

Calendar No. 441

114TH CONGRESS
2D SESSION**S. 1455**

To provide access to medication-assisted therapy, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 22, 2015

Mr. MARKEY (for himself, Mr. PAUL, Mrs. FEINSTEIN, Mr. DURBIN, Ms. HIRONO, Mr. BROWN, Ms. BALDWIN, Mr. FRANKEN, Mr. CASEY, Mrs. SHAHEEN, Mr. KING, Mr. LEAHY, Mr. SANDERS, Ms. COLLINS, Mr. MERKLEY, Mr. REED, Mr. MURPHY, Mr. MENENDEZ, Mr. HATCH, and Mrs. GILLIBRAND) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 27, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]**A BILL**

To provide access to medication-assisted therapy, and for
other purposes.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Recovery Enhancement
5 for Addiction Treatment Act” or the “TREAT Act”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Overdoses from opioids have increased dra-
4 matically in the United States.

5 (2) Deaths from drug overdose, largely from
6 prescription pain relievers, have tripled among men
7 and increased five-fold among women over the past
8 decade.

9 (3) Nationwide, drug overdoses now claim more
10 lives than car accidents.

11 (4) Opioid addiction is a chronic disease that,
12 untreated, places a large burden on the healthcare
13 system. Roughly 475,000 emergency room visits
14 each year are attributable to the misuse and abuse
15 of opioid pain medication.

16 (5) Effective medication-assisted treatment for
17 opioid addiction, in combination with counseling and
18 behavioral therapies, can decrease overdose deaths,
19 be cost-effective, reduce transmissions of HIV and
20 viral hepatitis, and reduce other social harms such
21 as criminal activity.

22 (6) Effective medication-assisted treatment pro-
23 grams for opioid addiction should include multiple
24 components, including medications, cognitive and be-
25 havioral supports and interventions, and drug test-
26 ing.

1 (7) Effective medication-assisted treatment pro-
 2 grams for opioid addiction may use a team of staff
 3 members, in addition to a prescribing provider, to
 4 deliver comprehensive care.

5 (8) Access to medication-assisted treatments,
 6 including office-based buprenorphine opioid treat-
 7 ment, remains limited in part due to current prac-
 8 tice regulations and an insufficient number of pro-
 9 viders.

10 (9) More than 10 years of experience in the
 11 United States with office-based buprenorphine opioid
 12 treatment has informed best practices for delivering
 13 successful, high quality care.

14 **SEC. 3. EXPANSION OF PATIENT LIMITS UNDER WAIVER.**

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

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

19 (2) in clause (iii)—

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

22 (B) by striking “, unless, not sooner” and
 23 all that follows through the end and inserting a
 24 period; and

1 (2) by inserting at the end the following new
2 clause:

3 “(iv) Not earlier than 1 year after the date
4 on which a qualifying practitioner obtained an
5 initial waiver pursuant to clause (iii), the quali-
6 fying practitioner may submit a second notifica-
7 tion to the Secretary of the need and intent of
8 the qualifying practitioner to treat an unlimited
9 number of patients, if the qualifying practi-
10 tioner—

11 “(I)(aa) satisfies the requirements of
12 item (aa), (bb), (cc), or (dd) of subpara-
13 graph (G)(ii)(I); and

14 “(bb) agrees to fully participate in the
15 Prescription Drug Monitoring Program of
16 the State in which the qualifying practi-
17 tioner is licensed, pursuant to applicable
18 State guidelines; or

19 “(H)(aa) satisfies the requirements of
20 item (ee), (ff), or (gg) of subparagraph
21 (G)(ii)(I);

22 “(bb) agrees to fully participate in the
23 Prescription Drug Monitoring Program of
24 the State in which the qualifying practi-

tioner is licensed, pursuant to applicable
State guidelines;

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

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

SEC. 4. DEFINITIONS.

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

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

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

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

“(aa) The physician holds a board certification in addiction psychiatry from the American Board of Medical Specialties.

“(bb) The physician holds an addiction certification from the American Society of Addiction Medicine.

