

ENSURING PATIENT ACCESS AND EFFECTIVE DRUG
 ENFORCEMENT ACT OF 2015

APRIL 20, 2015.—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. 471]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred
 the bill (H.R. 471) to improve enforcement efforts related to pre-
 scription drug diversion and abuse, and for other purposes, having
 considered the same, report favorably thereon without amendment
 and recommend that the bill do pass.

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PURPOSE AND SUMMARY

H.R. 471 would help prevent prescription drug abuse, while ensuring that patients have access to needed medications by fostering better collaboration between drug manufacturers, wholesalers, pharmacies, the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA).

BACKGROUND AND NEED FOR LEGISLATION

In accord with their professional medical caregivers, millions of Americans rely on prescription drugs to treat and cure illnesses, alleviate pain, and prolong and improve the quality of their lives. Unfortunately, despite the efforts of Federal agencies and private parties in the prescription drug supply chain to halt and prevent drug abuse and diversion, prescription drug abuse kills tens of thousands of Americans each year.¹

The supply chain involves a myriad of stakeholders, which includes drug manufacturers, wholesale distributors, doctors, nurses, pharmacists, hospitals, and retail pharmacies. In order to provide prescriptions to millions of Americans, the system must function efficiently and seamlessly, and deliver each dose to a pre-designated destination and patient.

Protecting the system from criminal exploitation while also ensuring its efficacy requires significant investment from both the government's enforcement and oversight agencies and the system's private operators. Law enforcement must have the tools to act decisively and quickly. Private industry must have the assurance that lawful conduct will ensure due process, protect them from secondary liability, and shield them from disabling disruptions—disruptions that endanger the health and safety of individual patients. The integrity of the system depends on clear rules for enforcement agencies and for providers.

H.R. 471 would clarify these rules by providing certainty with how Federal authorities will apply the law when undertaking enforcement actions, and by increasing the investment that private industry must make to ensure the integrity of the system.

HEARINGS

The Committee on Energy and Commerce held a hearing on January 27, 2015. The Subcommittee received testimony from:

- Mr. Ben D. Chlapek, Deputy Chief, Central Jackson County Fire, Blue Springs, Missouri;
- Mr. John L. Eadie, Director, Prescription Drug Monitoring Program Center of Excellence, Brandeis University;
- Dr. Blaine Enderson, Department of Surgery, University of Tennessee Medical Center;
- Dr. Nathan Fountain, Professor of Neurology, University of Virginia; and,
- Mr. Linden Barber, Partner and Director, DEA Compliance Operations, Quarles & Brady.

¹<http://www.cdc.gov/homeandrecreationalafety/rxbrief/>.

COMMITTEE CONSIDERATION

On February 4, 2015, the Subcommittee on Health met in open markup session to consider H.R. 471 and forwarded the bill to the full Committee, without amendment, by a voice vote. On February 11 and 12, 2015, the full Committee met in open markup session to consider H.R. 471 and ordered the bill favorably reported to the House, without amendment, 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. There were no record votes taken in connection with ordering H.R. 471 reported. A motion by Mr. Upton to order H.R. 471 reported to the House, without amendment, was agreed to by a voice vote.

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 address the nation's prescription drug abuse crisis by improving the working relationship between private industry, government agencies, providers, and patient advocates.

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. 471 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. 471 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.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,
 CONGRESSIONAL BUDGET OFFICE,
 Washington, DC, February 26, 2015.

Hon. FRED UPTON,
 Chairman, Committee on Energy and Commerce,
 House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 471, the Ensuring Patient Access and Effective Drug Enforcement Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Mark Grabowicz.

Sincerely,

DOUGLAS W. ELMENDORF,
 Director.

Enclosure.

H.R. 471—Ensuring Patient Access and Effective Drug Enforcement Act of 2015

H.R. 471 would modify certain administrative procedures followed by the Department of Justice in regulating legitimate uses of controlled substances. In addition, within one year of enactment, the bill would require the Department of Health and Human Services to assess the effect of law enforcement activities on access to medications, examine potential benefits to patients from collaborations between governments and stakeholders, and report to the Congress on these matters.

Based on the cost of similar activities, CBO estimates that implementing the bill would cost less than \$500,000 over the 2015–2016 period; any spending would be subject to the availability of appropriated funds. Enacting the legislation would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 471 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would impose no costs on state, local, or tribal governments.

The CBO staff contacts for this estimate are Mark Grabowicz and Chad Chirico. The estimate was approved by Theresa Gullo, Deputy Assistant Director for Budget Analysis.

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. 471 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. 471 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

This section provides the short title of “Ensuring Patient Access and Effective Drug Enforcement Act of 2015.”

*Section 2: Registration process under Controlled Substances Act**Part (a), Definitions*

In part (a), the bill would clarify two definitions within the Controlled Substances Act (CSA) essential to providing a clear path forward for the enforcement agencies and lawful purveyors of controlled substances. These two clarifications would establish clear standards for the Drug Enforcement Administration that will facilitate consistent enforcement of the CSA and protect the due process rights of lawful providers of controlled substances, preventing overly broad and unsubstantiated enforcement orders. The technical clarifications will promote certainty in the regulatory and enforcement regime, allowing law enforcement to use resources more efficiently and protecting patients from unintended disruptions in the supply chain.

