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(Original Signature of Member)

114TH CONGRESS
2D SESSION

H. R. ______

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

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON (for himself and Mr. TONKO) introduced the following bill; which was referred to the Committee on ______________________________

A BILL

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

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 Use Disorder
5 Treatment Expansion and Modernization Act’’.

6 **SEC. 2. FINDING.**

7 The Congress finds that opioid use disorder has be-
8 come a public health epidemic that must be addressed by
9 increasing awareness and access to all treatment options

1 for opioid use disorder, overdose reversal, and relapse pre-
2 vention.

3 **SEC. 3. OPIOID USE DISORDER TREATMENT MODERNIZA-**
4 **TION.**

5 (a) IN GENERAL.—Section 303(g)(2) of the Con-
6 trolled Substances Act (21 U.S.C. 823(g)(2)) is amend-
7 ed—

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

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

12 ''(ii) With respect to patients to whom the prac-
13 titioner will provide such drugs or combinations of
14 drugs, the practitioner has the capacity to provide
15 directly, by referral, or by providing the contact in-
16 formation for the nearest applicable practitioner—

17 ''(I) all schedule III, IV, and V drugs, as
18 well as unscheduled medications approved by
19 the Food and Drug Administration, for the
20 treatment of opioid use disorder, including such
21 drugs and medications for maintenance, detoxi-
22 fication, overdose reversal, and relapse preven-
23 tion, as available; and

24 ''(II) appropriate counseling and other ap-
25 propriate ancillary services.

1 "(iii)(I) The total number of such patients of
2 the practitioner at any one time will not exceed the
3 applicable number. Except as provided in subclauses
4 (II) and (III), the applicable number is 30.
5 "(II) The applicable number is 100 if, not soon-
6 er than 1 year after the date on which the practi-
7 tioner submitted the initial notification, the practi-
8 tioner submits a second notification to the Secretary
9 of the need and intent of the practitioner to treat up
10 to 100 patients.
11 "(III) The applicable number is 250 if the prac-
12 titioner is a qualifying physician meeting the re-
13 quirement of subclause (VI) and, not sooner than 1
14 year after the date on which the practitioner sub-
15 mitted a second notification under subclause (II),
16 the practitioner submits a third notification to the
17 Secretary of the need and intent of the practitioner
18 to treat up to 250 patients.
19 "(IV) The Secretary may by regulation change
20 such total number.
21 "(V) The Secretary may exclude from the appli-
22 cable number patients to whom such drugs or com-
23 binations of drugs are directly administered by the
24 qualifying practitioner in the office setting.

1 "(VI) For purposes of subclause (III), a quali-
2 fying physician meets the requirement of this sub-
3 clause if the practitioner or physician—
4 "(aa) holds a special certification in addic-
5 tion psychiatry or addiction medicine as de-
6 scribed in clause (ii) from the American Board
7 of Medical Specialties, the American Board of
8 Addiction Medicine, the American Osteopathic
9 Association, the American Society of Addiction
10 Medicine, or such other organization as the Sec-
11 retary determines to be appropriate for pur-
12 poses of this subclause; or
13 "(bb) completes at least 24 hours of train-
14 ing, with respect to the treatment and manage-
15 ment of opiate-dependent patients, addressing
16 the topics listed in subparagraph (G)(ii)(IV).
17 The Secretary may review and update the require-
18 ments of this subclause.
19 "(iv) In the case of a third notification under
20 clause (iii)(III), the practitioner maintains and im-
21 plements a diversion control plan that contains spe-
22 cific measures to reduce the likelihood of the diver-
23 sion of controlled substances prescribed by the prac-
24 titioner for the treatment of opioid use disorder.

