
10 beneficiary would prefer the PDP sponsor  
11 select in response to a notice under sub-  
12 paragraph (B), the PDP sponsor shall—

13 “(I) review such preferences;

14 “(II) select or change the selec-  
15 tion of prescribers and pharmacies for  
16 the beneficiary based on such pref-  
17 erences; and

18 “(III) inform the beneficiary of  
19 such selection or change of selection.

20 “(iv) EXCEPTION REGARDING BENE-  
21 FICIARY PREFERENCES.—In the case that  
22 the PDP sponsor determines that a change  
23 to the selection of prescriber or pharmacy  
24 under clause (iii)(II) by the PDP sponsor  
25 is contributing or would contribute to pre-



1           scription drug abuse or drug diversion by  
2           the beneficiary, the PDP sponsor may  
3           change the selection of prescriber or phar-  
4           macy for the beneficiary without regard to  
5           the preferences of the beneficiary described  
6           in clause (iii).

7           “(v) CONFIRMATION.—Before select-  
8           ing a prescriber (or prescribers) or phar-  
9           macy (or pharmacies) under this subpara-  
10          graph, a PDP sponsor must request and  
11          receive confirmation from such a prescriber  
12          or pharmacy acknowledging and accepting  
13          that the beneficiary involved is in the drug  
14          management program for at-risk bene-  
15          ficiaries.

16          “(E) TERMINATIONS AND APPEALS.—The  
17          identification of an individual as an at-risk ben-  
18          eficiary for prescription drug abuse under this  
19          paragraph, a coverage determination made  
20          under a drug management program for at-risk  
21          beneficiaries, and the selection of prescriber or  
22          pharmacy under subparagraph (D) with respect  
23          to such individual shall be subject to reconsider-  
24          ation and appeal under subsection (h) and the

1 option of an automatic escalation to external re-  
2 view to the extent provided by the Secretary.

3 “(F) TERMINATION OF IDENTIFICATION.—

4 “(i) IN GENERAL.—The Secretary  
5 shall develop standards for the termination  
6 of identification of an individual as an at-  
7 risk beneficiary for prescription drug abuse  
8 under this paragraph. Under such stand-  
9 ards such identification shall terminate as  
10 of the earlier of—

11 “(I) the date the individual dem-  
12 onstrates that the individual is no  
13 longer likely, in the absence of the re-  
14 strictions under this paragraph, to be  
15 an at-risk beneficiary for prescription  
16 drug abuse described in subparagraph  
17 (C)(i); and

18 “(II) the end of such maximum  
19 period of identification as the Sec-  
20 retary may specify.

21 “(ii) RULE OF CONSTRUCTION.—

22 Nothing in clause (i) shall be construed as  
23 preventing a plan from identifying an indi-  
24 vidual as an at-risk beneficiary for pre-  
25 scription drug abuse under subparagraph

1 (C)(i) after such termination on the basis  
2 of additional information on drug use oc-  
3 ccurring after the date of notice of such ter-  
4 mination.

5 “(G) FREQUENTLY ABUSED DRUG.—For  
6 purposes of this subsection, the term ‘frequently  
7 abused drug’ means a drug that is a controlled  
8 substance that the Secretary determines to be  
9 frequently abused or diverted.

10 “(H) DATA DISCLOSURE.—In the case of  
11 an at-risk beneficiary for prescription drug  
12 abuse whose access to coverage for frequently  
13 abused drugs under a prescription drug plan  
14 has been limited by a PDP sponsor under this  
15 paragraph, such PDP sponsor shall disclose  
16 data, including any necessary individually iden-  
17 tifiable health information, in a form and man-  
18 ner specified by the Secretary, about the deci-  
19 sion to impose such limitations and the limita-  
20 tions imposed by the sponsor under this part to  
21 other PDP sponsors that request such data.

22 “(I) EDUCATION.—The Secretary shall  
23 provide education to enrollees in prescription  
24 drug plans of PDP sponsors and providers re-  
25 garding the drug management program for at-

1 risk beneficiaries described in this paragraph,  
2 including education—

3 “(i) provided by Medicare administra-  
4 tive contractors through the improper pay-  
5 ment outreach and education program de-  
6 scribed in section 1874A(h); and

7 “(ii) through current education efforts  
8 (such as State health insurance assistance  
9 programs described in subsection (a)(1)(A)  
10 of section 119 of the Medicare Improve-  
11 ments for Patients and Providers Act of  
12 2008 (42 U.S.C. 1395b–3 note)) and ma-  
13 terials directed toward such enrollees.