First, the bill specifies that the phrase “consistent with the public health and safety” corresponds to a “substantial relationship to . . . preventing diversion and abuse of controlled substances.” The vague phrase “consistent with the public health and safety” requires explanation because it has created inconsistent enforcement actions and has left the courts of review with uncertainty about Congress’ intent. This clarification will ensure that law enforcement can investigate and target dangerous offenders more effectively without wasting resources on unconnected parties in the supply chain.

Current law does not define the phrase “consistent with public health and safety.” Its closest corollary, “consistent with the public interest,” has been the subject of numerous court decisions and regulatory proceedings within antitrust and administrative law, for example. Unlike the “public interest,” the Executive Branch has never promulgated regulations or issued legal guidance concerning the CSA’s “consistent with public health and safety.” Congress enacted the CSA to halt and prevent the diversion and abuse of controlled substances, and this clarification reaffirms this central pur-

pose of the CSA. The term “consistent with the public health and safety” now will be defined as having a substantial relationship to the CSA’s purpose of preventing diversion and abuse of controlled substances.

Second, the bill defines “imminent danger” to include those circumstances that pose a “significant and present risk of death or serious bodily harm that is more likely than not to occur in the absence of an immediate suspension order.” The vagueness of the term “imminent danger” has created uneven enforcement applications, and this clarification will ensure that action will take place only in the presence of direct and urgent danger.

This clarification harmonizes the CSA with other statutes using the “imminent danger” standard, namely the Federal Mine Safety and Health Act (“Mine Act”) and Occupational Safety and Health Act (“OSHA”). Both the Mine Act and OSHA authorize Federal authorities to take expedited action when serious, current, and persistent threats persist. The circumstances must be grave and immediate because such Federal action denies the subjects of the enforcement their ability to function.

Part (b), Opportunity to submit corrective action plan prior to revocation or suspension

To ensure transparency and due process, part (b) requires that when the Attorney General suspends or revokes a party’s registration—the registration that enables the party to operate lawfully within the controlled substance market—that the Attorney General must provide notice to the party, cite with specificity any laws that may have been contravened, and give the party the opportunity to submit a corrective action plan in order to remedy any potential violations. The Attorney General must weigh the registrant’s corrective action plan and suggest additional changes as any revocation or suspension actions proceed.

Preventing diversion and drug abuse depends on consistent application of the CSA, and this provision ensures that law enforcement and private registrants will collaborate to achieve these aims.

Section 3: Report to Congress on effects of law enforcement activities on patient access to medications

Finally, this bill would require the Secretary of Health and Human Services to work with the Commissioner of the Food and Drug Administration, Director of the Centers for Disease Control and Prevention, Administrator of the DEA, and Director of the Director of National Drug Control Policy to submit a report to Congress within one year of enactment. The report will assess how patient access to medication could be adversely affected by Federal and State law enforcement activities and identify how collaboration between agencies and stakeholders can benefit patients and prevent diversion and abuse of controlled substances. This report will incorporate feedback and recommendations from stakeholders, including: patient groups, pharmacies, drug manufacturers, common or contract carriers and warehousemen, hospitals, physicians, long term care providers, State attorneys general, law enforcement officials, health benefit plans and entities that provide pharmacy benefit management services on behalf of a health benefit plan, and wholesale drug distributors.

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, existing law in which no change is proposed is shown in roman):

CONTROLLED SUBSTANCES ACT

TITLE II—CONTROL AND ENFORCEMENT

* * * * *

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 interest. 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.

(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).

(ii) Upon receiving a notification 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). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician 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 practitioner 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.

(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.

(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.

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 Commissioner 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.

(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 making 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) *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.*

DENIAL, REVOCATION, OR SUSPENSION OF REGISTRATION

SEC. 304. (a) A registration pursuant to section 303 to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

(1) has materially falsified any application filed pursuant to or required by this title or title III;

(2) has been convicted of a felony under this title or title III or any other law of the United States, or of any State, relating to any substance defined in this title as a controlled substance or a list I chemical;

(3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;

(4) has committed such acts as would render his registration under section 303 inconsistent with the public interest as determined under such section; or

(5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1128(a) of the Social Security Act.

A registration pursuant to section 303(g)(1) to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 303(g)(1).

(b) The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

[(c) Before] *(c)(1) Before* taking action pursuant to this section, or pursuant to a denial of registration under section 303, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. **[Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5 of the United States Code. Such proceedings shall be independent of, and not in lieu of, criminal prosecution or other proceedings under this title or any other law of the United States.]**

(2) An order to show cause under paragraph (1) shall—

(A) contain a statement of the basis for the denial, revocation, or suspension, including specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but no less than thirty days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation or suspension pro-

ceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this title or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

[(d) The Attorney General] *(d)(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 303(g)(1) may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.*

(2) In this subsection, the phrase "imminent danger to the public health or safety" means that, in the absence of an immediate suspension order, controlled substances—

(A) will continue to be intentionally distributed or dispensed—

(i) outside the usual course of professional practice; or

(ii) in a manner that poses a present or foreseeable risk of serious adverse health consequences or death; or

(B) will continue to be intentionally diverted outside of legitimate distribution channels.

(e) The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 306.

(f) In the event the Attorney General suspends or revokes a registration granted under section 303, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 511(e). All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

(g) The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has

ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substances or list I chemicals seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

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