

OPIOID USE DISORDER TREATMENT EXPANSION AND
 MODERNIZATION ACT

MAY 10, 2016.—Committed to the Committee of the Whole House on the State of
 the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
 submitted the following

R E P O R T

[To accompany H.R. 4981]

The Committee on Energy and Commerce, to whom was referred
 the bill (H.R. 4981) to amend the Controlled Substances Act to im-
 prove access to opioid use disorder treatment, having considered
 the same, report favorably thereon with an amendment and rec-
 ommend that the bill as amended do pass.

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The amendment is as follows:
 Strike all after the enacting clause and insert the following:

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 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 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 applicable number is 250 if the practitioner is a qualifying physician meeting the requirement of subclause (VI) and, not sooner than 1 year after the date on which the physician submitted a second notification under subclause (II), the practitioner submits a third notification to the Secretary of the need and intent of the physician to treat up to 250 patients.

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

“(V) 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.

“(VI) For purposes of subclause (III), a qualifying physician meets the requirement of this subclause if the 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) has completed not fewer than 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 qualifying physician maintains and implements a diversion control plan that contains specific measures to reduce the likelihood of the diversion of controlled substances prescribed by the physician for the treatment of opioid use disorder.

“(v) In the case of a third notification under clause (iii)(III), the qualifying physician 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;

“(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.

“(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, 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 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 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 waived 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.

PURPOSE AND SUMMARY

H.R. 4981 would amend the Controlled Substances Act (CSA) to expand access to medication-assisted treatment (MAT) for patients with substance use disorder while improving the quality of care and minimizing the potential for drug diversion.

BACKGROUND AND NEED FOR LEGISLATION

In 2014, over ten million people in the United States misused prescription opioids and nearly one million reported heroin use.

More than two million Americans are living with substance use disorder and almost eighty people die every day from an opioid-related overdose. Evidence strongly suggests that expanding the use of MAT and recovery services would have a significant impact in combating this epidemic.

Section 303(g)(2) of the CSA permits qualifying physicians to prescribe buprenorphine, a Schedule III controlled substance, to patients for use in maintenance and detoxification treatment without registering as an opioid treatment program. The CSA imposes limits on the number of patients a qualifying physician may treat with buprenorphine at any one time. A physician who meets the qualifying criteria and files an initial notification of intent (NOI) can treat a maximum of 30 patients at a time. After one year, the practitioner can file a second NOI to treat up to 100 patients at a time. Unfortunately, adequate treatment capacity has not kept pace with the epidemic. By authorizing nurse practitioners and physician assistants to become qualifying practitioners and raising the uppermost patient cap for physicians, H.R. 4981 would expand access to MAT and recovery services. In the process, the bill would improve the quality of care patients receive and minimize diversion.

HEARINGS

The Committee on Energy and Commerce held a hearing on October 8, 2015. The Subcommittee on Health received testimony from:

- Allen Anderson, President, American Orthopaedic Society for Sports Medicine;
- Michael Botticelli, Director, Office of National Drug Control Policy;
- Richard Frank, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services;
- Paul Halverson, Dean, Indiana University, Richard M. Fairbanks School of Public Health;
- Kenneth Katz, Lehigh Valley Health Network, Department of Emergency Medicine;
- Chapman Sledge, Chief Medical Officer, Cumberland Heights; and,
- Robert Corey Waller, Chair, Legislative Advocacy Committee, American Society of Addiction Medicine.

COMMITTEE CONSIDERATION

On April 20, 2016, the Subcommittee on Health met in open markup session and forwarded a discussion draft entitled “Opioid Use Disorder Treatment Expansion and modernization Act,” as amended, to the full Committee by a voice vote. The discussion draft was identical to H.R. 4981. On April 26, 27, and 28, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 4981, as amended, favorably reported to the House by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion

to report legislation and amendments thereto. The following reflects the record votes taken during the Committee consideration:

**COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 60**

BILL: H.R. 4981, Opioid Use Disorder Treatment Expansion and Modernization Act

AMENDMENT: An amendment to H.R. 4981, offered by Ms. DeGette, No. 2, to increase the uppermost patient cap for prescribers from 250 to 500.

