

114TH CONGRESS  
1ST SESSION

# S. 636

To reduce prescription drug misuse and abuse.

---

IN THE SENATE OF THE UNITED STATES

MARCH 3, 2015

Mr. UDALL introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

---

## A BILL

To reduce prescription drug misuse and abuse.

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.**

4 This Act may be cited as the “Increasing the Safety  
5 of Prescription Drug Use Act of 2015”.

6 **TITLE I—HHS PROGRAMS**

7 **SEC. 101. AMENDMENT TO PURPOSE.**

8 Paragraph (1) of section 2 of the National All Sched-  
9 ules Prescription Electronic Reporting Act of 2005 (Public  
10 Law 109–60) is amended to read as follows:

1           “(1) foster the establishment of State-adminis-  
 2           tered controlled substance monitoring systems in  
 3           order to ensure that—

4                   “(A) health care providers have access to  
 5                   the accurate, timely prescription history infor-  
 6                   mation that they may use as a tool for the early  
 7                   identification of patients at risk for addiction in  
 8                   order to initiate appropriate medical interven-  
 9                   tions and avert the tragic personal, family, and  
 10                  community consequences of untreated addiction;  
 11                  and

12                  “(B) appropriate law enforcement, regu-  
 13                  latory, and State professional licensing authori-  
 14                  ties have access to prescription history informa-  
 15                  tion for the purposes of investigating drug di-  
 16                  version and prescribing and dispensing prac-  
 17                  tices of errant prescribers or pharmacists; and”.

18 **SEC. 102. PRESCRIPTION DRUG MONITORING PROGRAM.**

19           (a) CONTROLLED SUBSTANCE MONITORING PRO-  
 20           GRAM.—Section 3990 of the Public Health Service Act  
 21           (42 U.S.C. 280g-3) is amended—

22                   (1) in subsection (a)(1)—

23                           (A) in subparagraph (A), by striking “or”;

24                           (B) in subparagraph (B), by striking the  
 25                   period at the end and inserting “; or”; and

1 (C) by adding at the end the following:

2 “(C) to maintain and operate an existing  
3 State-controlled substance monitoring pro-  
4 gram.”;

5 (2) by amending subsection (b) to read as fol-  
6 lows:

7 “(b) MINIMUM REQUIREMENTS.—The Secretary  
8 shall maintain and, as appropriate, supplement or revise  
9 (after publishing proposed additions and revisions in the  
10 Federal Register and receiving public comments thereon)  
11 minimum requirements for criteria to be used by States  
12 for purposes of clauses (ii), (v), (vi), and (vii) of subsection  
13 (c)(1)(A).”;

14 (3) in subsection (c)—

15 (A) in paragraph (1)(B)—

16 (i) in the matter preceding clause (i),  
17 by striking “(a)(1)(B)” and inserting  
18 “(a)(1)(B) or (a)(1)(C)”;

19 (ii) in clause (i), by striking “program  
20 to be improved” and inserting “program to  
21 be improved or maintained”;

22 (iii) by redesignating clauses (iii) and  
23 (iv) as clauses (iv) and (v), respectively;

24 (iv) by inserting after clause (ii), the  
25 following:

1           “(iii) a plan to apply the latest ad-  
2 vances in health information technology in  
3 order to incorporate prescription drug  
4 monitoring program data directly into the  
5 workflow of prescribers and dispensers to  
6 ensure timely access to patients’ controlled  
7 prescription drug history;”;

8           (v) in clause (iv) (as so redesignated),  
9 by inserting before the semicolon the fol-  
10 lowing: “and at least one health informa-  
11 tion technology system such as electronic  
12 health records, health information ex-  
13 changes, and e-prescribing systems”; and

14           (vi) in clause (v) (as so redesignated),  
15 by striking “public health” and inserting  
16 “public health or public safety”;

17 (B) in paragraph (3)—

18           (i) by striking “If a State that sub-  
19 mits” and inserting the following:

20           “(A) IN GENERAL.—If a State that sub-  
21 mits”;

