113TH CONGRESS 2D Session

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

IN THE SENATE OF THE UNITED STATES

Mr. MARKEY (for himself, Mrs. FEINSTEIN, Mr. ROCKEFELLER, Mr. BROWN, and Ms. HIRONO) introduced the following bill; which was read twice and referred to the Committee on ______

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".

6 SEC. 2. FINDINGS.

7 Congress finds the following:

8 (1) Overdoses from opioids have increased dra-

9 matically in the United States.

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

5 (3) Nationwide, drug overdoses now claim more6 lives than car accidents.

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

12 (5) Effective medication-assisted treatment for
13 opioid addiction can decrease overdose deaths, be
14 cost-effective, reduce transmissions of HIV and viral
15 hepatitis, and reduce other social harms such as
16 criminal activity.

17 (6) Effective medication-assisted treatment pro18 grams for opioid addiction should include multiple
19 components, including medications, cognitive and be20 havioral supports and interventions, and drug test21 ing.

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

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(8) Access to medication-assisted treatments,
including office-based buprenorphine opioid treat-
ment, remains limited in part due to current prac-
tice regulations and an insufficient number of pro-
viders.
(9) More than 10 years of experience in the
United States with office-based buprenorphine opioid
treatment has informed best practices for delivering
successful, high quality care.
SEC. 3. EXPANSION OF PATIENT LIMITS UNDER WAIVER.
Section $303(g)(2)(B)$ of the Controlled Substances
Act (21 U.S.C. 823(g)(2)(B)) is amended—
(1) in clause (i), by striking "physician" and in-
serting "practitioner";
(2) in clause (iii)—
(A) by striking "30" and inserting "100";
and
(B) by striking ", unless, not sooner" and
all that follows through the end and inserting a
period; and
(3) by inserting at the end the following new
clause:
"(iv) Not earlier than 1 year after the date
on which a qualifying practitioner obtained an
initial waiver pursuant to clause (iii), the quali-

1	fying practitioner may submit a second notifica-
2	tion to the Secretary of the need and intent of
3	the qualifying practitioner to treat an unlimited
4	number of patients, if the qualifying practi-
5	tioner-
6	"(I)(aa) satisfies the requirements of
7	item (aa), (bb), (cc), or (dd) of subpara-
8	graph $(G)(ii)(I)$; and
9	"(bb) agrees to fully participate in the
10	Prescription Drug Monitoring Program of
11	the State in which the qualifying practi-
12	tioner is licensed, pursuant to applicable
13	State guidelines; or
14	"(II)(aa) satisfies the requirements of
15	item (ee), (ff), or (gg) of subparagraph
16	(G)(ii)(I);
17	"(bb) agrees to fully participate in the
18	Prescription Drug Monitoring Program of
19	the State in which the qualifying practi-
20	tioner is licensed, pursuant to applicable
21	State guidelines;
22	"(cc) practices in a qualified practice
23	setting; and
24	"(dd) has completed not less than 24
25	hours of training (through classroom situa-

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1	tions, seminars at professional society
2	meetings, electronic communications, or
3	otherwise) with respect to the treatment
4	and management of opiate-dependent pa-
5	tients for substance use disorders provided
6	by the American Society of Addiction Med-
7	icine, the American Academy of Addiction
8	Psychiatry, the American Medical Associa-
9	tion, the American Osteopathic Associa-
10	tion, the American Psychiatric Association,
11	or any other organization that the Sec-
12	retary determines is appropriate for pur-
10	
13	poses of this subclause.".
13 14	poses of this subclause.". SEC. 4. DEFINITIONS.
14 15	SEC. 4. DEFINITIONS.
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 14 15 16 17 18 19 20 21 22 	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 following: "(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