14 “(J) APPLICATION UNDER MA–PD  
15 PLANS.—Pursuant to section 1860D–21(c)(1),  
16 the provisions of this paragraph apply under  
17 part D to MA organizations offering MA–PD  
18 plans to MA eligible individuals in the same  
19 manner as such provisions apply under this  
20 part to a PDP sponsor offering a prescription  
21 drug plan to a part D eligible individual.”.

22 (2) INFORMATION FOR CONSUMERS.—Section  
23 1860D–4(a)(1)(B) of the Social Security Act (42  
24 U.S.C. 1395w–104(a)(1)(B)) is amended by adding  
25 at the end the following:

1                   “(v) The drug management program  
2                   for at-risk beneficiaries under subsection  
3                   (c)(5).”.

4           (b) UTILIZATION MANAGEMENT PROGRAMS.—Sec-  
5 tion 1860D–4(c) of the Social Security Act (42 U.S.C.  
6 1395w–104(c)), as amended by subsection (a)(1), is fur-  
7 ther amended—

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

10                           “(E) A utilization management tool to pre-  
11                   vent drug abuse (as described in paragraph  
12                   (6)(A)).”; and

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

15                           “(6) UTILIZATION MANAGEMENT TOOL TO PRE-  
16                   VENT DRUG ABUSE.—

17                                   “(A) IN GENERAL.—A tool described in  
18                   this paragraph is any of the following:

19   “(i) A utilization tool designed to pre-  
20                   vent the abuse of frequently abused drugs  
21                   by individuals and to prevent the diversion  
22                   of such drugs at pharmacies.

23   “(ii) Retrospective utilization review  
24                   to identify—

1           “(I) individuals that receive fre-  
2           quently abused drugs at a frequency  
3           or in amounts that are not clinically  
4           appropriate; and

5           “(II) providers of services or sup-  
6           pliers that may facilitate the abuse or  
7           diversion of frequently abused drugs  
8           by beneficiaries.

9           “(iii) Consultation with the contractor  
10          described in subparagraph (B) to verify if  
11          an individual enrolling in a prescription  
12          drug plan offered by a PDP sponsor has  
13          been previously identified by another PDP  
14          sponsor as an individual described in  
15          clause (ii)(I).

16          “(B) REPORTING.—A PDP sponsor offer-  
17          ing a prescription drug plan (and an MA orga-  
18          nization offering an MA–PD plan) in a State  
19          shall submit to the Secretary and the Medicare  
20          drug integrity contractor with which the Sec-  
21          retary has entered into a contract under section  
22          1893 with respect to such State a report, on a  
23          monthly basis, containing information on—

24                 “(i) any provider of services or sup-  
25                 plier described in subparagraph (A)(ii)(II)

1 that is identified by such plan sponsor (or  
2 organization) during the 30-day period be-  
3 fore such report is submitted; and

4 “(ii) the name and prescription  
5 records of individuals described in para-  
6 graph (5)(C).”.

7 (c) EXPANDING ACTIVITIES OF MEDICARE DRUG IN-  
8 TEGRITY CONTRACTORS (MEDICS).—

9 (1) IN GENERAL.—Section 1893 of the Social  
10 Security Act (42 U.S.C. 1395ddd) is amended by  
11 adding at the end the following new subsection:

12 “(j) EXPANDING ACTIVITIES OF MEDICARE DRUG  
13 INTEGRITY CONTRACTORS (MEDICS).—

14 “(1) ACCESS TO INFORMATION.—Under con-  
15 tracts entered into under this section with Medicare  
16 drug integrity contractors (including any successor  
17 entity to a Medicare drug integrity contractor), the  
18 Secretary shall authorize such contractors to directly  
19 accept prescription and necessary medical records  
20 from entities such as pharmacies, prescription drug  
21 plans, MA–PD plans, and physicians with respect to  
22 an individual in order for such contractors to pro-  
23 vide information relevant to the determination of  
24 whether such individual is an at-risk beneficiary for

1 prescription drug abuse, as defined in section  
2 1860D–4(c)(5)(C).