DISPOSITION: NOT AGREED TO, by a roll call vote of 21 yeas and 25 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Pallone	X		
Mr. Barton				Mr. Rush	X		
Mr. Whitfield		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Pitts		X		Mr. Green	X		
Mr. Walden		X		Ms. DeGette	X		
Mr. Murphy		X		Ms. Capps	X		
Mr. Burgess		X		Mr. Doyle			
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta		X		Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper		X		Mr. Sarbanes	X		
Mr. Lance		X		Mr. McNerney	X		
Mr. Guthrie				Mr. Welch	X		
Mr. Olson		X		Mr. Lujan	X		
Mr. McKinley		X		Mr. Tonko	X		
Mr. Pompeo		X		Mr. Yarmuth	X		
Mr. Kinzinger		X		Ms. Clarke	X		
Mr. Griffith		X		Mr. Loeb sack			
Mr. Bilirakis				Mr. Schrader	X		
Mr. Johnson		X		Mr. Kennedy	X		
Mr. Long		X		Mr. Cardenas	X		
Mrs. Ellmers		X					
Mr. Bucshon		X					
Mr. Flores		X					
Mrs. Brooks		X					
Mr. Mullin		X					
Mr. Hudson							
Mr. Collins		X					
Mr. Cramer		X					

4/27/2016

**COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 61**

BILL: H.R. 4981, Opioid Use Disorder Treatment Expansion and Modernization Act

AMENDMENT: An amendment to H.R. 4981, offered by Mr. Pallone, No. 3, to increase the uppermost patient cap for prescribers from 250 to 300.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas and 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Pallone	X		
Mr. Barton				Mr. Rush	X		
Mr. Whitfield		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Pitts		X		Mr. Green	X		
Mr. Walden		X		Ms. DeGette	X		
Mr. Murphy		X		Ms. Capps	X		
Mr. Burgess		X		Mr. Doyle			
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta		X		Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper		X		Mr. Sarbanes	X		
Mr. Lance		X		Mr. McNerney	X		
Mr. Guthrie		X		Mr. Welch	X		
Mr. Olson		X		Mr. Lujan	X		
Mr. McKinley		X		Mr. Tonko	X		
Mr. Pompeo		X		Mr. Yarmuth	X		
Mr. Kinzinger		X		Ms. Clarke	X		
Mr. Griffith		X		Mr. Loeb sack	X		
Mr. Bilirakis		X		Mr. Schrader	X		
Mr. Johnson		X		Mr. Kennedy	X		
Mr. Long		X		Mr. Cardenas	X		
Mrs. Elfmers		X					
Mr. Bucshon		X					
Mr. Flores		X					
Mrs. Brooks							
Mr. Mullin		X					
Mr. Hudson							
Mr. Collins							
Mr. Cramer							

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**COMMITTEE ON ENERGY AND COMMERCE -- 114TH CONGRESS
ROLL CALL VOTE # 62**

BILL: H.R. 4981, Opioid Use Disorder Treatment Expansion and Modernization Act

AMENDMENT: An amendment to H.R. 4981, offered by Mr. Lujan, No. 4, to authorize the appropriation of \$1,000,000 for fiscal years 2017 and 2018 to improve opioid prescribing practices to reduce opioid use disorders and overdose.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas and 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Upton		X		Mr. Pallone	X		
Mr. Barton		X		Mr. Rush	X		
Mr. Whitfield		X		Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Engel	X		
Mr. Pitts		X		Mr. Green	X		
Mr. Walden		X		Ms. DeGette	X		
Mr. Murphy		X		Ms. Capps	X		
Mr. Burgess		X		Mr. Doyle			
Mrs. Blackburn		X		Ms. Schakowsky	X		
Mr. Scalise				Mr. Butterfield	X		
Mr. Latta		X		Ms. Matsui	X		
Mrs. McMorris Rodgers				Ms. Castor	X		
Mr. Harper		X		Mr. Sarbanes	X		
Mr. Lance		X		Mr. McNeerney	X		
Mr. Guthrie		X		Mr. Welch	X		
Mr. Olson		X		Mr. Lujan	X		
Mr. McKinley		X		Mr. Tonko	X		
Mr. Pompeo		X		Mr. Yarmuth	X		
Mr. Kinzinger		X		Ms. Clarke	X		
Mr. Griffith		X		Mr. Loeb sack	X		
Mr. Bilirakis		X		Mr. Schrader	X		
Mr. Johnson		X		Mr. Kennedy	X		
Mr. Long		X		Mr. Cardenas	X		
Mrs. Ellmers							
Mr. Bueshon		X					
Mr. Flores		X					
Mrs. Brooks							
Mr. Mullin		X					
Mr. Hudson							
Mr. Collins							
Mr. Cramer							

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COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of this act is to expand access to medication assisted treatment for patients with opioid use disorders while improving the quality of care and minimizing the risk of diversion.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4981 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 4981 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

At the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 4981 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 4981 does not direct any specific rule making within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 provides the short title of “Opioid Use Disorder Treatment Expansion and Modernization Act.”

