117TH CONGRESS
2D SESSION

S. 3629

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

FEBRUARY 10, 2022

Mr. MARKEY (for himself and Mr. PAUL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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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.

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 ''Opioid Treatment Access Act of 2022''.

SEC. 2. STUDY ON EXEMPTIONS FOR TREATMENT OF OPIOID USE DISORDER THROUGH OPIOID TREATMENT PROGRAMS DURING THE COVID–19 PUBLIC HEALTH EMERGENCY.

(a) STUDY.—The Assistant Secretary for Mental Health and Substance Use shall conduct a study, in consultation with patients and other stakeholders, on activities carried out pursuant to exemptions granted—

(1) to a State (including the District of Columbia or any territory of the United States) or an opioid treatment program;

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

(3) during the period—

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

(B) ending on the earlier of—

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

(ii) the end of calendar year 2022.

(b) ISSUES TO BE STUDIED.—The study under subsection (a) shall, with respect to exemptions described in

such subsection, include consideration of each of the following:

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

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

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

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

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

(6) The number of participating opioid treatment programs in each State.

(7) The percentage of participating opioid treatment programs in each State relative to the total number of opioid treatment programs in the respective State.

(8) The demographic, socioeconomic, and geographic characteristics of the participating patients and opioid treatment programs.

(9) Any additional costs or savings from exemptions in each State.

(10) An analysis of differences in the use of exemptions among States.

(11) Rates of medication adherence and diversion.

(c) PRIVACY.—The section does not authorize the disclosure by the Department of Health and Human Services of individually identifiable information about patients.

(d) FEEDBACK.—In conducting the study under subsection (a), the Assistant Secretary for Mental Health and Substance Use shall gather feedback from the States and opioid treatment programs on their experiences in implementing exemptions described in subsection (a).

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

SEC. 3. CHANGES TO FEDERAL OPIOID TREATMENT STANDARDS.

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

''(3) Notwithstanding paragraph (1), a registrant that is dispensing pursuant to section 303(g) narcotic drugs to individuals for maintenance treatment or detoxification treatment shall not be required to have a separate registration to incorporate one or more mobile medication units into the registrant's practice to dispense such narcotics at locations other than the registrant's principal place of business or professional practice described in paragraph (1), so long as the registrant meets such standards for operation of a mobile medication unit as the Attorney General may establish.''.

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

(c) PERIODS FOR TAKE-HOME SUPPLY REQUIREMENTS.—

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

(A) the references to 90 days in paragraphs (i)(3)(i) through (i)(3)(iii) of such section 8.12 are each reduced to not more than 45 days;

(B) the reference to the remaining months of the first year in paragraph (i)(3)(iv) of such section 8.12 is reduced to the remaining days of not more than the first six months of treatment;

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

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

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

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

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

(C) include in such report recommendations for policy changes.

(3) SECOND REGULATION.—

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

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

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

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

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

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

(a) REGISTRATION; OTHER CARE BY TELEHEALTH.—Section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) is amended—

(1) in paragraph (1), by striking ''in paragraph (2)'' and inserting ''in paragraphs (2) and (3)''; and

(2) by adding at the end the following:

''(3)(A) At the request of a State, the Attorney General, in consultation with the Secretary, may, pursuant to paragraph (1), register persons described in subparagraph (B) to prescribe methadone to be dispensed through a pharmacy for individuals for unsupervised use.

''(B) 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) The prescribing of methadone pursuant to subparagraph (A) shall be—

''(i) exclusively by electronic prescribing;

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

''(iii) subject to the restrictions listed in section 8.12(i)(3) of title 42, Code of Federal Regulations, including any amendments or exemptions to such section pursuant to section 3(c) of the Opioid Treatment Access Act of 2022, or successor regulations or guidance.

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

''(E) 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 applicable when dispensing through an opioid treatment program versus dispensing through a pharmacy pursuant to subparagraph (A).

''(F) At the request of a State, the Attorney General, in consultation with the Secretary, 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 treatment or detoxification treatment provided pursuant to subparagraph (A), as well as other care provided in conjunction with such treatment, such as counseling and other ancillary services, may be provided by means of telehealth as determined jointly by the State and the Secretary to be feasible and appropriate.''.

(b) ANNUAL REPORTING.—Not later than 6 months 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 Enforcement Agency, acting jointly, shall submit a report to the Congress including—

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

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

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

SEC. 5. SENSE OF CONGRESS ON NEED TO REDUCE BARRIERS TO PATIENT CARE THROUGH OPIOID TREATMENT PROGRAMS.

It is the sense of the Congress that—

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

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

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