3 “(2) REQUIREMENT FOR ACKNOWLEDGMENT  
4 OF REFERRALS.—If a PDP sponsor or MA organiza-  
5 tion refers information to a contractor described in  
6 paragraph (1) in order for such contractor to assist  
7 in the determination described in such paragraph,  
8 the contractor shall—

9 “(A) acknowledge to the sponsor or organi-  
10 zation receipt of the referral; and

11 “(B) in the case that any PDP sponsor or  
12 MA organization contacts the contractor re-  
13 questing to know the determination by the con-  
14 tractor of whether or not an individual has been  
15 determined to be an individual described such  
16 paragraph, shall inform such sponsor or organi-  
17 zation of such determination on a date that is  
18 not later than 15 days after the date on which  
19 the sponsor or organization contacts the con-  
20 tractor.

21 “(3) MAKING DATA AVAILABLE TO OTHER EN-  
22 TITIES.—

23 “(A) IN GENERAL.—For purposes of car-  
24 rying out this subsection, subject to subpara-  
25 graph (B), the Secretary shall authorize MED-



1 ICs to respond to requests for information from  
2 PDP sponsors and MA organizations, State  
3 prescription drug monitoring programs, and  
4 other entities delegated by such sponsors or or-  
5 ganizations using available programs and sys-  
6 tems in the effort to prevent fraud, waste, and  
7 abuse.

8 “(B) HIPAA COMPLIANT INFORMATION  
9 ONLY.—Information may only be disclosed by a  
10 MEDIC under subparagraph (A) if the disclo-  
11 sure of such information is permitted under the  
12 Federal regulations (concerning the privacy of  
13 individually identifiable health information) pro-  
14 mulgated under section 264(c) of the Health  
15 Insurance Portability and Accountability Act of  
16 1996 (42 U.S.C. 1320d–2 note).”.

17 (2) OIG STUDY AND REPORT ON EFFECTIVE-  
18 NESS OF MEDICS.—

19 (A) STUDY.—The Inspector General of the  
20 Department of Health and Human Services  
21 shall conduct a study on the effectiveness of  
22 Medicare drug integrity contractors with which  
23 the Secretary of Health and Human Services  
24 has entered into a contract under section 1893  
25 of the Social Security Act (42 U.S.C. 1395ddd)

1 in identifying, combating, and preventing fraud  
2 under the Medicare Program, including under  
3 the authority provided under section 1893(j) of  
4 the Social Security Act, added by paragraph  
5 (1).

6 (B) REPORT.—Not later than 1 year after  
7 the date of the enactment of this Act, the In-  
8 spector General shall submit to Congress a re-  
9 port on the study conducted under subpara-  
10 graph (A). Such report shall include such rec-  
11 ommendations for improvements in the effec-  
12 tiveness of such contractors as the Inspector  
13 General determines appropriate.

14 (d) TREATMENT OF CERTAIN COMPLAINTS FOR PUR-  
15 POSSES OF QUALITY OR PERFORMANCE ASSESSMENT.—  
16 Section 1860D–42 of the Social Security Act (42 U.S.C.  
17 1395w–152) is amended by adding at the end the fol-  
18 lowing new subsection:

19 “(d) TREATMENT OF CERTAIN COMPLAINTS FOR  
20 PURPOSES OF QUALITY OR PERFORMANCE ASSESS-  
21 MENT.—In conducting a quality or performance assess-  
22 ment of a PDP sponsor, the Secretary shall develop or  
23 utilize existing screening methods for reviewing and con-  
24 sidering complaints that are received from enrollees in a  
25 prescription drug plan offered by such PDP sponsor and

1 that are complaints regarding the lack of access by the  
2 individual to prescription drugs due to a drug manage-  
3 ment program for at-risk beneficiaries.”.

4 (e) SENSE OF CONGRESS REGARDING USE OF TECH-  
5 NOLOGY TOOLS TO COMBAT FRAUD.—It is the sense of  
6 Congress that MA organizations and PDP sponsors  
7 should consider using e-prescribing and other health infor-  
8 mation technology tools to support combating fraud under  
9 MA–PD plans and prescription drug plans under parts C  
10 and D of the Medicare Program.