“(cc) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

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

“(ee) The physician has completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) with respect to the treat-

1 ment and management of opiate-de-
2 pendent patients for substance use
3 disorders provided by the American
4 Society of Addiction Medicine, the
5 American Academy of Addiction Psy-
6 chiatry, the American Medical Asso-
7 ciation, the American Osteopathic As-
8 sociation, the American Psychiatric
9 Association, or any other organization
10 that the Secretary determines is ap-
11 propriate for purposes of this sub-
12 clause.

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

22 “(gg) The physician has such
23 other training or experience as the
24 Secretary determines will demonstrate
25 the ability of the physician to treat

1 and manage opiate-dependent pa-
2 tients.

3 “(H) A nurse practitioner or physi-
4 cian assistant who is licensed under State
5 law and meets all of the following condi-
6 tions:

7 “(aa) The nurse practitioner or
8 physician assistant is licensed under
9 State law to prescribe schedule III,
10 IV, or V medications for pain.

11 “(bb) The nurse practitioner or
12 physician assistant satisfies 1 or more
13 of the following:

14 “(AA) Has completed not
15 fewer than 24 hours of training
16 (through classroom situations,
17 seminars at professional society
18 meetings, electronic communica-
19 tions, or otherwise) with respect
20 to the treatment and manage-
21 ment of opiate-dependent pa-
22 tients for substance use disorders
23 provided by the American Society
24 of Addiction Medicine, the Amer-
25 ican Academy of Addiction Psy-

1 chiatry, the American Medical
 2 Association, the American Osteo-
 3 pathic Association, the American
 4 Psychiatric Association, or any
 5 other organization that the Sec-
 6 retary determines is appropriate
 7 for purposes of this subclause.

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

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

22 “(AA) the supervising physi-
 23 cian satisfies the conditions of
 24 item (aa), (bb), (cc), or (dd) of
 25 subclause (I); or

1 “(BB) both the supervising
2 physician and the nurse practi-
3 tioner or physician assistant
4 practice in a qualified practice
5 setting.

6 “(HH) A nurse practitioner who is li-
7 censed under State law and meets all of
8 the following conditions:

9 “(aa) The nurse practitioner is li-
10 censed under State law to prescribe
11 schedule III, IV, or V medications for
12 pain.

13 “(bb) The nurse practitioner has
14 training or experience that the Sec-
15 retary determines demonstrates spe-
16 cialization in the ability to treat opi-
17 ate-dependent patients, such as a cer-
18 tification in addiction specialty accred-
19 ited by the American Board of Nurs-
20 ing Specialties or the National Com-
21 mission for Certifying Agencies, or a
22 certification in addiction nursing as a
23 Certified Addiction Registered
24 Nurse—Advanced Practice.

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

8 “(dd) The nurse practitioner
 9 practices in a qualified practice set-
 10 ting.”; and

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

12 “(iii) The term ‘qualified practice setting’
 13 means 1 or more of the following treatment set-
 14 tings:

15 “(I) A National Committee for Qual-
 16 ity Assurance-recognized Patient-Centered
 17 Medical Home or Patient-Centered Spe-
 18 cialty Practice.

19 “(II) A Centers for Medicaid & Medi-
 20 care Services-recognized Accountable Care
 21 Organization.

22 “(III) A clinical facility administered
 23 by the Department of Veterans Affairs,
 24 Department of Defense, or Indian Health
 25 Service.

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

3 ~~“(V) A Federally-qualified health cen-~~
4 ~~ter (as defined in section 1905(l)(2)(B) of~~
5 ~~the Social Security Act (42 U.S.C.~~
6 ~~1396d(l)(2)(B))) or a Federally-qualified~~
7 ~~health center look-alike.~~

8 “(VI) A Substance Abuse and Mental
9 Health Services-certified Opioid Treatment
10 Program.

11 “(VII) A clinical program of a State
12 or Federal jail, prison, or other facility
13 where individuals are incarcerated.

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

19 “(IX) A treatment setting that is part
20 of an Accreditation Council for Graduate
21 Medical Education, American Association
22 of Colleges of Osteopathic Medicine, or
23 American Osteopathic Association-accred-
24 ited residency or fellowship training pro-
25 gram.