1 "(v) In the case of a third notification under
2 clause (iii)(III), the practitioner obtains a written
3 agreement from each patient, including the patient's
4 signature, that the patient—
5 "(I) will receive an initial assessment and
6 treatment plan and periodic assessments and
7 treatment plans thereafter;
8 "(II) will be subject to medication adher-
9 ence and substance use monitoring; and
10 "(III) understands available treatment op-
11 tions, including all drugs approved by the Food
12 and Drug Administration for the treatment of
13 opioid use disorder, including their potential
14 risks and benefits.
15 "(vi) The practitioner will comply with the re-
16 porting requirements of subparagraph (D)(i)(IV).";
17 (2) in subparagraph (D)—
18 (A) in clause (i), by adding at the end the
19 following:
20 "(IV) The practitioner reports to the Secretary,
21 at such times and in such manner as specified by
22 the Secretary, such information and assurances as
23 the Secretary determines necessary to assess wheth-
24 er the practitioner continues to meet the require-
25 ments for a waiver under this paragraph.";

1 (B) in clause (ii), by striking ''Upon re-
2 ceiving a notification under subparagraph (B)''
3 and inserting ''Upon receiving a determination
4 from the Secretary under clause (iii) finding
5 that a practitioner meets all requirements for a
6 waiver under subparagraph (B)''; and
7 (C) in clause (iii)—
8 (i) by inserting ''and shall forward
9 such determination to the Attorney Gen-
10 eral'' before the period at the end of the
11 first sentence; and
12 (ii) by striking ''physician'' and in-
13 serting ''practitioner'';
14 (3) in subparagraph (G)—
15 (A) by amending clause (ii)(IV) to read as
16 follows:
17 ''(IV) The physician has, with respect to
18 the treatment and management of opiate-de-
19 pendent patients, completed not less than eight
20 hours of training (through classroom situations,
21 seminars at professional society meetings, elec-
22 tronic communications, or otherwise) that is
23 provided by the American Society of Addiction
24 Medicine, the American Academy of Addiction
25 Psychiatry, the American Medical Association,

1 the American Osteopathic Association, the
2 American Psychiatric Association, or any other
3 organization that the Secretary determines is
4 appropriate for purposes of this subclause. Such
5 training shall address—
6 "(aa) opioid maintenance and detoxi-
7 fication;
8 "(bb) appropriate clinical use of all
9 drugs approved by the Food and Drug Ad-
10 ministration for the treatment of opioid
11 use disorder;
12 "(cc) initial and periodic patient as-
13 sessments (including substance use moni-
14 toring);
15 "(dd) individualized treatment plan-
16 ning; overdose reversal; relapse prevention;
17 "(ee) counseling and recovery support
18 services;
19 "(ff) staffing roles and considerations;
20 "(gg) diversion control; and
21 "(hh) other best practices, as identi-
22 fied by the Secretary."; and
23 (B) by adding at the end the following:
24 "(iii) The term 'qualifying practitioner'
25 means—

1 "(I) a qualifying physician, as defined in
2 clause (ii); or
3 "(II) a qualifying other practitioner, as de-
4 fined in clause (iv).
5 "(iv) The term 'qualifying other practitioner'
6 means a nurse practitioner or physician assistant
7 who satisfies each of the following:
8 "(I) The nurse practitioner or physician
9 assistant is licensed under State law to pre-
10 scribe schedule III, IV, or V medications for the
11 treatment of pain.
12 "(II) The nurse practitioner or physician
13 assistant satisfies 1 or more of the following:
14 "(aa) Has completed not fewer than
15 24 hours of initial training addressing each
16 of the topics listed in clause (ii)(IV)
17 (through classroom situations, seminar at
18 professional society meetings, electronic
19 communications, or otherwise) provided by
20 the American Society of Addiction Medi-
21 cine, the American Academy of Addiction
22 Psychiatry, the American Medical Associa-
23 tion, the American Osteopathic Associa-
24 tion, the American Nurses Credentialing
25 Center, the American Psychiatric Associa-

