113TH CONGRESS
2D SESSION

S. _____

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Recovery Enhancement for Addiction Treatment Act'' or the ''TREAT Act''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Overdoses from opioids have increased dramatically in the United States.

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

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

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

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

(6) Effective medication-assisted treatment programs for opioid addiction should include multiple components, including medications, cognitive and behavioral supports and interventions, and drug testing.

(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.

(8) Access to medication-assisted treatments, including office-based buprenorphine opioid treatment, remains limited in part due to current practice regulations and an insufficient number of providers.

(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 inserting ''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-

fying practitioner may submit a second notification to the Secretary of the need and intent of the qualifying practitioner to treat an unlimited number of patients, if the qualifying practitioner—

"(I)(aa) satisfies the requirements of item (aa), (bb), (cc), or (dd) of subparagraph (G)(ii)(I); and

"(bb) agrees to fully participate in the Prescription Drug Monitoring Program of the State in which the qualifying practitioner is licensed, pursuant to applicable State guidelines; or

"(II)(aa) satisfies the requirements of item (ee), (ff), or (gg) of subparagraph (G)(ii)(I);

"(bb) agrees to fully participate in the Prescription Drug Monitoring Program of the State in which the qualifying practitioner 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 patients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes 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 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 following conditions:

''(aa) The physician holds a board certification in addiction psychi-

atry 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, seminar at professional society meetings, electronic communications, or otherwise) with respect to the treatment and management of opiate-dependent patients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic As-

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

''(ff) The physician has participated as an investigator in 1 or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by this sponsor of such approved drug.

''(gg) The physician has such other training or experience as the Secretary determines will demonstrate the ability of the physician to treat and manage opiate-dependent patients.

''(II) A nurse practitioner or physician assistant who is licensed under State law and meets all of the following conditions:

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

"(bb) The nurse practitioner or physician assistant satisfies 1 or more of the following:

"(AA) Has completed not fewer than 24 hours of training (through classroom situations, seminar at professional society meetings, electronic communications, or otherwise) with respect to the treatment and management of opiate-dependent patients for substance use disorders provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Sec-

retary determines is appropriate for purposes of this subclause.

"(BB) Has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

"(cc) The nurse practitioner or physician assistant practices under the supervision of a licensed physician who holds an active waiver to prescribe schedule III, IV, or V narcotic medications for opioid addiction therapy, and—

"(AA) the supervising physician satisfies the conditions of item (aa), (bb), (cc), or (dd) of subclause (I); or

"(BB) both the supervising physician and the nurse practitioner or physician assistant practice in a qualified practice setting.

"(III) A nurse practitioner who is licensed under State law and meets all of the following conditions:

"(aa) The nurse practitioner is licensed under State law to prescribe schedule III, IV, or V medications for pain.

"(bb) The nurse practitioner has training or experience that the Secretary determines demonstrates specialization in the ability to treat opiate-dependent patients, such as a certification in addiction specialty accredited by the American Board of Nursing Specialties or the National Commission for Certifying Agencies, or a certification in addiction nursing as a Certified Addiction Registered Nurse - Advanced Practice.

"(cc) In accordance with State law, the nurse practitioner prescribes opioid addiction therapy in collaboration with a physician who holds an active 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.

"(II) A Centers for Medicaid & Medicare 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 accredited by the Joint Commission.

"(V) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C.

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 Addiction 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-accredited residency or fellowship training program.

''(X) Any other practice setting approved by a State regulatory board or State Medicaid Plan to provide addiction treatment services.

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

SEC. 5. GAO EVALUATION.

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

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

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

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

(4) diversion of opioid addiction treatment medication;

(5) changes in State or local policies and legislation 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

of patient care and prevent diversion of opioid addiction medication;

(8) the findings of Drug Enforcement Agency inspections of waived practitioners, including the frequency with which the Drug Enforcement Agency finds no documentation of access to behavioral health services; and

(9) the effectiveness of cross-agency collaboration between Department of Health and Human Services and the Drug Enforcement Agency for expanding effective opioid addiction treatment.