Section 2. Finding

This section includes a Congressional finding 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.

Section 3. Opioid use disorder treatment modernization

Section 303(g)(2) of the CSA sets forth the conditions that a practitioner must certify they meet as part of a notification of intent (NOI) that must be submitted to the Secretary of Health and Human Services (HHS) prior to being permitted to dispense or prescribe Schedule III, IV, or V controlled substances to patients for maintenance or detoxification treatment in an office-based setting. Currently, buprenorphine, a Schedule III controlled substance, is the only such medication. Section 3 of H.R. 4981 updates such conditions by requiring a practitioner to certify that they can provide directly, by referral, or in such other manner as determined by the Secretary, all FDA-approved drugs, including unscheduled medications, for the treatment of opioid use disorder as well as appropriate counseling and other ancillary services.

Currently, qualifying physicians must be board certified specialists, have completed not fewer than 8 hours of approved training with respect to the treatment and management of opioid-dependent patients, or have met certain other qualifying criteria. After submitting an initial NOI, such practitioner may treat up to 30 patients with buprenorphine at any one time in their office setting. After one year of treating such patients, a practitioner may file a second NOI to treat up to 100 patients at a time. Section 3 of H.R. 4981 would specify the topics that must be covered as part of the 8 hours of approved training that meets the qualifying physician requirement included in 303(g)(2).

Section 3 of H.R. 4981 amends section 303(g)(2) to authorize nurse practitioners and physician assistants to become qualifying practitioners. After completing not fewer than 24 hours of initial training on topics described in this section or meeting other training or experience requirements that may be established by the Secretary, such practitioner may submit an initial NOI to treat up to

30 patients and, after one year, can submit a second NOI to treat up to 100 patients at a time.

Section 3 of H.R. 4981 further amends section 303(g)(2) authorizing qualifying practitioners who are physicians to submit a third NOI, not sooner than a year after submitting their second, to treat up to 250 patients at a time. In the case of a physician who has submitted a third NOI to treat up to 250 patients, a number of additional requirements would apply pursuant to section 3 of H.R. 4981, including implementation of a diversion control plan as well as obtaining written agreements from each patient that they will receive periodic assessments and that they understand that receiving regular counseling services is critical to recovery.

Not later than one year after enactment, the Secretary of HHS, in consultation with outside experts, is required to update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. Not later than two years after enactment and not less than every five years thereafter, the Secretary, in consultation with the Drug Enforcement Administration (DEA) and outside experts, is required to submit a report to Congress after performing a thorough review of the provision of opioid use disorder treatment services in the U.S. Such report shall assess compliance with the requirements of section 303(g)(2) of the CSA, as amended by H.R. 4981; whether there is further need to increase or decrease the number of patients qualifying practitioners are permitted to treat; the percentage of patients receiving counseling and recovery support services; among other items described in this section.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

PART A—SHORT TITLE; FINDINGS AND DECLARATION; DEFINITIONS

* * * * *

DEFINITIONS

SEC. 102. As used in this title:

(1) The term “addict” means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term “administer” refers to the direct application of a controlled substance to the body of a patient or research subject by—

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,
whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(4) The term "Drug Enforcement Administration" means the Drug Enforcement Administration in the Department of Justice.

(5) The term "control" means to add a drug or other substance, or immediate precursor, to a schedule under part B of this title, whether by transfer from another schedule or otherwise.

(6) The term "controlled substance" means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this title. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1954.

(7) The term "counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms "deliver" or "delivery" mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term "depressant or stimulant substance" means—

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

(10) The term "dispense" means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term “distribute” means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical.

(12) The term “drug” has the meaning given that term by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act.

(13) The term “felony” means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term “isomer” means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term “isomer” means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term “isomer” means any optical or geometric isomer.

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance.

(16) The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term “narcotic drug” means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term “opiate” or “opioid” means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term “opium poppy” means the plant of the species *Papaver somniferum* L., except the seed thereof.