1 tion, or any other organization that the
2 Secretary determines is appropriate for
3 purposes of this subclause.
4 "(bb) Has such other training or ex-
5 perience as the Secretary determines will
6 demonstrate the ability of the nurse practi-
7 tioner or physician assistant to treat and
8 manage opiate-dependent patients.
9 "(III) If required by State law, the nurse
10 practitioner or physician assistant prescribes
11 medications for the treatment of opioid use dis-
12 order in collaboration with or under supervision
13 of a physician.
14 The Secretary may review and update the require-
15 ments for being a qualifying other practitioner under
16 this clause."; and
17 (4) in subparagraph (H)—
18 (A) in clause (i), by adding at the end the
19 following:
20 "(III) Such other elements of the requirements
21 under this paragraph as the Secretary determines
22 necessary for purposes of implementing such re-
23 quirements."; and
24 (B) by amending clause (ii) to read as fol-
25 lows:

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

9 (b) RECOMMENDATION OF REVOCATION OR SUSPEN-
10 SION OF REGISTRATION IN CASE OF SUBSTANTIAL NON-
11 COMPLIANCE.—The Secretary of Health and Human
12 Services may recommend to the Attorney General that the
13 registration of a practitioner be revoked or suspended if
14 the Secretary determines, according to such criteria as the
15 Secretary establishes by regulation, that a practitioner
16 who is registered under section 303(g)(2) of the Controlled
17 Substances Act (21 U.S.C. 823(g)(2)) is not in substantial
18 compliance with the requirements of such section, as
19 amended by this Act.

20 (c) OPIOID DEFINED.—Section 102(18) of the Con-
21 trolled Substances Act (42 U.S.C. 802(18)) is amended
22 by inserting ''or 'opioid' '' after ''The term 'opiate' ''.

23 (d) REPORTS TO CONGRESS.—

24 (1) IN GENERAL.—Not later than 2 years after
25 the date of enactment of this Act and not less than

1 over every 5 years thereafter, the Secretary of
2 Health and Human Services, in consultation with
3 the Drug Enforcement Administration and experts
4 in opioid use disorder research and treatment,
5 shall—
6 (A) perform a thorough review of the pro-
7 vision of opioid use disorder treatment services
8 in the United States, including services pro-
9 vided in opioid treatment programs and other
10 specialty and non-specialty settings; and
11 (B) submit a report to the Congress on the
12 findings and conclusions of such review.
13 (2) CONTENTS.—Each report under paragraph
14 (1) shall include an assessment of—
15 (A) compliance with the requirements of
16 section 303(g)(2) of the Controlled Substances
17 Act (21 U.S.C. 823(g)(2)), as amended by this
18 Act;
19 (B) the measures taken by the Secretary of
20 Health and Human Services to ensure such
21 compliance;
22 (C) whether there is further need to in-
23 crease or decrease the number of patients a
24 waivered practitioner is permitted to treat, as

1 provided for by the amendment made by sub-
2 section (a)(1);
3 (D) the extent to which, and proportions
4 with which, the full range of Food and Drug
5 Administration-approved treatments for opioid
6 use disorder are used in routine health care set-
7 tings and specialty substance use disorder treat-
8 ment settings;
9 (E) access to, and use of, other behavioral
10 health and recovery supports;
11 (F) changes in State or local policies and
12 legislation relating to opioid use disorder treat-
13 ment;
14 (G) the use of prescription drug moni-
15 toring programs by practitioners who are per-
16 mitted to dispense narcotic drugs to individuals
17 pursuant to a waiver under section 303(g)(2) of
18 the Controlled Substances Act (21 U.S.C.
19 823(g)(2));
20 (H) the findings resulting from inspections
21 by the Drug Enforcement Administration of
22 practitioners described in subparagraph (G);
23 and
24 (I) the effectiveness of cross-agency col-
25 laboration between Department of Health and

1 Human Services and the Drug Enforcement
2 Administration for expanding effective opioid
3 use disorder treatment.