22           (ii) by inserting before the period at  
23 the end “and include timelines for full im-  
24 plementation of such interoperability. The  
25 State shall also describe the manner in

1           which it will achieve interoperability be-  
2           tween its monitoring program and health  
3           information technology systems, as allow-  
4           able under State law, and include timelines  
5           for the implementation of such interoper-  
6           ability”; and

7                     (iii) by adding at the end the fol-  
8           lowing:

9                     “(B) MONITORING OF EFFORTS.—The  
10           Secretary shall monitor State efforts to achieve  
11           interoperability, as described in subparagraph  
12           (A).”;

13                    (C) in paragraph (5)—

14                     (i) by striking “implement or im-  
15           prove” and inserting “establish, improve,  
16           or maintain”; and

17                     (ii) by adding at the end the fol-  
18           lowing: “The Secretary shall redistribute  
19           any funds that are so returned among the  
20           remaining grantees under this section in  
21           accordance with the formula described in  
22           subsection (a)(2)(B).”;

23           (4) in subsection (d)—

24                     (A) in the matter preceding paragraph  
25           (1)—

1 (i) by striking “In implementing or  
2 improving” and all that follows through  
3 “(a)(1)(B)” and inserting “In establishing,  
4 improving, or maintaining a controlled sub-  
5 stance monitoring program under this sec-  
6 tion, a State shall comply, or with respect  
7 to a State that applies for a grant under  
8 subparagraph (B) or (C) of subsection  
9 (a)(1)”;

10 (ii) by striking “public health” and in-  
11 sserting “public health or public safety”;  
12 and

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

14 “(5) The State shall report on interoperability  
15 with the controlled substance monitoring program of  
16 Federal agencies, where appropriate, interoperability  
17 with health information technology systems such as  
18 electronic health records, health information ex-  
19 changes, and e-prescribing, where appropriate, and  
20 whether or not the State provides automatic, real-  
21 time or daily information about a patient when a  
22 practitioner (or the designee of a practitioner, where  
23 permitted) requests information about such pa-  
24 tient.”;

1           (5) in subsection (e), by adding at the end the  
2 following:

3           “(5) The State shall—

4               “(A) ensure that the database—

5                   “(i) is interoperable with the con-  
6 trolled substance monitoring program of  
7 other States and other Federal agencies  
8 and across appropriate State agencies, in-  
9 cluding health agencies, as determined by  
10 the Secretary;

11                   “(ii) is interoperable with electronic  
12 health records and e-prescribing, where ap-  
13 propriate; and

14                   “(iii) provides automatic, real-time or  
15 daily information about a patient when a  
16 practitioner (or the designee of a practi-  
17 tioner, where permitted) requests informa-  
18 tion about such patient;

19               “(B) require practitioners to use State  
20 database information to help determine whether  
21 to prescribe or renew a prescription for a con-  
22 trolled substance; and

23               “(C) require dispensers, or their designees,  
24 where permitted, to enter data required by the  
25 Secretary, including the name of the patient,

1           the date, and prescription dose, into the data-  
2           base for a controlled substance.

3           “(6) Notwithstanding section 543 and any  
4           other provision of law, the data required to be en-  
5           tered under paragraph (5)(C) shall include informa-  
6           tion with respect to methadone that is dispensed to  
7           a patient, if applicable.

8           “(7) The State shall ensure that—

9                   “(A) any person who receives patient infor-  
10                  mation through the database may disclose and  
11                  use such information only to carry out the offi-  
12                  cial duties of that person with regard to the pa-  
13                  tient; and

14                   “(B) notwithstanding subsection (f)(1)(B),  
15                  no information kept in accordance with a data-  
16                  base established, improved, or maintained  
17                  through a grant under this section may be used  
18                  to conduct a criminal investigation or substan-  
19                  tiate any criminal charges against a patient or  
20                  to conduct any investigation of a patient relat-  
21                  ing to methadone use of the patient.”;