(20) The term “poppy straw” means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term “production” includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term “immediate precursor” means a substance—

(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term “Secretary”, unless the context otherwise indicates, means the Secretary of Health, Education, and Welfare.

(25) The term “serious bodily injury” means bodily injury which involves—

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, or organ, or mental faculty.

(26) The term “State” means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term “ultimate user” means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term “United States”, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term “maintenance treatment” means the dispensing, for a period in excess of twenty-one days, of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term “detoxification treatment” means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate

adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term "Convention on Psychotropic Substances" means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term "Single Convention on Narcotic Drugs" means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term "controlled substance analogue" means a substance—

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include—

(i) a controlled substance;

(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term "listed chemical" means any list I chemical or any list II chemical.

(34) The term "list I chemical" means a chemical specified by regulation to the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

- (E) Ergotamine and its salts.
- (F) N-Acetylanthranilic acid, its esters, and its salts.
- (G) Norpseudoephedrine, its salts, optical isomers, and salts of
 - (H) Phenylacetic acid, its esters, and its salts.
 - (I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.
 - (J) Piperidine and its salts.
 - (K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.
 - (L) 3,4-Methylenedioxyphenyl-2-propanone.
 - (M) Methylamine.
 - (N) Ethylamine.
 - (O) Propionic anhydride.
 - (P) Isosafrole.
 - (Q) Safrole.
 - (R) Piperonal.
 - (S) N-Methylephedrine.
 - (T) N-methylpseudoephedrine.
 - (U) Hydriodic acid.
 - (V) Benzaldehyde.
 - (W) Nitroethane.
 - (X) Gamma butyrolactone.
 - (Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term "list II chemical" means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this title, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

- (A) Acetic anhydride.
- (B) Acetone.
- (C) Benzyl chloride.
- (D) Ethyl ether.
- (F) Potassium permanaganate.
- (G) 2-Butanone (or Methyl Ethyl Ketone).
- (H) Toluene.
- (I) Iodine.
- (J) Hydrochloric gas.

(36) The term "regular customer" means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term "regular importer" means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term "regulated transaction" means—

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include—

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with section 310;

(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this title or title III;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to clause (v), unless—

(I) the Attorney General has determined under section 204 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under section 310(b)(3); or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this title and title III based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term “chemical mixture” means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not in-

clude any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes—

- (i) androstenediol—
 - (I) 3 β ,17 β -dihydroxy-5 α -androstane; and
 - (II) 3 α ,17 β -dihydroxy-5 α -androstane;
- (ii) androstenedione (5 α -androst-3,17-dione);
- (iii) androstenediol—
 - (I) 1-androstenediol (3 β ,17 β -dihydroxy-5 α -androst-1-ene);
 - (II) 1-androstenediol (3 α ,17 β -dihydroxy-5 α -androst-1-ene);
 - (III) 4-androstenediol (3 β ,17 β -dihydroxy-androst-4-ene);
 - and
 - (IV) 5-androstenediol (3 β ,17 β -dihydroxy-androst-5-ene);
- (iv) androstenedione—
 - (I) 1-androstenedione ([5 α]-androst-1-en-3,17-dione);
 - (II) 4-androstenedione (androst-4-en-3,17-dione); and
 - (III) 5-androstenedione (androst-5-en-3,17-dione);
- (v) bolasterone (7 α ,17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one);
- (vi) boldenone (17 β -hydroxyandrost-1,4,-diene-3-one);
- (vii) calusterone (7 β ,17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one);
- (viii) clostebol (4-chloro-17 β -hydroxyandrost-4-en-3-one);
- (ix) dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1,4-dien-3-one);
- (x) Δ 1-dihydrotestosterone (a.k.a. “1-testosterone”) (17 β -hydroxy-5 α -androst-1-en-3-one);
- (xi) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one);
- (xii) drostanolone (17 β -hydroxy-2 α -methyl-5 α -androstan-3-one);
- (xiii) ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene);
- (xiv) fluoxymesterone (9-fluoro-17 α -methyl-11 β ,17 β -dihydroxyandrost-4-en-3-one);
- (xv) formebolone (2-formyl-17 α -methyl-11 α ,17 β -dihydroxyandrost-1,4-dien-3-one);
- (xvi) furazabol (17 α -methyl-17 β -hydroxyandrostano[2,3-c]-furazan);
- (xvii) 13 β -ethyl-17 β -hydroxygon-4-en-3-one;
- (xviii) 4-hydroxytestosterone (4,17 β -dihydroxy-androst-4-en-3-one);
- (xix) 4-hydroxy-19-nortestosterone (4,17 β -dihydroxy-estr-4-en-3-one);
- (xx) mestanolone (17 α -methyl-17 β -hydroxy-5 α -androstan-3-one);
- (xxi) mesterolone (1 α -methyl-17 β -hydroxy-[5 α]-androstan-3-one);
- (xxii) methandienone (17 α -methyl-17 β -hydroxyandrost-1,4-dien-3-one);
- (xxiii) methandriol (17 α -methyl-3 β ,17 β -dihydroxyandrost-5-ene);

