

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: In the nature of a substitute.

**IN THE SENATE OF THE UNITED STATES—118th Cong., 1st Sess.**

**S. 644**

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

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended  
to be proposed by \_\_\_\_\_

Viz:

1 Strike all after the enacting clause and insert the fol-  
2 lowing:

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

11 (1) in paragraph (1)—

1 (A) in the matter preceding subparagraph  
2 (A), in the first sentence, by inserting “(other  
3 than narcotic drugs in schedule III, IV, or V)”  
4 after “drugs”; and

5 (B) by striking subparagraph (B) and in-  
6 serting the following:

7 “(B) if the Attorney General determines that  
8 the applicant will comply with standards established  
9 by the Attorney General respecting—

10 “(i) security of stocks of narcotic drugs for  
11 such treatment; and

12 “(ii) the maintenance of records (in ac-  
13 cordance with section 307) on such drugs;  
14 and”; and

15 (2) by striking paragraph (2) and inserting the  
16 following:

17 “(2)(A) The requirements of paragraph (1) applica-  
18 ble to methadone medication for opioid use disorder are  
19 waived, and the Attorney General, in consultation with the  
20 Secretary, shall separately register persons described in  
21 subparagraph (B) to prescribe methadone for opioid use  
22 disorder to be dispensed through a pharmacy for individ-  
23 uals for unsupervised use.

24 “(B) Persons described in this subparagraph are per-  
25 sons who—

1           “(i) are licensed, registered, or otherwise per-  
2           mitted, by the United States or the jurisdiction in  
3           which they practice, to prescribe controlled sub-  
4           stances in the course of professional practice; and

5           “(ii) are addiction medicine physicians or addic-  
6           tion psychiatrists who hold a subspecialty board cer-  
7           tification in addiction medicine from the American  
8           Board of Preventive Medicine, a board certification  
9           in addiction medicine from the American Board of  
10          Addiction Medicine, a subspecialty board certifi-  
11          cation in addiction psychiatry from the American  
12          Board of Psychiatry and Neurology, or a sub-  
13          specialty board certification in addiction medicine  
14          from the American Osteopathic Association.

15          “(C) The prescribing of methadone pursuant to sub-  
16          paragraph (A) shall be—

17                 “(i) exclusively by electronic prescribing and  
18                 dispensed to the patient treated pursuant to sub-  
19                 paragraph (A);

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

22                 “(iii) subject to the restrictions listed in section  
23                 8.12(i)(3) of title 42, Code of Federal Regulations,  
24                 or successor regulation or guidance.

1       “(D) The dispensing of methadone to an individual  
2 pursuant to subparagraph (A) shall be in addition to the  
3 other care that the individual continues to have access to  
4 through an opioid treatment program.

5       “(E) Persons registered pursuant to subparagraph  
6 (A) shall—

7           “(i) ensure and document, with respect to each  
8 patient treated pursuant to subparagraph (A), in-  
9 formed consent to treatment; and

10          “(ii) include in such informed consent, specific  
11 informed consent regarding differences in confiden-  
12 tiality protections applicable when dispensing  
13 through an opioid treatment program versus dis-  
14 pensing through a pharmacy pursuant to subpara-  
15 graph (A).

16       “(F) At the request of a State, the Attorney General  
17 shall—

18           “(i) cease registering persons in the State pur-  
19 suant to subparagraph (A); and

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

22       “(G) Maintenance treatment or detoxification treat-  
23 ment provided pursuant to subparagraph (A) and other  
24 care provided in conjunction with such treatment, such as

1 counseling and other ancillary services, may be provided  
2 by means of telehealth.

3 “(3) Not later than 180 days after the date of enact-  
4 ment of this paragraph, and annually thereafter, the As-  
5 sistant Secretary for Mental Health and Substance Use  
6 and the Administrator of the Drug Enforcement Adminis-  
7 tration shall jointly submit to Congress a report that in-  
8 cludes—

9 “(A) the number of persons registered pursuant  
10 to paragraph (2);

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