22           (6) in subsections (e), (f)(1), and (g), by strik-  
23           ing “implementing or improving” each place it ap-  
24           pears and inserting “establishing, improving, or  
25           maintaining”;

1 (7) in subsection (f)—

2 (A) in paragraph (1)(B) by striking “mis-  
3 use of a schedule II, III, or IV substance” and  
4 inserting “misuse of a controlled substance in-  
5 cluded in schedule II, III, or IV of section  
6 202(c) of the Controlled Substance Act”; and

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

8 “(3) EVALUATION AND REPORTING.—Subject  
9 to subsection (g), a State receiving a grant under  
10 subsection (a) shall provide the Secretary with ag-  
11 gregate data and other information determined by  
12 the Secretary to be necessary to enable the Sec-  
13 retary—

14 “(A) to evaluate the success of the State’s  
15 program in achieving its purposes; or

16 “(B) to prepare and submit the report to  
17 Congress required by subsection (k)(2).

18 “(4) RESEARCH BY OTHER ENTITIES.—A de-  
19 partment, program, or administration receiving non-  
20 identifiable information under paragraph (1)(D)  
21 may make such information available to other enti-  
22 ties for research purposes.”;

23 (8) by striking subsection (k);

24 (9) by redesignating subsections (h) through (j)  
25 as subsections (i) through (k), respectively;

1           (10) in subsections (c)(1)(A)(iv) and (d)(4), by  
2 striking “subsection (h)” each place it appears and  
3 inserting “subsection (i)”;

4           (11) by inserting after subsection (g) the fol-  
5 lowing:

6           “(h) EDUCATION AND ACCESS TO THE MONITORING  
7 SYSTEM.—A State receiving a grant under subsection (a)  
8 shall take steps to—

9           “(1) facilitate prescriber and dispenser use of  
10 the State’s controlled substance monitoring system;  
11 and

12           “(2) educate prescribers and dispenser on the  
13 benefits of the system both to them and society.”;

14           (12) in subsection (k)(2)(A), as redesignated—

15           (A) in clause (ii), by striking “or affected”  
16 and inserting “, established or strengthened ini-  
17 tiatives to ensure linkages to substance use dis-  
18 order services, or affected”; and

19           (B) in clause (iii), by striking “including  
20 an assessment” and inserting “between con-  
21 trolled substance monitoring programs and  
22 health information technology systems, and in-  
23 cluding an assessment”;

1           (13) in subsection (l)(1), by striking “establish-  
2           ment, implementation, or improvement” and insert-  
3           ing “establishment, improvement, or maintenance”;

4           (14) in subsection (m)(8), by striking “and the  
5           District of Columbia” and inserting “, the District  
6           of Columbia, and any commonwealth or territory of  
7           the United States”; and

8           (15) by amending subsection (n), to read as fol-  
9           lows:

10          “(o) AUTHORIZATION OF APPROPRIATIONS.—To  
11 carry out this section, there are authorized to be appro-  
12 priated \$7,000,000 for each of fiscal years 2016 through  
13 2020.”.

14          (b) CONFIDENTIALITY OF RECORDS.—Section 543(a)  
15 of the Public Health Service Act (42 U.S.C. 290dd–2(a))  
16 is amended by inserting “or, with respect to methadone,  
17 as required under section 3990(e)(6)” before the period  
18 at the end.

19          (c) REQUIREMENTS FOR FEDERAL HEALTH CARE  
20 PROGRAMS.—Health care practitioners (as defined in  
21 paragraph (7) of section 3990(m) of the Public Health  
22 Service Act (42 U.S.C. 280g–3(m))) and dispensers (as  
23 defined in paragraph (4) of such section) who participate  
24 in or are employed by a Federal health care program or  
25 federally funded health care program, including the Indian

1 Health Service, the Department of Veterans Affairs, the  
2 Department of Defense, the Federal Bureau of Prisons,  
3 the Medicare program under title XVIII of the Social Se-  
4 curity Act (42 U.S.C. 1395 et seq.), a State Medicaid plan  
5 under title XIX of the Social Security Act (42 U.S.C.  
6 1396 et seq.), the Children’s Health Insurance Program  
7 under title XXI of the Social Security Act (42 U.S.C.  
8 1397aa et seq.), and Federally qualified health centers,  
9 shall use the databases of the controlled substance moni-  
10 toring programs under section 399O of the Public Health  
11 Service Act (42 U.S.C. 280g–3), if such databases are  
12 available to the practitioner or dispenser.