- (xxiv) methenolone (1-methyl-17 β -hydroxy-5 α -androst-1-en-3-one);
- (xxv) 17 α -methyl-3 β , 17 β -dihydroxy-5 α -androstane;
- (xxvi) 17 α -methyl-3 α , 17 β -dihydroxy-5 α -androstane;
- (xxvii) 17 α -methyl-3 β , 17 β -dihydroxyandrost-4-ene.
- (xxviii) 17 α -methyl-4-hydroxynandrolone (17 α -methyl-4-hydroxy-17 β -hydroxyestr-4-en-3-one);
- (xxix) methyldienolone (17 α -methyl-17 β -hydroxyestra-4,9(10)-dien-3-one);
- (xxx) methyltrienolone (17 α -methyl-17 β -hydroxyestra-4,9-11-trien-3-one);
- (xxxi) methyltestosterone (17 α -methyl-17 β -hydroxyandrost-4-en-3-one);
- (xxxii) mibolerone (7 α , 17 α -dimethyl-17 β -hydroxyestr-4-en-3-one);
- (xxxiii) 17 α -methyl- Δ 1-dihydrotestosterone (17 β -hydroxy-17 α -methyl-5 α -androst-1-en-3-one) (a.k.a. "17- α -methyl-1-testosterone");
- (xxxiv) nandrolone (17 β -hydroxyestr-4-en-3-one);
- (xxxv) norandrostenediol—
 - (I) 19-nor-4-androstenediol (3 β , 17 β -dihydroxyestr-4-ene);
 - (II) 19-nor-4-androstenediol (3 α , 17 β -dihydroxyestr-4-ene);
 - (III) 19-nor-5-androstenediol (3 β , 17 β -dihydroxyestr-5-ene); and
 - (IV) 19-nor-5-androstenediol (3 α , 17 β -dihydroxyestr-5-ene);
- (xxxvi) norandrostenedione—
 - (I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and
 - (II) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
- (xxxvii) norbolethone (13 β , 17 α -diethyl-17 β -hydroxygon-4-en-3-one);
- (xxxviii) norclostebol (4-chloro-17 β -hydroxyestr-4-en-3-one);
- (xxxix) norethandrolone (17 α -ethyl-17 β -hydroxyestr-4-en-3-one);
- (xl) normethandrolone (17 α -methyl-17 β -hydroxyestr-4-en-3-one);
- (xli) oxandrolone (17 α -methyl-17 β -hydroxy-2-oxa-[5 α]-androstan-3-one);
- (xlii) oxymesterone (17 α -methyl-4,17 β -dihydroxyandrost-4-en-3-one);
- (xliii) oxymetholone (17 α -methyl-2-hydroxymethylene-17 β -hydroxy-[5 α]-androstan-3-one);
- (xliv) stanozolol (17 α -methyl-17 β -hydroxy-[5 α]-androst-2-eno[3,2-c]-pyrazole);
- (xlv) stenbolone (17 β -hydroxy-2-methyl-[5 α]-androst-1-en-3-one);
- (xlvi) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
- (xlvii) testosterone (17 β -hydroxyandrost-4-en-3-one);
- (xlviii) tetrahydrogestrinone (13 β , 17 α -diethyl-17 β -hydroxygon-4,9,11-trien-3-one);
- (xlix) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one);
- (l) 5 α -Androstan-3,6,17-trione;
- (li) 6-bromo-androstan-3,17-dione;

