

117TH CONGRESS
1ST SESSION

S. _____

To authorize a study on certain exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID–19 public health emergency, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. MARKEY introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To authorize a study on certain exemptions for treatment of opioid use disorder through opioid treatment programs during the COVID–19 public health emergency, and for other purposes.

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 “Opioid Treatment Ac-
5 cess Act of 2022”.

1 **SEC. 2. STUDY ON EXEMPTIONS FOR TREATMENT OF**
2 **OPIOID USE DISORDER THROUGH OPIOID**
3 **TREATMENT PROGRAMS DURING THE COVID-**
4 **19 PUBLIC HEALTH EMERGENCY.**

5 (a) **STUDY.**—The Assistant Secretary for Mental
6 Health and Substance Use shall conduct a study, in con-
7 sultation with patients and other stakeholders, on activi-
8 ties carried out pursuant to exemptions granted—

9 (1) to a State (including the District of Colum-
10 bia or any territory of the United States) or an
11 opioid treatment program;

12 (2) pursuant to section 8.11(h) of title 42, Code
13 of Federal Regulations; and

14 (3) during the period—

15 (A) beginning on the declaration of the
16 public health emergency for the COVID-19
17 pandemic under section 319 of the Public
18 Health Service Act (42 U.S.C. 274); and

19 (B) ending on the earlier of—

20 (i) the termination of such public
21 health emergency, including extensions
22 thereof pursuant to such section 319; and

23 (ii) the end of calendar year 2022.

24 (b) **ISSUES TO BE STUDIED.**—The study under sub-
25 section (a) shall, with respect to exemptions described in

1 such subsection, include consideration of each of the fol-
2 lowing:

3 (1) The number of participating patients in
4 each State.

5 (2) The percentage of participating patients in
6 each State relative to the total number of patients
7 in the respective State receiving treatment through
8 an opioid treatment program.

9 (3) The number of participating patients in
10 each State who cease treatment.

11 (4) The number of participating patients in
12 each State who overdose on an opioid and cease
13 treatment.

14 (5) The number of participating patients in
15 each State who overdose on an opioid and continue
16 treatment.

17 (6) The number of participating opioid treat-
18 ment programs in each State.

19 (7) The percentage of participating opioid treat-
20 ment programs in each State relative to the total
21 number of opioid treatment programs in the respec-
22 tive State.

23 (8) The demographic, socioeconomic, and geo-
24 graphic characteristics of the participating patients
25 and opioid treatment programs.

1 (9) Any additional costs or savings from exemp-
2 tions in each State.

3 (10) An analysis of differences in the use of ex-
4 emptions among States.

5 (11) Rates of medication adherence and diver-
6 sion.

7 (c) PRIVACY.—The section does not authorize the dis-
8 closure by the Department of Health and Human Services
9 of individually identifiable information about patients.

10 (d) FEEDBACK.—In conducting the study under sub-
11 section (a), the Assistant Secretary for Mental Health and
12 Substance Use shall gather feedback from the States and
13 opioid treatment programs on their experiences in imple-
14 menting exemptions described in subsection (a).

15 (e) REPORT.—Not later than 180 days after the end
16 of the period described in subsection (a)(3)(B), and sub-
17 ject to subsection (c), the Assistant Secretary for Mental
18 Health and Substance Use shall publish a report on the
19 results of the study under this section.

20 **SEC. 3. CHANGES TO FEDERAL OPIOID TREATMENT STAND-**
21 **ARDS.**

22 (a) MOBILE MEDICATION UNITS.—Section 302(e) of
23 the Controlled Substances Act (21 U.S.C. 822(e)) is
24 amended by adding at the end the following:

1 “(3) Notwithstanding paragraph (1), a registrant
2 that is dispensing pursuant to section 303(g) narcotic
3 drugs to individuals for maintenance treatment or detoxi-
4 fication treatment shall not be required to have a separate
5 registration to incorporate one or more mobile medication
6 units into the registrant’s practice to dispense such nar-
7 cotics at locations other than the registrant’s principal
8 place of business or professional practice described in
9 paragraph (1), so long as the registrant meets such stand-
10 ards for operation of a mobile medication unit as the At-
11 torney General may establish.”.

12 (b) CLARIFICATION IN CONSIDERATION OF PA-
13 TIENTS’ RESPONSIBILITY IN HANDLING OPIOID DRUGS
14 FOR UNSUPERVISED USE.—Not later than 90 days after
15 the date of enactment of this Act, the Secretary of Health
16 and Human Services shall promulgate a final regulation,
17 or issue guidance, clarifying section 8.12(i)(2)(i) of title
18 42, Code of Federal Regulations (and making such other
19 changes as may be necessary) so that a medical director
20 may determine that a patient is sufficiently responsible in
21 handling opioid drugs for unsupervised use, as described
22 in such section 8.12(i)(2) of such title 42, even if there
23 is evidence of recent use of drugs (opioid or nonnarcotic,
24 including alcohol).

