114TH CONGRESS
2D SESSION

H. R. 4981

AN ACT

To amend the Controlled Substances Act to improve access to opioid use disorder treatment.

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 Use Disorder Treatment Expansion and Modernization Act''.

SEC. 2. FINDING.

The Congress finds that opioid use disorder has become a public health epidemic that must be addressed by increasing awareness and access to all treatment options for opioid use disorder, overdose reversal, and relapse prevention.

SEC. 3. OPIOID USE DISORDER TREATMENT MODERNIZATION.

(a) IN GENERAL.—Section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is amended—

(1) in subparagraph (B), by striking clauses (i), (ii), and (iii) and inserting the following:

''(i) The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

''(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary—

''(I) all schedule III, IV, and V drugs, as well as unscheduled medications approved by the Food and Drug Administration, for the

treatment of opioid use disorder, including such drugs and medications for maintenance, detoxification, overdose reversal, and relapse prevention, as available; and

''(II) appropriate counseling and other appropriate ancillary services.

''(iii)(I) The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

''(II) The applicable number is 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients.

''(III) The Secretary may by regulation change such total number.

''(IV) The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

''(iv) If the Secretary by regulation increases the total number of patients which a qualifying practitioner is permitted to treat pursuant to clause

(iii)(II), the Secretary shall require such a practitioner to obtain a written agreement from each patient, including the patient's signature, that the patient—

''(I) will receive an initial assessment and treatment plan and periodic assessments and treatment plans thereafter;

''(II) will be subject to medication adherence and substance use monitoring;

''(III) understands available treatment options, including all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including their potential risks and benefits; and

''(IV) understands that receiving regular counseling services is critical to recovery.

''(v) The practitioner will comply with the reporting requirements of subparagraph (D)(i)(IV).'';

(2) in subparagraph (D)—

(A) in clause (i), by adding at the end the following:

''(IV) The practitioner reports to the Secretary, at such times and in such manner as specified by the Secretary, such information and assurances as the Secretary determines necessary to assess wheth-

er the practitioner continues to meet the requirements for a waiver under this paragraph.'';

(B) in clause (ii), by striking ''Upon receiving a notification under subparagraph (B)'' and inserting ''Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)''; and

(C) in clause (iii)—

(i) by inserting ''and shall forward such determination to the Attorney General'' before the period at the end of the first sentence; and

(ii) by striking ''physician'' and inserting ''practitioner'';

(3) in subparagraph (G)—

(A) by amending clause (ii)(IV) to read as follows:

''(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction

Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall address—

''(aa) opioid maintenance and detoxification;

''(bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

''(cc) initial and periodic patient assessments (including substance use monitoring);

''(dd) individualized treatment planning; overdose reversal; relapse prevention;

''(ee) counseling and recovery support services;

''(ff) staffing roles and considerations;

''(gg) diversion control; and

''(hh) other best practices, as identified by the Secretary.''; and

(B) by adding at the end the following:

"(iii) The term 'qualifying practitioner' means—

"(I) a qualifying physician, as defined in clause (ii); or

"(II) during the period beginning on the date of the enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act and ending on the date that is 3 years after such date of enactment, a qualifying other practitioner, as defined in clause (iv).

"(iv) The term 'qualifying other practitioner' means a nurse practitioner or physician assistant who satisfies each of the following:

"(I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

"(II) The nurse practitioner or physician assistant satisfies one or more of the following:

"(aa) Has completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by

the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause.

''(bb) Has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

''(III) The nurse practitioner or physician assistant is supervised by or works in collaboration with a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may review and update the requirements for being a qualifying other practitioner under this clause.''; and

(4) in subparagraph (H)—

(A) in clause (i), by inserting after subclause (II) the following:

''(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.''; and

(B) by amending clause (ii) to read as follows:

''(ii) Not later than 1 year after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.''.

(b) RECOMMENDATION OF REVOCATION OR SUSPENSION OF REGISTRATION IN CASE OF SUBSTANTIAL NONCOMPLIANCE.—The Secretary of Health and Human Services may recommend to the Attorney General that the registration of a practitioner be revoked or suspended if

the Secretary determines, according to such criteria as the Secretary establishes by regulation, that a practitioner who is registered under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) is not in substantial compliance with the requirements of such section, as amended by this Act.

(c) OPIOID DEFINED.—Section 102(18) of the Controlled Substances Act (21 U.S.C. 802(18)) is amended by inserting ''or 'opioid' '' after ''The term 'opiate' ''.

(d) REPORTS TO CONGRESS.—

(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act and not less than over every 5 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

(A) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

(B) submit a report to the Congress on the findings and conclusions of such review.

(2) CONTENTS.—Each report under paragraph (1) shall include an assessment of—

(A) compliance with the requirements of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), as amended by this Act;

(B) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

(C) whether there is further need to increase or decrease the number of patients a waivered practitioner is permitted to treat, as provided for by the amendment made by subsection (a)(1);

(D) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings and specialty substance use disorder treatment settings;

(E) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

(F) changes in State or local policies and legislation relating to opioid use disorder treatment;

(G) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2));

(H) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in subparagraph (G); and

(I) the effectiveness of cross-agency collaboration between Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.

SEC. 4. SENSE OF CONGRESS.

It is the Sense of Congress that, with respect to the total number of patients that a qualifying physician (as defined in subparagraph (G)(iii) of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)) can treat at any one time pursuant to such section, the Secretary of Health and Human Services should consider

raising such total number to 250 patients following a third notification to the Secretary of the need and intent of the physician to treat up to 250 patients that is submitted to the Secretary not sooner than 1 year after the date on which the physician submitted to the Secretary a second notification to treat up to 100 patients.

SEC. 5. PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

''(f) PARTIAL FILLS OF SCHEDULE II CONTROLLED SUBSTANCES.—

''(1) PARTIAL FILLS.—

''(A) IN GENERAL.—A prescription for a controlled substance in schedule II may be partially filled if—

''(i) it is not prohibited by State law;

''(ii) the prescription is written and filled in accordance with the Controlled Substances Act (21 U.S.C. 801 et seq.), regulations prescribed by the Attorney General, and State law;

"(iii) the partial fill is requested by the patient or the practitioner that wrote the prescription; and

"(iv) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

"(B) OTHER CIRCUMSTANCES.—A prescription for a controlled substance in schedule II may be partially filled in accordance with section 1306.13 of title 21, Code of Federal Regulations (as in effect on the date of enactment of the Reducing Unused Medications Act of 2016).

"(2) REMAINING PORTIONS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), remaining portions of a partially filled prescription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 30 days after the date on which the prescription is written.

"(B) EMERGENCY SITUATIONS.—In emergency situations, as described in subsection (a), the remaining portions of a partially filled pre-

scription for a controlled substance in schedule II—

"(i) may be filled; and

"(ii) shall be filled not later than 72 hours after the prescription is issued.".

(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to affect the authority of the Attorney General to allow a prescription for a controlled substance in schedule III, IV, or V of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) to be partially filled.

Passed the House of Representatives May 11, 2016.

Attest:

Clerk.

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