- (lii) 6-bromo-androsta-1,4-diene-3,17-dione;
- (liii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (liv) 4-chloro-17 α -methyl-androst-4-ene-3 β ,17 β -diol;
- (lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-en-3-one;
- (lvi) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-ene-3,11-dione;
- (lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -androstan-3-one;
- (lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -androstan-3-one;
- (lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-17 β -ol;
- (lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;
- (lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;
- (lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;
- (lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lxv) Estra-4,9,11-triene-3,17-dione;
- (lxvi) 18 α -Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
- (lxvii) 6 α -Methyl-androst-4-ene-3,17-dione;
- (lxviii) 17 α -Methyl-androstan-3-hydroxyimine-17 β -ol;
- (lxix) 17 α -Methyl-5 α -androstan-17 β -ol;
- (lxx) 17 β -Hydroxy-androstano[2,3-d]isoxazole;
- (lxxi) 17 β -Hydroxy-androstano[3,2-c]isoxazole;
- (lxxii) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;
- (lxxiii) [3,2-c]pyrazole-androst-4-en-17 β -ol;
- (lxxiv) [3,2-c]pyrazole-5 α -androstan-17 β -ol; and
- (lxxv) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of subsections (a) through (c) of section 201.

(B)(i) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(ii) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this Act if—

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either—

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting

that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it—

(I) is—

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical;

or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(III) is not anabolic or androgenic.

(iii) In accordance with section 515(a), any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(42) The term “international transaction” means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms “broker” and “trader” mean a person that assists in arranging an international transaction in a listed chemical by—

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term “felony drug offense” means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45)(A) The term “scheduled listed chemical product” means, subject to subparagraph (B), a product that—

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under section 201(a) added to any of the schedules under section 202(c). In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term “regulated seller” means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term “mobile retail vendor” means a person or entity that makes sales at retail from a stand that is intended to be tem-

porary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term “at retail”, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49)(A) The term “retail distributor” means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

(51) The term “deliver, distribute, or dispense by means of the Internet” refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term “online pharmacy”—

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include—

(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 303(f) and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f);

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under section 303(f) whose dispensing of controlled substances via the Internet consists solely of—

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an “online pharmacy”.

(53) The term “homepage” means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term “practice of telemedicine” means, for purposes of this title, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act, which practice—

(A) is being conducted—

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f); and

(ii) by a practitioner—

(I) acting in the usual course of professional practice;

(II) acting in accordance with applicable State law; and

(III) registered under section 303(f) in the State in which the patient is located, unless the practitioner—

(aa) is exempted from such registration in all States under section 302(d); or

(bb) is—

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

- (BB) registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);
- (B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—
- (i) acting in the usual course of professional practice;
 - (ii) acting in accordance with applicable State law; and
 - (iii) registered under section 303(f) in the State in which the patient is located, unless the practitioner—
 - (I) is exempted from such registration in all States under section 302(d); or
 - (II) is—
 - (aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and
 - (bb) registered under section 303(f) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);
- (C) is being conducted by a practitioner—
- (i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;
 - (ii) acting within the scope of the employment, contract, or compact described in clause (i); and
 - (iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);
- (D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and
- (ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;
- (E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);
- (F) is being conducted—
- (i) in a medical emergency situation—
 - (I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(f) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;
 - (II) that prevents the patient from being physically present at a hospital or clinic operated by the Depart-

ment of Veterans Affairs registered under section 303(f);

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner that—

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f); and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(55) The term “refilling prescriptions for controlled substances in schedule III, IV, or V”—

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of subsections (b) and (c) of section 309, as appropriate; and

(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if—

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 309 (in this paragraph referred to as the “original prescription”);

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

* * * * *

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES; PIPERIDINE REPORTING

* * * * *

REGISTRATION REQUIREMENTS

SEC. 303. (a) The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on the effective date of this part. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

(2) compliance with applicable State and local law;

(3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;

(4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 306.

(d) The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

(e) The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) past experience in the distribution of controlled substances; and
- (5) such other factors as may be relevant to and consistent with the public health and safety.

(f) The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public in-

terest. In determining the public interest, the following factors shall be considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 304(a). Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this title.

(g)(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)—

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 307) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including

the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

[(i) The practitioner is a qualifying physician (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 refer the patients for appropriate counseling and other appropriate ancillary services.

[(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, 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. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.]

(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 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 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 applicable number is 250 if the practitioner is a qualifying physician meeting the requirement of subclause (VI) and, not sooner than 1 year after the date on

which the physician submitted a second notification under subclause (II), the practitioner submits a third notification to the Secretary of the need and intent of the physician to treat up to 250 patients.

