S. 644

To expand the take-home prescribing of methadone through pharmacies.

IN THE SENATE OF THE UNITED STATES

MARCH 2, 2023

Mr. Markey (for himself, Mr. Paul, Mr. Sanders, Mr. Braun, Mr. Booker, and Ms. Hassan) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To expand the take-home prescribing of methadone through pharmacies.

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 “Modernizing Opioid Treatment Access Act”.

SEC. 2. EXPANSION OF METHADONE FOR OPIOID USE DISORDER THROUGH PRESCRIBING AND PHARMACIES.

(a) Registration; Other Care by Telehealth.—
(1) **DEFINITIONS.**—In this subsection:

(A) **CONTROLLED SUBSTANCE; DETOXIFICATION TREATMENT; DISPENSE; MAINTENANCE TREATMENT; OPIOID.**—The terms "controlled substance", "detoxification treatment", "dispense", "maintenance treatment", and "opioid" have the meanings given the terms in section 102 of the Controlled Substances Act (21 U.S.C. 802).

(B) **SECRETARY.**—The term "Secretary" means the Secretary of Health and Human Services.

(2) **WAIVER.**—

(A) **IN GENERAL.**—The requirements of section 303(h) of Controlled Substances Act (21 U.S.C. 823(h)) applicable to methadone medication for opioid use disorder are waived, and the Attorney General, in consultation with the Secretary, shall register persons described in subparagraph (B) to prescribe methadone for opioid use disorder to be dispensed through a pharmacy for individuals for unsupervised use.

(B) **PERSONS DESCRIBED.**—Persons described in this subparagraph are persons who—
(i) are licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which they practice, to prescribe controlled substances in the course of professional practice; and

(ii) are—

(I) employees or contractors of an opioid treatment program; or

(II) addiction medicine physicians or addiction psychiatrists who hold a subspecialty board certification in addiction medicine from the American Board of Preventive Medicine, a board certification in addiction medicine from the American Board of Addiction Medicine, a subspecialty board certification in addiction psychiatry from the American Board of Psychiatry and Neurology, or a subspecialty board certification in addiction medicine from the American Osteopathic Association.

(C) REQUIREMENTS FOR PRESCRIBING METHADONE.—The prescribing of methadone pursuant to subparagraph (A) shall be—
(i) exclusively by electronic prescribing and dispensed to the patient treated pursuant to subparagraph (A);

(ii) for a supply of not more than 30 days pursuant to each prescription; and

(iii) subject to the restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations, or successor regulation or guidance.

(D) REQUIREMENTS FOR DISPENSING METHADONE.—The dispensing of methadone to an individual pursuant to subparagraph (A) shall be in addition to the other care that the individual continues to have access to through an opioid treatment program.

(E) REGISTRATION REQUIREMENTS.—Persons registered in a State pursuant to subparagraph (A) shall—

(i) ensure and document, with respect to each patient treated pursuant to subparagraph (A), informed consent to treatment; and

(ii) include in such informed consent, specific informed consent regarding differences in confidentiality protections ap-
plicable when dispensing through an opioid
treatment program versus dispensing
through a pharmacy pursuant to subpara-
graph (A).

(F) CESSATION AND WITHDRAWAL OF
REGISTRATION.—At the request of a State, the
Attorney General, in consultation with the Sec-
retary, shall—

(i) cease registering persons in the
State pursuant to subparagraph (A); and

(ii) withdraw any such registration in
effect for a person in the State.

(G) MAINTENANCE AND DETOXIFICATION
TREATMENT.—Maintenance treatment or de-
toxification treatment provided pursuant to sub-
paragraph (A) and other care provided in con-
junction with such treatment, such as coun-
seling and other ancillary services, may be pro-
vided by means of telehealth, as determined
jointly by the State and the Secretary to be fea-
sible and appropriate.

(b) ANNUAL REPORTING.—Not later than 180 days
after the date of enactment of this Act, and annually
thereafter, the Assistant Secretary for Mental Health and
Substance Use and the Administrator of the Drug En-
forcement Administration shall jointly submit a report to Congress that includes—

(1) the number of persons registered pursuant to subsection (a);

(2) the number of patients being prescribed methadone pursuant to subsection (a); and

(3) a list of the States in which persons are registered pursuant to such subsection (a).

SEC. 3. SENSE OF CONGRESS ON NEED TO REDUCE BARRIERS TO PATIENT CARE THROUGH OPIOID TREATMENT PROGRAMS.

It is the sense of Congress that—

(1) patients receiving services through opioid treatment programs face barriers to their care; and

(2) each State should align the regulation of opioid treatment programs in a manner that is consistent with the intent of this Act.