1 “(X) Any other practice setting ap-
 2 proved by a State regulatory board or
 3 State Medicaid Plan to provide addiction
 4 treatment services.

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

7 **SEC. 5. GAO EVALUATION.**

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

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

18 (2) the quality of medication-assisted treatment
 19 programs;

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

22 (4) diversion of opioid addiction treatment
 23 medication;

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

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

3 (7) the use of Prescription Drug Monitoring
4 Programs by waived practitioners to maximize safety
5 of patient care and prevent diversion of opioid addic-
6 tion medication;

7 (8) the findings of Drug Enforcement Adminis-
8 tration inspections of waived practitioners, including
9 the frequency with which the Drug Enforcement Ad-
10 ministration finds no documentation of access to be-
11 havioral health services; and

12 (9) the effectiveness of cross-agency collabora-
13 tion between Department of Health and Human
14 Services and the Drug Enforcement Administration
15 for expanding effective opioid addiction treatment.

16 **SECTION 1. SHORT TITLE.**

17 *This Act may be cited as the “Recovery Enhancement*
18 *for Addiction Treatment Act” or the “TREAT Act”.*

19 **SEC. 2. EXPANSION OF PATIENT LIMITS UNDER WAIVER.**

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

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

24 (2) in clause (iii)—

1 (A) by striking “The total number” and in-
2 serting “(I) The total number”;

3 (B) by striking “30” and inserting “100”;

4 (C) by striking “, unless, not sooner” and
5 all that follows through “of this subparagraph”;
6 and

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

8 “(II) If a patient is referred by a qualifying
9 practitioner that is a physician to another quali-
10 fying practitioner that is a physician that pro-
11 vides short-term services (such as induction or ti-
12 tration), the patient shall only be included in the
13 total number of such patients of the qualifying
14 physician that makes the referral.

15 “(III) In this clause, the term ‘the total
16 number of such patients’ shall not include a pa-
17 tient to whom a qualifying practitioner that is
18 a physician meeting the requirements described
19 in clause (iv)(I), or an authorized agent of such
20 qualifying practitioner that is a physician, di-
21 rectly administers such drugs or combination
22 drugs.”; and

23 (4) by adding at the end the following:

24 “(iv) Not earlier than 1 year after the date on
25 which a qualifying practitioner that is a physician

1 *obtained an initial waiver pursuant to clause (iii),*
 2 *such qualifying practitioner may submit a second no-*
 3 *tification to the Secretary of the need and intent of*
 4 *such qualifying practitioner to treat up to 500 pa-*
 5 *tients, if such qualifying practitioner—*

6 *“(I)(aa) satisfies the requirements of item (aa),*
 7 *(bb), (cc), or (dd) of subparagraph (G)(ii)(I); and*

8 *“(bb) agrees to fully participate in the Prescrip-*
 9 *tion Drug Monitoring Program of the State in which*
 10 *the qualifying practitioner is licensed, pursuant to*
 11 *applicable State guidelines; or*

12 *“(II)(aa) satisfies the requirements of item (ee),*
 13 *(ff), or (gg) of subparagraph (G)(ii)(I);*

14 *“(bb) agrees to fully participate in the Prescrip-*
 15 *tion Drug Monitoring Program of the State in which*
 16 *the qualifying practitioner is licensed, pursuant to*
 17 *applicable State guidelines; and*

18 *“(cc) has completed not less than 24 hours of*
 19 *training (through classroom situations, seminars at*
 20 *professional society meetings, electronic communica-*
 21 *tions, or otherwise) with respect to the treatment and*
 22 *management of opiate-dependent patients for sub-*
 23 *stance use disorders provided by the American Society*
 24 *of Addiction Medicine, the American Academy of Ad-*
 25 *diction Psychiatry, the American Medical Associa-*

tion, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

“(v) The qualifying practitioner shall maintain records relating to the dispensing of drugs or combinations of drugs to treat patients under this paragraph, including—

“(I) whether the qualifying practitioner provides counseling services on-site, and how frequently patients are using such services;

“(II) whether the qualifying practitioner referred patients for counseling services off-site, the percentage of the patients of the qualifying practitioner using such services, and how frequently the patients are using such services; and

“(III) the frequency with which patients being treated under this paragraph terminate the treatment against medical advice.”.