1	atry from the American Board of
2	Medical Specialties.
3	"(bb) The physician holds an ad-
4	diction certification from the Amer-
5	ican Society of Addiction Medicine.
6	"(cc) The physician holds a
7	board certification in addiction medi-
8	cine from the American Osteopathic
9	Association.
10	"(dd) The physician holds a
11	board certification from the American
12	Board of Addiction Medicine.
13	"(ee) The physician has com-
14	pleted not less than 8 hours of train-
15	ing (through classroom situations,
16	seminar at professional society meet-
17	ings, electronic communications, or
18	otherwise) with respect to the treat-
19	ment and management of opiate-de-
20	pendent patients for substance use
21	disorders provided by the American
22	Society of Addiction Medicine, the
23	American Academy of Addiction Psy-
24	chiatry, the American Medical Asso-
25	ciation, the American Osteopathic As-

1	sociation, the American Psychiatric
2	Association, or any other organization
3	that the Secretary determines is ap-
4	propriate for purposes of this sub-
5	clause.
6	"(ff) The physician has partici-
7	pated as an investigator in 1 or more
8	clinical trials leading to the approval
9	of a narcotic drug in schedule III, IV,
10	or V for maintenance or detoxification
11	treatment, as demonstrated by a
12	statement submitted to the Secretary
13	by this sponsor of such approved
14	drug.
15	"(gg) The physician has such
16	other training or experience as the
17	Secretary determines will demonstrate
18	the ability of the physician to treat
19	and manage opiate-dependent pa-
20	tients.
21	"(II) A nurse practitioner or physi-
22	cian assistant who is licensed under State
23	law and meets all of the following condi-
24	tions:

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1	"(aa) The nurse practitioner or
2	physician assistant is licensed under
3	State law to prescribe schedule III,
4	IV, or V medications for pain.
5	"(bb) The nurse practitioner or
6	physician assistant satisfies 1 or more
7	of the following:
8	"(AA) Has completed not
9	fewer than 24 hours of training
10	(through classroom situations,
11	seminar at professional society
12	meetings, electronic communica-
13	tions, or otherwise) with respect
14	to the treatment and manage-
15	ment of opiate-dependent pa-
16	tients for substance use disorders
17	provided by the American Society
18	of Addiction Medicine, the Amer-
19	ican Academy of Addiction Psy-
20	chiatry, the American Medical
21	Association, the American Osteo-
22	pathic Association, the American
23	Psychiatric Association, or any
24	other organization that the Sec-

1	retary determines is appropriate
2	for purposes of this subclause.
3	"(BB) Has such other train-
4	ing or experience as the Sec-
5	retary determines will dem-
6	onstrate the ability of the nurse
7	practitioner or physician assist-
8	ant to treat and manage opiate-
9	dependent patients.
10	"(cc) The nurse practitioner or
11	physician assistant practices under
12	the supervision of a licensed physician
13	who holds an active waiver to pre-
14	scribe schedule III, IV, or V narcotic
15	medications for opioid addiction ther-
16	apy, and—
17	"(AA) the supervising physi-
18	cian satisfies the conditions of
19	item (aa), (bb), (cc), or (dd) of
20	subclause (I); or
21	"(BB) both the supervising
22	physician and the nurse practi-
23	tioner or physician assistant
24	practice in a qualified practice
25	setting.

	10
1	"(III) A nurse practitioner who is li-
2	censed under State law and meets all of
3	the following conditions:
4	"(aa) The nurse practitioner is li-
5	censed under State law to prescribe
6	schedule III, IV, or V medications for
7	pain.
8	"(bb) The nurse practitioner has
9	training or experience that the Sec-
10	retary determines demonstrates spe-
11	cialization in the ability to treat opi-
12	ate-dependent patients, such as a cer-
13	tification in addiction specialty accred-
14	ited by the American Board of Nurs-
15	ing Specialties or the National Com-
16	mission for Certifying Agencies, or a
17	certification in addiction nursing as a
18	Certified Addiction Registered Nurse -
19	Advanced Practice.
20	"(cc) In accordance with State
21	law, the nurse practitioner prescribes
22	opioid addiction therapy in collabora-
23	tion with a physician who holds an ac-
24	tive waiver to prescribe schedule III,

