

# Calendar No. 318

118TH CONGRESS  
2D SESSION

# S. 644

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

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## IN THE SENATE OF THE UNITED STATES

MARCH 2, 2023

Mr. MARKEY (for himself, Mr. PAUL, Mr. SANDERS, Mr. BRAUN, Mr. BOOKER, Ms. HASSAN, Mr. LUJÁN, Mr. WELCH, Mr. LEE, Ms. WARREN, Mr. CASEY, and Mr. HEINRICH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

FEBRUARY 1, 2024

Reported by Mr. SANDERS, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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## 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~~”.

1 **SEC. 2. EXPANSION OF METHADONE FOR OPIOID USE DIS-**  
2 **ORDER THROUGH PRESCRIBING AND PHAR-**  
3 **MACIES.**

4 (a) REGISTRATION; OTHER CARE BY TELE-  
5 HEALTH.—

6 (1) DEFINITIONS.—In this subsection:

7 (A) CONTROLLED SUBSTANCE; DETOXI-  
8 FICATION TREATMENT; DISPENSE; MAINTE-  
9 NANCE TREATMENT; OPIOID.—The terms “con-  
10 trolled substance”, “detoxification treatment”,  
11 “dispense”, “maintenance treatment”, and  
12 “opioid” have the meanings given the terms in  
13 section 102 of the Controlled Substances Act  
14 (21 U.S.C. 802).

15 (B) SECRETARY.—The term “Secretary”  
16 means the Secretary of Health and Human  
17 Services.

18 (2) WAIVER.—

19 (A) IN GENERAL.—The requirements of  
20 section 303(h) of Controlled Substances Act (21  
21 U.S.C. 823(h)) applicable to methadone medica-  
22 tion for opioid use disorder are waived, and the  
23 Attorney General, in consultation with the Sec-  
24 retary, shall register persons described in sub-  
25 paragraph (B) to prescribe methadone for

1           opioid use disorder to be dispensed through a  
2           pharmacy for individuals for unsupervised use.

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

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

10                   (ii) are—

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

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

1                   eine from the American Osteopathic  
2                   Association.

3                   (C) REQUIREMENTS FOR PRESCRIBING  
4                   METHADONE.—The prescribing of methadone  
5                   pursuant to subparagraph (A) shall be—

6                   (i) exclusively by electronic prescribing  
7                   and dispensed to the patient treated pursu-  
8                   ant to subparagraph (A);

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

11                  (iii) subject to the restrictions listed  
12                  in section 8.12(i)(3) of title 42, Code of  
13                  Federal Regulations, or successor regula-  
14                  tion or guidance.

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

21                  (E) REGISTRATION REQUIREMENTS.—Per-  
22                  sons registered in a State pursuant to subpara-  
23                  graph (A) shall—

24                  (i) ensure and document, with respect  
25                  to each patient treated pursuant to sub-

1 paragraph (A), informed consent to treat-  
2 ment; and

3 (ii) include in such informed consent,  
4 specific informed consent regarding dif-  
5 ferences in confidentiality protections ap-  
6 plicable when dispensing through an opioid  
7 treatment program versus dispensing  
8 through a pharmacy pursuant to subpara-  
9 graph (A).

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

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

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

18 ~~(G) MAINTENANCE AND DETOXIFICATION~~  
19 ~~TREATMENT.—~~Maintenance treatment or de-  
20 toxification treatment provided pursuant to sub-  
21 paragraph (A) and other care provided in con-  
22 junction with such treatment, such as coun-  
23 seling and other ancillary services, may be pro-  
24 vided by means of telehealth, as determined

1 jointly by the State and the Secretary to be fea-  
2 sible and appropriate.