13 **SEC. 103. PILOT PROJECT.**

14 (a) IN GENERAL.—The Secretary of Health and  
15 Human Services (referred to in this section as the “Sec-  
16 retary”) shall award grants to one or more States to carry  
17 out a 1-year pilot project to develop a standardized peer  
18 review process and methodology to review and evaluate  
19 prescribing and pharmacy dispensing patterns, through a  
20 review of prescription drug monitoring programs (referred  
21 to in this section as “PDMP”) in the States receiving such  
22 grants.

23 (b) METHODOLOGY.—The recipients of a grant under  
24 this section shall develop a systematic, standardized meth-  
25 odology to identify and investigate questionable or inap-

1 appropriate prescribing and dispensing patterns of sub-  
2 stances on schedule II or III under section 202 of the Con-  
3 trolled Substances Act (21 U.S.C. 812). Such peer review  
4 methodology and prescribing and dispensing patterns shall  
5 be shared with the appropriate State health profession  
6 board.

7 (c) REQUIREMENTS.—A State receiving a grant  
8 under this section—

9 (1) with respect to controlled substances for  
10 which a prescriber is required to have a license  
11 issued by the Drug Enforcement Administration in  
12 order to prescribe such controlled substances, shall  
13 make the information with respect to such controlled  
14 substances from the PDMP available to State regu-  
15 lation and licensing boards; and

16 (2) with respect to any other controlled sub-  
17 stances, may make the information with respect to  
18 such controlled substances from the PDMP available  
19 to State regulation and licensing boards.

20 (d) SUBGRANTEES.—A quality improvement organi-  
21 zation with which the Secretary has entered into a con-  
22 tract under part B of title XI of the Social Security Act  
23 (42 U.S.C. 1320c et seq.) may serve as the subgrantee  
24 under this subsection to develop peer review processes as  
25 described in subsection (a).

1 **SEC. 104. PRESCRIPTION DRUG AND OTHER CONTROLLED**  
2 **SUBSTANCE ABUSE PREVENTION.**

3 Part P of title III of the Public Health Service Act  
4 (42 U.S.C. 280g et seq.) is amended by adding at the end  
5 the following:

6 **“SEC. 399V-6. PRESCRIPTION DRUG AND OTHER CON-**  
7 **TROLLED SUBSTANCE ABUSE PREVENTION.**

8 “(a) TRAINING GRANTS.—

9 “(1) IN GENERAL.—The Secretary shall award  
10 5-year grants to eligible entities to facilitate training  
11 in order to increase the capacity of health care pro-  
12 viders to conduct patient screening and brief inter-  
13 ventions, such as in health care settings, to prevent  
14 the abuse of prescription drugs and other controlled  
15 substances. The grant program under this section  
16 may be coordinated with the Screening Brief Inter-  
17 vention and Referral to Treatment grant program of  
18 the Substance Abuse and Mental Health Services  
19 Administration, or other appropriate program.

20 “(2) ELIGIBLE ENTITIES.—In this subsection,  
21 the term ‘eligible entity’ includes—

22 “(A) States;

23 “(B) continuing education entities, such as  
24 health profession boards or health accrediting  
25 bodies; and

1                   “(C) other appropriate health or profes-  
2                   sional education organizations or institutions.