SEC. 3. DEFINITIONS.

Section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)) is amended by striking clause (ii) and inserting the following:

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

1 “(I) *A physician who is licensed under*
2 *State law and who meets 1 or more of the*
3 *following conditions:*

4 “(aa) *The physician holds a board*
5 *certification in addiction psychiatry or*
6 *addiction medicine from the American*
7 *Board of Medical Specialties.*

8 “(bb) *The physician holds an ad-*
9 *diction certification from the American*
10 *Society of Addiction Medicine or the*
11 *American Board of Addiction Medi-*
12 *cine.*

13 “(cc) *The physician holds a board*
14 *certification in addiction medicine*
15 *from the American Osteopathic Asso-*
16 *ciation.*

17 “(dd) *The physician holds a board*
18 *certification from the American Board*
19 *of Addiction Medicine.*

20 “(ee) *The physician has completed*
21 *not less than 8 hours of training*
22 *(through classroom situations, semi-*
23 *nars at professional society meetings,*
24 *electronic communications, or other-*
25 *wise) with respect to the treatment and*

1 *management of opiate-dependent pa-*
2 *tients for substance use disorders pro-*
3 *vided by the American Society of Ad-*
4 *diction Medicine, the American Acad-*
5 *emy of Addiction Psychiatry, the*
6 *American Medical Association, the*
7 *American Osteopathic Association, the*
8 *American Psychiatric Association, or*
9 *any other organization that the Sec-*
10 *retary determines is appropriate for*
11 *purposes of this subclause, after notice*
12 *and the opportunity for comment.*

13 “(ff) *The physician has partici-*
14 *pated as an investigator in 1 or more*
15 *clinical trials leading to the approval*
16 *of a narcotic drug in schedule III, IV,*
17 *or V for maintenance or detoxification*
18 *treatment, as demonstrated by a state-*
19 *ment submitted to the Secretary by*
20 *this sponsor of such approved drug.*

21 “(gg) *The physician has such*
22 *other training or experience as the Sec-*
23 *retary determines will demonstrate the*
24 *ability of the physician to treat and*
25 *manage opiate dependent patients.*

1 “(II) *A nurse practitioner or physician*
2 *assistant who is licensed under State law*
3 *and meets all of the following conditions:*

4 “(aa) *The nurse practitioner or*
5 *physician assistant is licensed under*
6 *State law to prescribe schedule III, IV,*
7 *or V medications.*

8 “(bb) *The nurse practitioner or*
9 *physician assistant has completed not*
10 *fewer than 24 hours of training*
11 *(through classroom situations, semi-*
12 *nars at professional society meetings,*
13 *electronic communications, or other-*
14 *wise) with respect to the treatment and*
15 *management of opiate-dependent pa-*
16 *tients for substance use disorders pro-*
17 *vided by the American Society of Ad-*
18 *diction Medicine, the American Acad-*
19 *emy of Addiction Psychiatry, the*
20 *American Medical Association, the*
21 *American Osteopathic Association, the*
22 *American Psychiatric Association, the*
23 *American Association of Nurse Practi-*
24 *tioners, the American Academy of Phy-*
25 *sician Assistants, or any other organi-*

1 *zation that the Secretary determines is*
 2 *appropriate for purposes of this sub-*
 3 *clause, after notice and opportunity for*
 4 *comment.*

5 *“(cc) If required by State law, the*
 6 *nurse practitioner or physician assist-*
 7 *ant prescribes opioid addiction therapy*
 8 *in collaboration with or under the su-*
 9 *per vision of, as applicable, a physi-*
 10 *cian.”.*

11 **SEC. 4. STATE FLEXIBILITY.**

12 *Section 303(g)(2) of the Controlled Substances Act (21*
 13 *U.S.C. 823(g)(2)) is amended by striking subparagraphs (I)*
 14 *and (J), and inserting the following:*

15 *“(I) Notwithstanding section 708, nothing in*
 16 *this paragraph shall be construed to preempt any*
 17 *State law that—*