11 (f) EFFECTIVE DATE.—

12 (1) IN GENERAL.—The amendments made by  
13 this section shall apply to prescription drug plans  
14 (and MA–PD plans) for plan years beginning more  
15 than 1 year after the date of the enactment of this  
16 Act.

17 (2) STAKEHOLDER MEETINGS PRIOR TO EFFEC-  
18 TIVE DATE.—

19 (A) IN GENERAL.—Not later than January  
20 1, 2016, the Secretary of Health and Human  
21 Services shall convene stakeholders, including  
22 individuals entitled to benefits under part A of  
23 title XVIII of the Social Security Act or en-  
24 rolled under part B of such title of such Act,  
25 advocacy groups representing such individuals,

1 physicians, pharmacists, and other clinicians,  
2 retail pharmacies, plan sponsors, entities dele-  
3 gated by plan sponsors, and biopharmaceutical  
4 manufacturers for input regarding the topics  
5 described in subparagraph (B).

6 (B) TOPICS DESCRIBED.—The topics de-  
7 scribed in this subparagraph are the topics of—

8 (i) the anticipated impact of drug  
9 management programs for at-risk bene-  
10 ficiaries under paragraph (5) of section  
11 1860D–4(c) of the Social Security Act (42  
12 U.S.C. 1395w–104(c)) on cost-sharing and  
13 ensuring accessibility to prescription drugs  
14 for enrollees in prescription drug plans of  
15 PDP sponsors, and enrollees in MA–PD  
16 plans, who are at-risk beneficiaries for pre-  
17 scription drug abuse (as defined in sub-  
18 paragraph (C) of such paragraph);

19 (ii) the use of an expedited appeals  
20 process under which such an enrollee may  
21 appeal an identification of such enrollee as  
22 an at-risk beneficiary for prescription drug  
23 abuse under such paragraph (similar to the  
24 processes established under the Medicare  
25 Advantage program under part C of title

1 XVIII of the Social Security Act that allow  
2 an automatic escalation to external review  
3 of claims submitted under such part);

4 (iii) the types of enrollees that should  
5 be treated as exempted individuals, as de-  
6 scribed in subparagraph (C)(ii) of such  
7 paragraph;

8 (iv) the manner in which terms and  
9 definitions in such paragraph should be ap-  
10 plied, such as the use of clinical appro-  
11 priateness in determining whether an en-  
12 rollee is an at-risk beneficiary for prescrip-  
13 tion drug abuse as defined in subpara-  
14 graph (C) of such paragraph;

15 (v) the information to be included in  
16 the notices described in subparagraph (B)  
17 of such paragraph and the standardization  
18 of such notices; and

19 (vi) with respect to a PDP sponsor  
20 (or Medicare Advantage organization) that  
21 establishes a drug management program  
22 for at-risk beneficiaries under such para-  
23 graph, the responsibilities of such PDP  
24 sponsor (or organization) with respect to  
25 the implementation of such program.

1 (g) RULEMAKING.—The Secretary of Health and  
2 Human Services shall promulgate regulations based on the  
3 input gathered pursuant to subsection (f)(2)(A).

4 **SEC. 502. EXCLUSION OF AUTHORIZED GENERIC DRUGS**  
5 **FROM CALCULATION OF AVERAGE MANUFAC-**  
6 **TURER PRICE FOR BRAND NAME DRUGS.**

7 (a) IN GENERAL.—Section 1927(k)(1)(C) of the So-  
8 cial Security Act (42 U.S.C. 1396r–8(k)(1)(C)) is amend-  
9 ed—

10 (1) in the subparagraph heading, by striking  
11 “INCLUSION” and inserting “EXCLUSION”;

12 (2) by striking “a new drug application” and  
13 inserting “the manufacturer’s new drug applica-  
14 tion”; and

15 (3) by striking “inclusive” and inserting “exclu-  
16 sive”.

17 (b) EFFECTIVE DATE.—The amendments made by  
18 subsection (a) shall take effect one year after the date of  
19 the enactment of this section.

○