3           “(b) FEDERAL HEALTH CARE WORKERS.—Health  
4 care providers who participate in or are employed by a  
5 Federal health care program, including the Indian Health  
6 Service, the Department of Veterans Affairs, the Depart-  
7 ment of Defense, the Federal Bureau of Prisons, the  
8 Medicare program under title XVIII of the Social Security  
9 Act (42 U.S.C. 1395 et seq.), a State Medicaid plan under  
10 title XIX of the Social Security Act (42 U.S.C. 1396 et  
11 seq.), the State Children’s Health Insurance Program  
12 under title XXI of the Social Security Act (42 U.S.C.  
13 1397aa et seq.), and Federally qualified health centers,  
14 shall screen patients for abuse of prescription drugs or  
15 other controlled substances, conduct brief interventions,  
16 and provide referrals for known or suspected abuse of pre-  
17 scription drugs or other controlled substances, as appro-  
18 priate.

19           “(c) EXPANSION OF PRESCRIBING AUTHORITY.—  
20 The Secretary, acting through the Administrator of the  
21 Health Resources and Services Administration, shall  
22 award grants to States for the purpose of evaluating the  
23 prospect of the health professions board of such States  
24 reviewing and expanding prescribing authorities of pro-  
25 viders, such as advance practice nurses and physician as-

1 sistants, in order to control the abuse of prescription  
2 drugs or other controlled substances with respect to spe-  
3 cific drugs and other controlled substances, as appro-  
4 priate.”.

5 **SEC. 105. PRESCRIPTION DRUG ABUSE TRAINING AND**  
6 **SCREENING PROGRAMS.**

7 (a) CONTINUING EDUCATION GRANTS.—The Sec-  
8 retary of Health and Human Services (referred to in this  
9 section as the “Secretary”) shall award grants to States  
10 to develop continuing education criteria and review proc-  
11 esses that allow State health profession boards or State  
12 agencies to certify appropriate education and training for  
13 informed and safe prescribing of opioids and other drugs  
14 on schedule II and III under section 202 of the Controlled  
15 Substances Act (21 U.S.C. 812).

16 (b) REGISTRATION WITH DEA.—A practitioner who  
17 registers or renews a registration under section 303(f) of  
18 the Controlled Substances Act (21 U.S.C. 823(f)) shall,  
19 at the time of registering, certify to the Attorney General  
20 that such practitioner has completed continuing medical  
21 education or nursing continuing education, as applicable—

22 (1) in the case of a practitioner registering for  
23 the first time, with respect to prescription drug  
24 abuse; and

1           (2) in the case of a practitioner renewing a reg-  
2           istration, with respect to medical understanding of  
3           the proper use of all drugs listed in the schedules  
4           under section 202 of the Controlled Substances Act  
5           (21 U.S.C. 812).

6           (c) SCREENING PROGRAM.—The Attorney General  
7           shall require that a practitioner registered under section  
8           303(f) of the Controlled Substances Act (21 U.S.C.  
9           823(f)) conduct patient screening for potential drug mis-  
10          use or abuse before prescribing a drug listed on schedule  
11          II or III under section 202 of the Controlled Substances  
12          Act (21 U.S.C. 812), according to standards established  
13          by the applicable State licensing body.

14          **SEC. 106. FDA REVIEW OF NALOXONE.**

15          The Secretary of Health and Human Services, acting  
16          through the Commissioner of Food and Drugs, shall con-  
17          duct a review of naloxone to consider whether naloxone  
18          should cease to be subject to section 503(b)(1) of the Fed-  
19          eral Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1))  
20          and be available as a behind-the-counter drug, in order  
21          to increase access of such drug to community-based orga-  
22          nizations and street outreach organizations.

23          **SEC. 107. PRESCRIPTION DRUG DISPOSAL.**

24          The Secretary of Health and Human Services shall  
25          convene or coordinate with an existing entity an inter-

1 agency working group to encourage States and local gov-  
 2 ernments to increase opportunities for disposal of opiates,  
 3 such as frequent “take-back programs” and fixed medi-  
 4 cine disposal sites at law enforcement public buildings,  
 5 and to reduce opportunities for abuse of opiates, such as  
 6 establishing opioid dispensing limits at hospital emergency  
 7 departments.

