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.

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
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 by providing the contact information for the nearest applicable practitioner—

“(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 subclauses
(II) and (III), the applicable number is 30.

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

“(III) The applicable number is 250 if the prac-
titioner is a qualifying physician meeting the re-
quirement of subclause (VI) and, not sooner than 1
year after the date on which the practitioner sub-
mitted a second notification under subclause (II),
the practitioner submits a third notification to the
Secretary of the need and intent of the practitioner
to treat up to 250 patients.

“(IV) The Secretary may by regulation change
such total number.

“(V) The Secretary may exclude from the appli-
cable number patients to whom such drugs or com-
binations of drugs are directly administered by the
qualifying practitioner in the office setting.
“(VI) For purposes of subclause (III), a qualifying physician meets the requirement of this subclause if the practitioner or physician—

“(aa) holds a special certification in addiction psychiatry or addiction medicine as described in clause (ii) from the American Board of Medical Specialties, the American Board of Addiction Medicine, the American Osteopathic Association, the American Society of Addiction Medicine, or such other organization as the Secretary determines to be appropriate for purposes of this subclause; or

“(bb) completes at least 24 hours of training, with respect to the treatment and management of opiate-dependent patients, addressing the topics listed in subparagraph (G)(ii)(IV).

The Secretary may review and update the requirements of this subclause.

“(iv) In the case of a third notification under clause (iii)(III), the practitioner maintains and implements a diversion control plan that contains specific measures to reduce the likelihood of the diversion of controlled substances prescribed by the practitioner for the treatment of opioid use disorder.
“(v) In the case of a third notification under clause (iii)(III), the practitioner obtains 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; and

“(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.

“(vi) 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 whether 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 eight 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) 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 1 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, seminar 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 Associa-
tion, 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) If required by State law, the nurse practitioner or physician assistant prescribes medications for the treatment of opioid use disorder in collaboration with or under 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 (II)—

(A) in clause (i), by adding at the end 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 one 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 Non-Compliance.—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 (42 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 non-specialty 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 waived practitioner is permitted to treat, as
provided for by the amendment made by sub-
section (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 set-
tings and specialty substance use disorder treat-
ment settings;

(E) access to, and use of, other behavioral
health and recovery supports;

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

(G) the use of prescription drug moni-
toring programs by practitioners who are per-
mitted 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 col-
laboration between Department of Health and
Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.