 IV, or V narcotic medications for opioid addiction therapy. "(dd) The nurse practitioner practices in a qualified practice setting."; and (2) by adding at the end the following: "(iii) The term 'qualified practice setting' means 1 or more of the following treatment settings: "(I) A National Committee for Quality Assurance-recognized Patient-Centered Medical Home or Patient-Centered Specialty Practice.
 "(dd) The nurse practitioner practices in a qualified practice setting."; and (2) by adding at the end the following: "(iii) The term 'qualified practice setting' means 1 or more of the following treatment settings: "(I) A National Committee for Quality Assurance-recognized Patient-Centered Medical Home or Patient-Centered Spe-
practices in a qualified practice set- ting."; and (2) by adding at the end the following: "(iii) The term 'qualified practice setting' means 1 or more of the following treatment set- tings: "(I) A National Committee for Qual- ity Assurance-recognized Patient-Centered Medical Home or Patient-Centered Spe-
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Medical Home or Patient-Centered Spe-
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cialty Practice.
"(II) A Centers for Medicaid & Medi-
care Services-recognized Accountable Care
Organization.
"(III) A clinical facility administered
by the Department of Veterans Affairs,
Department of Defense, or Indian Health
Service.
"(IV) A Behavioral Health Home ac-
credited by the Joint Commission.
"(V) A Federally-qualified health cen-
ter (as defined in section $1905(l)(2)(B)$ of

1396d(l)(2)(B))) or a Federally-qualified
health center look-alike.
"(VI) A Substance Abuse and Mental
Health Services-certified Opioid Treatment
Program.
"(VII) A clinical program of a State
or Federal jail, prison, or other facility
where individuals are incarcerated.
"(VIII) A clinic that demonstrates
compliance with the Model Policy on
DATA 2000 and Treatment of Opioid Ad-
diction in the Medical Office issued by the
Federation of State Medical Boards.
"(IX) A treatment setting that is part
of an Accreditation Council for Graduate
Medical Education, American Association
of Colleges of Osteopathic Medicine, or
American Osteopathic Association-accred-
ited residency or fellowship training pro-
gram.
"(X) Any other practice setting ap-
proved by a State regulatory board or
State Medicaid Plan to provide addiction

"(XI) Any other practice setting ap proved by the Secretary.".

3 SEC. 5. GAO EVALUATION.

4 Two years after the date on which the first notifica-5 tion under clause (iv) of section 303(g)(2)(B) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(B)), as added 6 7 by this Act, is received by the Secretary of Health and 8 Human Services, the Comptroller General of the United 9 States shall initiate an evaluation of the effectiveness of 10 the amendments made by this Act, which shall include an 11 evaluation of-

12 (1) any changes in the availability and use of13 medication-assisted treatment for opioid addiction;

14 (2) the quality of medication-assisted treatment15 programs;

16 (3) the integration of medication-assisted treat-17 ment with routine healthcare services;

18 (4) diversion of opioid addiction treatment19 medication;

20 (5) changes in State or local policies and legis21 lation relating to opioid addiction treatment;

(6) the use of nurse practitioners and physician
assistants who prescribe opioid addiction medication;
(7) the use of Prescription Drug Monitoring
Programs by waived practitioners to maximize safety

1	of patient care and prevent diversion of opioid addic-
2	tion medication;
3	(8) the findings of Drug Enforcement Agency
4	inspections of waived practitioners, including the fre-
5	quency with which the Drug Enforcement Agency
6	finds no documentation of access to behavioral
7	health services; and
8	(9) the effectiveness of cross-agency collabora-
9	tion between Department of Health and Human
10	Services and the Drug Enforcement Agency for ex-
11	panding effective opioid addiction treatment.