8 **SEC. 108. GAO REPORT.**

9       The Comptroller General of the United States shall  
 10 review prescription drug abuse programs and policies in  
 11 Federal agencies and best practices with respect to pre-  
 12 scription drug abuse programs of the States and, not later  
 13 than 18 months after the date of enactment of this Act,  
 14 shall issue a report to Congress on its findings and rec-  
 15 ommendations on ways to reduce prescription drug abuse.

16                   **TITLE II—TREAT ACT**

17 **SEC. 201. SHORT TITLE.**

18       This title may be cited as the “Recovery Enhance-  
 19 ment for Addiction Treatment Act” or the “TREAT Act”.

20 **SEC. 202. EXPANSION OF PATIENT LIMITS UNDER WAIVER.**

21       Section 303(g)(2)(B) of the Controlled Substances  
 22 Act (21 U.S.C. 823(g)(2)(B)) is amended—

23                   (1) in clause (i), by striking “physician” and in-  
 24 serting “practitioner”;

25                   (2) in clause (iii)—

1 (A) by striking “30” and inserting “100”;

2 and

3 (B) by striking “, unless, not sooner” and

4 all that follows through the end and inserting a

5 period; and

6 (3) by inserting at the end the following new

7 clause:

8 “(iv) Not earlier than 1 year after the date

9 on which a qualifying practitioner obtained an

10 initial waiver pursuant to clause (iii), the quali-

11 fying practitioner may submit a second notifica-

12 tion to the Secretary of the need and intent of

13 the qualifying practitioner to treat an unlimited

14 number of patients, if the qualifying practi-

15 tioner—

16 “(I)(aa) satisfies the requirements of

17 item (aa), (bb), (cc), or (dd) of subpara-

18 graph (G)(ii)(I); and

19 “(bb) agrees to fully participate in the

20 Prescription Drug Monitoring Program of

21 the State in which the qualifying practi-

22 tioner is licensed, pursuant to applicable

23 State guidelines; or

1           “(II)(aa) satisfies the requirements of  
2           item (ee), (ff), or (gg) of subparagraph  
3           (G)(ii)(I);

4           “(bb) agrees to fully participate in the  
5           Prescription Drug Monitoring Program of  
6           the State in which the qualifying practi-  
7           tioner is licensed, pursuant to applicable  
8           State guidelines;

9           “(cc) practices in a qualified practice  
10          setting; and

11          “(dd) has completed not less than 24  
12          hours of training (through classroom situa-  
13          tions, seminars at professional society  
14          meetings, electronic communications, or  
15          otherwise) with respect to the treatment  
16          and management of opiate-dependent pa-  
17          tients for substance use disorders provided  
18          by the American Society of Addiction Med-  
19          icine, the American Academy of Addiction  
20          Psychiatry, the American Medical Associa-  
21          tion, the American Osteopathic Associa-  
22          tion, the American Psychiatric Association,  
23          or any other organization that the Sec-  
24          retary determines is appropriate for pur-  
25          poses of this subclause.”.

1 **SEC. 203. DEFINITIONS.**

2 Section 303(g)(2)(G) of the Controlled Substances  
3 Act (21 U.S.C. 823(g)(2)(G)) is amended—

4 (1) by striking clause (ii) and inserting the fol-  
5 lowing:

6 “(ii) The term ‘qualifying practitioner’  
7 means the following:

8 “(I) A physician who is licensed under  
9 State law and who meets 1 or more of the  
10 following conditions:

11 “(aa) The physician holds a  
12 board certification in addiction psychi-  
13 atry from the American Board of  
14 Medical Specialties.

15 “(bb) The physician holds an ad-  
16 diction certification from the Amer-  
17 ican Society of Addiction Medicine.

18 “(cc) The physician holds a  
19 board certification in addiction medi-  
20 cine from the American Osteopathic  
21 Association.

22 “(dd) The physician holds a  
23 board certification from the American  
24 Board of Addiction Medicine.