18 *“(i) permits a qualifying practitioner to*
 19 *dispense narcotic drugs in schedule III, IV, or V,*
 20 *or combinations of such drugs, for maintenance*
 21 *or detoxification treatment in accordance with*
 22 *this paragraph to a total number of patients*
 23 *that is more than 30 or less than the total num-*
 24 *ber applicable to the qualifying practitioner*
 25 *under clause (iv) of subparagraph (B) if a State*

1 enacts a law modifying such total number and
 2 the Attorney General is notified by the State of
 3 such modification; or

4 “(ii) requires a qualifying practitioner to
 5 comply with additional requirements relating to
 6 the dispensing of narcotic drugs in schedule III,
 7 IV, or V, or combinations of such drugs, includ-
 8 ing requirements relating to the practice setting
 9 in which the qualifying practitioner practices
 10 and education, training, and reporting require-
 11 ments.”.

12 **SEC. 5. UPDATE REGULATIONS.**

13 Not later than 1 year after the date of enactment of
 14 this Act, the Attorney General shall update regulations re-
 15 garding waived practitioners (as amended by this Act) to
 16 include nurse practitioners and physician assistants to en-
 17 sure the quality of patient care and prevent diversion.

18 **SEC. 6. EVALUATIONS.**

19 (a) *DEFINITION.*—In this section, the term “appro-
 20 priate committees of Congress” means—

21 (1) the Committee on Health, Education, Labor,
 22 and Pensions and the Committee on the Judiciary of
 23 the Senate; and

1 (2) *the Committee on Energy and Commerce and*
2 *the Committee on the Judiciary of the House of Rep-*
3 *resentatives.*

4 (b) *HHS.—Not later than 2 years after the date of*
5 *enactment of this Act, the Secretary of Health and Human*
6 *Services, in coordination with the Attorney General, shall*
7 *submit to the appropriate committees of Congress a report*
8 *on the effect on the amendments made by this title on the*
9 *availability of evidence-based treatment and any increased*
10 *risk in diversion, including the impact of nurse practi-*
11 *tioners and physician assistants as qualifying practi-*
12 *tioners.*

13 (c) *GAO.—*

14 (1) *IN GENERAL.—Four years after the date on*
15 *which the first notification under clause (iv) of sec-*
16 *tion 303(g)(2)(B) of the Controlled Substances Act (21*
17 *U.S.C. 823(g)(2)(B)), as added by this Act, is received*
18 *by the Secretary of Health and Human Services, the*
19 *Comptroller General of the United States shall ini-*
20 *tiate an evaluation of the effectiveness of the amend-*
21 *ments made by this Act, which shall include an eval-*
22 *uation of—*

23 (A) *any changes in the availability and use*
24 *of medication-assisted treatment for opioid ad-*
25 *diction;*

1 (B) the quality of medication-assisted treat-
2 ment programs;

3 (C) the integration of medication-assisted
4 treatment with routine healthcare services;

5 (D) diversion of opioid addiction treatment
6 medication;

7 (E) changes in State or local policies and
8 legislation relating to opioid addiction treat-
9 ment;

10 (F) the use of nurse practitioners and phy-
11 sician assistants who prescribe opioid addiction
12 medication;

13 (G) the use of Prescription Drug Moni-
14 toring Programs by waived practitioners to
15 maximize safety of patient care and prevent di-
16 version of opioid addiction medication;

17 (H) the findings of Drug Enforcement
18 Agency inspections of waived practitioners, in-
19 cluding the frequency with which the Drug En-
20 forcement Agency finds no documentation of ac-
21 cess to behavioral health services; and

22 (I) the effectiveness of cross-agency collabo-
23 ration between Department of Health and
24 Human Services and the Drug Enforcement

1 *Agency for expanding effective opioid addiction*
2 *treatment.*

3 (2) *REPORT.—The Comptroller General shall*
4 *submit to the appropriate committees of Congress a*
5 *report regarding the evaluation conducted under*
6 *paragraph (1).*

Calendar No. 441

114TH CONGRESS
2^D Session

S. 1455

A BILL

To provide access to medication-assisted therapy,
and for other purposes.

APRIL 27, 2016

Reported with an amendment