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

(V) 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.

(VI) For purposes of subclause (III), a qualifying physician meets the requirement of this subclause if the 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) has completed not fewer than 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 qualifying physician maintains and implements a diversion control plan that contains specific measures to reduce the likelihood of the diversion of controlled substances prescribed by the physician for the treatment of opioid use disorder.

(v) In the case of a third notification under clause (iii)(III), the qualifying physician 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;

(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.

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

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(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.*

(ii) **Upon receiving a notification under subparagraph (B)** *Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).*

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) *and shall forward such determination to the Attorney General.* If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the **physician** *practitioner* an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 304(a)(4), consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practi-

tioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term “group practice” has the meaning given such term in section 1877(h)(4) of the Social Security Act.

(ii) The term “qualifying physician” means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.

(II) The physician holds an addiction certification from the American Society of Addiction Medicine.

(III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.

[(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.]

(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.*

(V) *The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.*

(VI) *The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.*

(VII) *The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.*

(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, 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.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

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

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

[(ii) Not later than 120 days after the date of the enactment of the Drug Addiction Treatment Act of 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commis-

sioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.】

(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.

(I) During the 3-year period beginning on the date of the enactment of the Drug Addiction Treatment Act of 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.

(J)(i) This paragraph takes effect on the date of the enactment of the Drug Addiction Treatment Act of 2000, and remains in effect thereafter.

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on the date of the enactment of the Office of National Drug Control Policy Reauthorization Act of 2006, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this Act; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective 60 days after the date on which the decision is so published. The Secretary shall in mak-

ing any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 102(39)(A). In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(i)(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 304(c), unless the Attorney General has granted a hearing on the application under section 1008(i) of the Controlled Substances Import and Export Act.

(j) In this section, the phrase “factors as may be relevant to and consistent with the public health and safety” means factors that are relevant to and consistent with the findings contained in section 101.

* * * * *

EXCHANGE OF LETTERS WITH ADDITIONAL COMMITTEES OF REFERRAL

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HANSERL G. JEFFERS, New York
DAVID DUNLAP, Rhode Island
SCOTT PETERS, California

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON THE JUDICIARY
2138 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-8218
(202) 225-3551
<http://www.house.gov/judiciary>

May 3, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Upton,

I am writing with respect to H.R. 4981, the "Opioid Use Disorder Treatment Expansion and Modernization Act," which was referred to the Committee on Energy and Commerce and in addition to the Committee on the Judiciary. As a result of your having consulted with us on provisions in H.R. 4981 that fall within the Rule X jurisdiction of the Committee on the Judiciary, I agree to discharge our Committee from further consideration of this bill so that it may proceed expeditiously to the House floor for consideration.

The Judiciary Committee takes this action with our mutual understanding that by foregoing consideration of H.R. 4981 at this time, we do not waive any jurisdiction over subject matter contained in this or similar legislation, and that our Committee will be appropriately consulted and involved as this bill or similar legislation moves forward so that we may address any remaining issues in our jurisdiction. Our Committee also reserves the right to seek appointment of an appropriate number of conferees to any House-Senate conference involving this or similar legislation, and asks that you support any such request.

I would appreciate a response to this letter confirming this understanding with respect to H.R. 4981, and would ask that a copy of our exchange of letters on this matter be included in the *Congressional Record* during Floor consideration of H.R. 4981.

Sincerely,

Bob Goodlatte
Chairman

cc: The Honorable John Conyers, Jr.
The Honorable Frank Pallone
The Honorable Paul Ryan, Speaker
Mr. Thomas J. Wickham, Jr., Parliamentarian

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
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May 3, 2016

The Honorable Bob Goodlatte
Chairman
Committee on the Judiciary
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Goodlatte,

Thank you for your letter regarding H.R. 4891, the "Opioid Use Disorder Treatment Expansion and Modernization Act."

I appreciate your willingness to forgo action on the bill, and I agree that your decision will in no way diminish or alter the jurisdiction of the Committee on the Judiciary with respect to the appointment of conferees or to any future jurisdictional claim over the subject matters contained in the bill or similar legislation.

I will include a copy of your letter and this response in the *Congressional Record* during consideration of H.R. 4891 on the House floor.

Sincerely,



Fred Upton
Chairman