25 “(ee) The physician has com-  
26 pleted not less than 8 hours of train-

1           ing (through classroom situations,  
2           seminar at professional society meet-  
3           ings, electronic communications, or  
4           otherwise) with respect to the treat-  
5           ment and management of opiate-de-  
6           pendent patients for substance use  
7           disorders provided by the American  
8           Society of Addiction Medicine, the  
9           American Academy of Addiction Psy-  
10          chiatry, the American Medical Asso-  
11          ciation, the American Osteopathic As-  
12          sociation, the American Psychiatric  
13          Association, or any other organization  
14          that the Secretary determines is ap-  
15          propriate for purposes of this sub-  
16          clause.

17                 “(ff) The physician has partici-  
18                 pated as an investigator in 1 or more  
19                 clinical trials leading to the approval  
20                 of a narcotic drug in schedule III, IV,  
21                 or V for maintenance or detoxification  
22                 treatment, as demonstrated by a  
23                 statement submitted to the Secretary  
24                 by this sponsor of such approved  
25                 drug.

1                   “(gg) The physician has such  
2                   other training or experience as the  
3                   Secretary determines will demonstrate  
4                   the ability of the physician to treat  
5                   and manage opiate-dependent pa-  
6                   tients.

7                   “(II) A nurse practitioner or physi-  
8                   cian assistant who is licensed under State  
9                   law and meets all of the following condi-  
10                  tions:

11                   “(aa) The nurse practitioner or  
12                   physician assistant is licensed under  
13                   State law to prescribe schedule III,  
14                   IV, or V medications for pain.

15                   “(bb) The nurse practitioner or  
16                   physician assistant satisfies 1 or more  
17                   of the following:

18                   “(AA) Has completed not  
19                   fewer than 24 hours of training  
20                   (through classroom situations,  
21                   seminar at professional society  
22                   meetings, electronic communica-  
23                   tions, or otherwise) with respect  
24                   to the treatment and manage-  
25                   ment of opiate-dependent pa-

1           tients for substance use disorders  
2           provided by the American Society  
3           of Addiction Medicine, the Amer-  
4           ican Academy of Addiction Psy-  
5           chiatry, the American Medical  
6           Association, the American Osteo-  
7           pathic Association, the American  
8           Psychiatric Association, or any  
9           other organization that the Sec-  
10          retary determines is appropriate  
11          for purposes of this subclause.

12                   “(BB) Has such other train-  
13                   ing or experience as the Sec-  
14                   retary determines will dem-  
15                   onstrate the ability of the nurse  
16                   practitioner or physician assist-  
17                   ant to treat and manage opiate-  
18                   dependent patients.

19                   “(cc) The nurse practitioner or  
20                   physician assistant practices under  
21                   the supervision of a licensed physician  
22                   who holds an active waiver to pre-  
23                   scribe schedule III, IV, or V narcotic  
24                   medications for opioid addiction ther-  
25                   apy, and—

1                   “(AA) the supervising physi-  
2                   cian satisfies the conditions of  
3                   item (aa), (bb), (cc), or (dd) of  
4                   subclause (I); or

5                   “(BB) both the supervising  
6                   physician and the nurse practi-  
7                   tioner or physician assistant  
8                   practice in a qualified practice  
9                   setting.

10                  “(III) A nurse practitioner who is li-  
11                  censed under State law and meets all of  
12                  the following conditions:

13                   “(aa) The nurse practitioner is li-  
14                   censed under State law to prescribe  
15                   schedule III, IV, or V medications for  
16                   pain.

17                   “(bb) The nurse practitioner has  
18                   training or experience that the Sec-  
19                   retary determines demonstrates spe-  
20                   cialization in the ability to treat opi-  
21                   ate-dependent patients, such as a cer-  
22                   tification in addiction specialty accred-  
23                   ited by the American Board of Nurs-  
24                   ing Specialties or the National Com-  
25                   mission for Certifying Agencies, or a

1 certification in addiction nursing as a  
2 Certified Addiction Registered  
3 Nurse—Advanced Practice.

