

118TH CONGRESS
1ST SESSION

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.

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 “Modernizing Opioid
5 Treatment Access Act”.

6 **SEC. 2. EXPANSION OF METHADONE FOR OPIOID USE DIS-**
7 **ORDER THROUGH PRESCRIBING AND PHAR-**
8 **MACIES.**

9 (a) REGISTRATION; OTHER CARE BY TELE-
10 HEALTH.—

1 (1) DEFINITIONS.—In this subsection:

2 (A) CONTROLLED SUBSTANCE; DETOXI-
3 FICATION TREATMENT; DISPENSE; MAINTEN-
4 NANCE TREATMENT; OPIOID.—The terms “con-
5 trolled substance”, “detoxification treatment”,
6 “dispense”, “maintenance treatment”, and
7 “opioid” have the meanings given the terms in
8 section 102 of the Controlled Substances Act
9 (21 U.S.C. 802).

10 (B) SECRETARY.—The term “Secretary”
11 means the Secretary of Health and Human
12 Services.

13 (2) WAIVER.—

14 (A) IN GENERAL.—The requirements of
15 section 303(h) of Controlled Substances Act (21
16 U.S.C. 823(h)) applicable to methadone medica-
17 tion for opioid use disorder are waived, and the
18 Attorney General, in consultation with the Sec-
19 retary, shall register persons described in sub-
20 paragraph (B) to prescribe methadone for
21 opioid use disorder to be dispensed through a
22 pharmacy for individuals for unsupervised use.

23 (B) PERSONS DESCRIBED.—Persons de-
24 scribed in this subparagraph are persons who—

1 (i) are licensed, registered, or other-
2 wise permitted, by the United States or the
3 jurisdiction in which they practice, to pre-
4 scribe controlled substances in the course
5 of professional practice; and

6 (ii) are—

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

9 (II) addiction medicine physi-
10 cians or addiction psychiatrists who
11 hold a subspecialty board certification
12 in addiction medicine from the Amer-
13 ican Board of Preventive Medicine, a
14 board certification in addiction medi-
15 cine from the American Board of Ad-
16 diction Medicine, a subspecialty board
17 certification in addiction psychiatry
18 from the American Board of Psychi-
19 atry and Neurology, or a subspecialty
20 board certification in addiction medi-
21 cine from the American Osteopathic
22 Association.

23 (C) REQUIREMENTS FOR PRESCRIBING
24 METHADONE.—The prescribing of methadone
25 pursuant to subparagraph (A) shall be—

1 (i) exclusively by electronic prescribing
2 and dispensed to the patient treated pursu-
3 ant to subparagraph (A);

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

6 (iii) subject to the restrictions listed
7 in section 8.12(i)(3) of title 42, Code of
8 Federal Regulations, or successor regula-
9 tion or guidance.

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

16 (E) REGISTRATION REQUIREMENTS.—Per-
17 sons registered in a State pursuant to subpara-
18 graph (A) shall—

19 (i) ensure and document, with respect
20 to each patient treated pursuant to sub-
21 paragraph (A), informed consent to treat-
22 ment; and

23 (ii) include in such informed consent,
24 specific informed consent regarding dif-
25 ferences in confidentiality protections ap-

1 plicable when dispensing through an opioid
2 treatment program versus dispensing
3 through a pharmacy pursuant to subpara-
4 graph (A).

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

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

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

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

22 (b) ANNUAL REPORTING.—Not later than 180 days
23 after the date of enactment of this Act, and annually
24 thereafter, the Assistant Secretary for Mental Health and
25 Substance Use and the Administrator of the Drug En-

1 enforcement Administration shall jointly submit a report to
2 Congress that includes—

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

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

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

9 **SEC. 3. SENSE OF CONGRESS ON NEED TO REDUCE BAR-**
10 **RIERS TO PATIENT CARE THROUGH OPIOID**
11 **TREATMENT PROGRAMS.**

12 It is the sense of Congress that—

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

15 (2) each State should align the regulation of
16 opioid treatment programs in a manner that is con-
17 sistent with the intent of this Act.

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