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

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

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

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

15 **SEC. 3. SENSE OF CONGRESS ON NEED TO REDUCE BAR-**  
16 **RIERS TO PATIENT CARE THROUGH OPIOID**  
17 **TREATMENT PROGRAMS.**

18 It is the sense of Congress that—

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

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

1 **SECTION 1. SHORT TITLE.**

2 *This Act may be cited as the “Modernizing Opioid*  
 3 *Treatment Access Act”.*

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

7 *Section 303(h) of the Controlled Substances Act (21*  
 8 *U.S.C. 823(h)), is amended—*

9 *(1) in paragraph (1)—*

10 *(A) in the matter preceding subparagraph*  
 11 *(A), in the first sentence, by inserting “(other*  
 12 *than narcotic drugs in schedule III, IV, or V)”*  
 13 *after “drugs”; and*

14 *(B) by striking subparagraph (B) and in-*  
 15 *serting the following:*

16 *“(B) if the Attorney General determines that the*  
 17 *applicant will comply with standards established by*  
 18 *the Attorney General respecting—*

19 *“(i) security of stocks of narcotic drugs for*  
 20 *such treatment; and*

21 *“(ii) the maintenance of records (in accord-*  
 22 *ance with section 307) on such drugs; and”;* and

23 *(2) by striking paragraph (2) and inserting the*  
 24 *following:*

25 *“(2)(A) The requirements of paragraph (1) applicable*  
 26 *to methadone medication for opioid use disorder are*

1 *waived, and the Attorney General, in consultation with the*  
2 *Secretary, shall separately register persons described in sub-*  
3 *paragraph (B) to prescribe methadone for opioid use dis-*  
4 *order to be dispensed through a pharmacy for individuals*  
5 *for unsupervised use.*

6       “(B) *Persons described in this subparagraph are per-*  
7 *sons who—*

8               “(i) *are licensed, registered, or otherwise per-*  
9 *mitted, by the United States or the jurisdiction in*  
10 *which they practice, to prescribe controlled substances*  
11 *in the course of professional practice; and*

12               “(ii) *are addiction medicine physicians or ad-*  
13 *diction psychiatrists who hold a subspecialty board*  
14 *certification in addiction medicine from the Amer-*  
15 *ican Board of Preventive Medicine, a board certifi-*  
16 *cation in addiction medicine from the American*  
17 *Board of Addiction Medicine, a subspecialty board*  
18 *certification in addiction psychiatry from the Amer-*  
19 *ican Board of Psychiatry and Neurology, or a sub-*  
20 *specialty board certification in addiction medicine*  
21 *from the American Osteopathic Association.*

22       “(C) *The prescribing of methadone pursuant to sub-*  
23 *paragraph (A) shall be—*



1           “(i) exclusively by electronic prescribing and dis-  
2           pensed to the patient treated pursuant to subpara-  
3           graph (A);

4           “(ii) for a supply of not more than 30 days pur-  
5           suant to each prescription; and

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

9           “(D) The dispensing of methadone to an individual  
10          pursuant to subparagraph (A) shall be in addition to the  
11          other care that the individual continues to have access to  
12          through an opioid treatment program.

13          “(E) Persons registered pursuant to subparagraph (A)  
14          shall—

15               “(i) ensure and document, with respect to each  
16               patient treated pursuant to subparagraph (A), in-  
17               formed consent to treatment; and

18               “(ii) include in such informed consent, specific  
19               informed consent regarding differences in confiden-  
20               tiality protections applicable when dispensing  
21               through an opioid treatment program versus dis-  
22               pensing through a pharmacy pursuant to subpara-  
23               graph (A).

24          “(F) At the request of a State, the Attorney General  
25          shall—

1           “(i) cease registering persons in the State pursu-  
2           ant to subparagraph (A); and

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

5           “(G) Maintenance treatment or detoxification treat-  
6           ment provided pursuant to subparagraph (A) and other  
7           care provided in conjunction with such treatment, such as  
8           counseling and other ancillary services, may be provided  
9           by means of telehealth.

10          “(3) Not later than 180 days after the date of enact-  
11          ment of this paragraph, and annually thereafter, the Assist-  
12          ant Secretary for Mental Health and Substance Use and  
13          the Administrator of the Drug Enforcement Administration  
14          shall jointly submit to Congress a report that includes—

15                 “(A) the number of persons registered pursuant  
16                 to paragraph (2);

17                 “(B) a list of States in which persons are reg-  
18                 istered pursuant to paragraph (2).”.



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