4 “(cc) In accordance with State  
5 law, the nurse practitioner prescribes  
6 opioid addiction therapy in collabora-  
7 tion with a physician who holds an ac-  
8 tive waiver to prescribe schedule III,  
9 IV, or V narcotic medications for  
10 opioid addiction therapy.

11 “(dd) The nurse practitioner  
12 practices in a qualified practice set-  
13 ting.”; and

14 (2) by adding at the end the following:

15 “(iii) The term ‘qualified practice setting’  
16 means 1 or more of the following treatment set-  
17 tings:

18 “(I) A National Committee for Qual-  
19 ity Assurance-recognized Patient-Centered  
20 Medical Home or Patient-Centered Spe-  
21 cialty Practice.

22 “(II) A Centers for Medicaid & Medi-  
23 care Services-recognized Accountable Care  
24 Organization.

1           “(III) A clinical facility administered  
2 by the Department of Veterans Affairs,  
3 Department of Defense, or Indian Health  
4 Service.

5           “(IV) A Behavioral Health Home ac-  
6 credited by the Joint Commission.

7           “(V) A Federally-qualified health cen-  
8 ter (as defined in section 1905(l)(2)(B) of  
9 the Social Security Act (42 U.S.C.  
10 1396d(l)(2)(B))) or a Federally-qualified  
11 health center look-alike.

12           “(VI) A Substance Abuse and Mental  
13 Health Services-certified Opioid Treatment  
14 Program.

15           “(VII) A clinical program of a State  
16 or Federal jail, prison, or other facility  
17 where individuals are incarcerated.

18           “(VIII) A clinic that demonstrates  
19 compliance with the Model Policy on  
20 DATA 2000 and Treatment of Opioid Ad-  
21 diction in the Medical Office issued by the  
22 Federation of State Medical Boards.

23           “(IX) A treatment setting that is part  
24 of an Accreditation Council for Graduate  
25 Medical Education, American Association

1 of Colleges of Osteopathic Medicine, or  
2 American Osteopathic Association-accred-  
3 ited residency or fellowship training pro-  
4 gram.

5 “(X) Any other practice setting ap-  
6 proved by a State regulatory board or  
7 State Medicaid Plan to provide addiction  
8 treatment services.

9 “(XI) Any other practice setting ap-  
10 proved by the Secretary.”.

11 **SEC. 204. GAO EVALUATION.**

12 Two years after the date on which the first notifica-  
13 tion under clause (iv) of section 303(g)(2)(B) of the Con-  
14 trolled Substances Act (21 U.S.C. 823(g)(2)(B)), as added  
15 by this title, is received by the Secretary of Health and  
16 Human Services, the Comptroller General of the United  
17 States shall initiate an evaluation of the effectiveness of  
18 the amendments made by this title, which shall include  
19 an evaluation of—

20 (1) any changes in the availability and use of  
21 medication-assisted treatment for opioid addiction;

22 (2) the quality of medication-assisted treatment  
23 programs;

24 (3) the integration of medication-assisted treat-  
25 ment with routine healthcare services;

1           (4) diversion of opioid addiction treatment  
2 medication;

3           (5) changes in State or local policies and legis-  
4 lation relating to opioid addiction treatment;

5           (6) the use of nurse practitioners and physician  
6 assistants who prescribe opioid addiction medication;

7           (7) the use of Prescription Drug Monitoring  
8 Programs by waived practitioners to maximize safety  
9 of patient care and prevent diversion of opioid addic-  
10 tion medication;

11           (8) the findings of Drug Enforcement Agency  
12 inspections of waived practitioners, including the fre-  
13 quency with which the Drug Enforcement Agency  
14 finds no documentation of access to behavioral  
15 health services; and

16           (9) the effectiveness of cross-agency collabora-  
17 tion between Department of Health and Human  
18 Services and the Drug Enforcement Agency for ex-  
19 panding effective opioid addiction treatment.

○