1 (c) PERIODS FOR TAKE-HOME SUPPLY REQUIRE-
2 MENTS.—

3 (1) FIRST REGULATION.—Not later than 90
4 days after the date of enactment of this Act, the
5 Secretary of Health and Human Services shall pro-
6 mulgate a final regulation amending paragraphs
7 (i)(3)(i) through (i)(3)(vi) of section 8.12 of title 42,
8 Code of Federal Regulations (and making such other
9 changes as may be necessary) so that—

10 (A) the references to 90 days in para-
11 graphs (i)(3)(i) through (i)(3)(iii) of such sec-
12 tion 8.12 are each reduced to not more than 45
13 days;

14 (B) the reference to the remaining months
15 of the first year in paragraph (i)(3)(iv) of such
16 section 8.12 is reduced to the remaining days of
17 not more than the first six months of treat-
18 ment;

19 (C) the reference to 1 year in paragraph
20 (i)(3)(v) of such section 8.12 is reduced to not
21 more than 6 months; and

22 (D) the reference to 2 years in paragraph
23 (i)(3)(vi) of such section 8.12 is reduced to not
24 more than 1 year.

1 (2) STUDY.—Not later than 18 months after
2 the date of enactment of this Act, the Assistant Sec-
3 retary for Mental Health and Substance Use shall—

4 (A) complete a study, in consultation with
5 patients and other stakeholders, on the impacts
6 on patient rehabilitation of the changes made
7 by the regulation under paragraph (1) to the
8 periods specified in section 8.12(i)(3) of title
9 42, Code of Federal Regulations;

10 (B) submit a report to the Congress on the
11 results of such study; and

12 (C) include in such report recommenda-
13 tions for policy changes.

14 (3) SECOND REGULATION.—

15 (A) IN GENERAL.—Not later than two
16 years after the date of enactment of this Act,
17 the Secretary of Health and Human Services
18 shall promulgate a final regulation amending
19 paragraphs (i)(3)(i) through (i)(3)(vi) of section
20 8.12 of title 42, Code of Federal Regulations,
21 as appropriate based on the findings of the
22 study under paragraph (2).

23 (B) LIMITATION.—The regulation under
24 subparagraph (A) shall not amend section 8.12

1 of title 42, Code of Federal Regulations, so as
2 to—

3 (i) allow the dispensing of more than
4 two consecutive doses of methadone for
5 take-home use per week before the pa-
6 tient's 30th day of treatment; or

7 (ii) prohibit a patient determined to
8 be responsible in handling opioids from
9 being given a maximum of a one-month
10 supply of methadone for take-home use
11 after two years of continuous treatment.

12 **SEC. 4. EXPANSION OF TAKE-HOME PRESCRIBING OF**
13 **METHADONE THROUGH PHARMACIES.**

14 (a) **REGISTRATION; OTHER CARE BY TELE-**
15 **HEALTH.**—Section 303(g) of the Controlled Substances
16 Act (21 U.S.C. 823(g)) is amended—

17 (1) in paragraph (1), by striking “in paragraph
18 (2)” and inserting “in paragraphs (2) and (3)”; and

19 (2) by adding at the end the following:

20 “(3)(A) At the request of a State, the Attorney Gen-
21 eral, in consultation with the Secretary, may, pursuant to
22 paragraph (1), register persons described in subparagraph
23 (B) to prescribe methadone to be dispensed through a
24 pharmacy for individuals for unsupervised use.

1 “(B) Persons described in this subparagraph are per-
2 sons who—

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

7 “(ii) are—

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

10 “(II) addiction medicine physicians or ad-
11 diction psychiatrists who hold a subspecialty
12 board certification in addiction medicine from
13 the American Board of Preventive Medicine, a
14 board certification in addiction medicine from
15 the American Board of Addiction Medicine, a
16 subspecialty board certification in addiction
17 psychiatry from the American Board of Psychi-
18 atry and Neurology, or a subspecialty board
19 certification in addiction medicine from the
20 American Osteopathic Association.

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

23 “(i) exclusively by electronic prescribing;

24 “(ii) for a supply of not more than 1 month
25 pursuant to each prescription; and

1 “(iii) subject to the restrictions listed in section
2 8.12(i)(3) of title 42, Code of Federal Regulations,
3 including any amendments or exemptions to such
4 section pursuant to section 3(c) of the Opioid Treat-
5 ment Access Act of 2022, or successor regulations or
6 guidance.

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

11 “(E) Persons registered in a State pursuant to sub-
12 paragraph (A) shall—

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

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

22 “(F) At the request of a State, the Attorney General,
23 in consultation with the Secretary, shall—

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

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

3 “(G) Maintenance treatment or detoxification treat-
4 ment provided pursuant to subparagraph (A), as well as
5 other care provided in conjunction with such treatment,
6 such as counseling and other ancillary services, may be
7 provided by means of telehealth as determined jointly by
8 the State and the Secretary to be feasible and appro-
9 priate.”.

10 (b) ANNUAL REPORTING.—Not later than 6 months
11 after the date of enactment of this Act, and annually
12 thereafter, the Assistant Secretary for Mental Health and
13 Substance Use and the Administrator of the Drug En-
14 forcement Agency, acting jointly, shall submit a report to
15 the Congress including—

16 (1) the number of persons registered pursuant
17 to section 303(g)(3) of the Controlled Substances
18 Act, as added by subsection (a);

19 (2) the number of patients being prescribed
20 methadone pursuant to such section 303(g)(3); and

21 (3) a list of the States in which persons are
22 registered pursuant to such section 303(g)(3).

1 **SEC. 5. SENSE OF CONGRESS ON NEED TO REDUCE BAR-**
2 **RIERS TO PATIENT CARE THROUGH OPIOID**
3 **TREATMENT PROGRAMS.**

4 It is the sense of the Congress that—

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

7 (2) each State should align its regulation of
8 opioid treatment programs in a manner that is con-
9 sistent with the intent of this Act.