Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act

Members Present:

William T. Winsley (OH), *chair and Executive Committee liaison*; Susan DelMonico (RI); Rebecca Deschamps (MT); Benjamin Fry (TX); Caroline Juran (VA); Suzan Kedron (TX); Susan Martin (CO); Jerry Moore (AL); Suzanne Neuber (OH); Frank Whitchurch (KA).

Others Present:

Carmen Catizone, Melissa Madigan, Eileen Lewalski, Emily Shaffer, Deborah Zak, *NABP staff.*

Introduction:

The Task Force to Review and Recommend Revisions to the Controlled Substances Act met January 24-25, 2012, at NABP Headquarters. This task force was held subsequent to the 2011 task force of the same name, which was established in response to Resolution 106-6-10. During that initial task force meeting, members reviewed and identified potential revisions to the Controlled Substances Act (CSA) and accompanying regulations. In continuation of the original meeting, task force members discussed the proposed recommendations, introduced additional revisions, and agreed upon requesting amendments to several provisions of the CSA.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review the recommendations made by the 2010-2011 Task Force to Review and Recommend Revisions to the Controlled Substances Act.
2. Recommend additional revisions, if necessary, to the Controlled Substances Act or accompanying Code of Federal Regulations.
3. Present recommendations to Congress.

<u>Recommendation 1: NABP Recommends Revising the Controlled Substances Act</u>

The task force recommends the following revisions to the CSA, which are denoted by <u>underlines</u> and ~~strikethroughs~~.

SUBCHAPTER I -- CONTROL AND ENFORCEMENT

Part A -- Introductory Provisions

Section 801. Congressional Findings and Declarations: Controlled Substances

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Section 802. Definitions

As used in this subchapter:

(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.~~ an individual who suffers from addiction, which is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as 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.~~

means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or by 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~~ prescribing practitioner, dispenser, or ultimate user; 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.

…

(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.

…

(10) The term "dispense" means to deliver a controlled substance to an ultimate user, ultimate user's agent, 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, ultimate user's agent, 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.

…

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacist, 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 prescribe, 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 “prescribe” means a direction or authorization, by prescription, permitting an ultimate user to lawfully obtain or be administered controlled substances from any person authorized by law to dispense or administer such substances.

(23) The term “prescription” means a written, electronic, or oral order for a controlled substance issued by a practitioner for an ultimate user.

…

(~~27~~29) The term "ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his or her own use ~~or for the use of a member of his household~~ or for an animal owned by him or her ~~or by a member of his household~~.

…

~~(51)~~ (52) The term "deliver, distribute, prescribe, or dispense, by means of the Internet" refers, respectively, to any delivery, distribution, prescribing, or dispensing, of a controlled substance that is caused or facilitated by means of the Internet.

Part B -- Authority to Control; Standards and Schedules

Section 811. Authority and Criteria for Classification of Substances

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Section 812. Schedules of Controlled Substances

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Section 813. Treatment of Controlled Substance Analogues

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Section 814. Removal of Exemption of Certain Drugs

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Part C -- Registration of Manufacturers, Distributors, Prescribers, and Dispensers of Controlled Substances

Section 821. Rules and Regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, prescribing, and dispensing of controlled substances and to listed chemicals.

Section 822. Persons Required to Register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who prescribes or dispenses, or who proposes to prescribe or dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, prescribe, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, prescribe, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, prescriber, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25) \1\ of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, prescribers, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

Section 823. Registration Requirements

(a) Manufacturers of controlled substances in schedule I or II

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 May 1, 1971. 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, prescribing 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) Distributors of controlled substances in schedule I or II

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 control 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, prescribing, 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) Limits of authorized activities

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 826 of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

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, prescribing, or dispensing of such substances;

(5) past experience in the manufacture, distribution, prescribing, 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) Distributors of controlled substances in schedule III, IV, or V

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, prescribing, 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) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to prescribe, 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 prescribe, 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 prescribing, 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, prescribing, 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.

…

(g) Practitioners prescribing and dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who prescribe or 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 827 of this title) 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 prescribing and 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 prescribing or 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 prescribing or 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 [21 U.S.C. 301 et seq.] or section 262 of title 42, 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) of this section.

(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) of this section.

(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) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has <u>prescribed or</u> 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), <u>prescribes or</u> 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 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section 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 <u>prescribing or</u> 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, prescribe, or 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 1395nn(h)(4) of title 42.

(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) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination 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.

…

(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 prescribed or dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

…

Section 824. Denial, Revocation, or Suspension of Registration

Grounds

(a) A registration pursuant to section 823 of this title to manufacture, distribute, prescribe, 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 subchapter or subchapter II of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter or any other law of the United States, or of any State, relating to any substance defined in this subchapter 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, prescribing, or dispensing of controlled substances or a 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 823 of this title 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 1320a-7(a) of Title 42.

A registration pursuant to section 823(g) of this title to prescribe or 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 823(g)(1) of this title.

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Section 829. Prescriptions

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user or ultimate user's agent, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C. 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be filled six months after date of issuance or be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user or ultimate user's agent, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act [21 U.S.C. 353(b)]. Such prescriptions may not be filled or refilled more than six months after the date of issuance ~~thereo~~f or be refilled more than five times after the date of issuance of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential

Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) Controlled substances dispensed to practitioner for administration to ultimate user

Controlled substances may be dispensed directly to a practitioner for immediate administration to an ultimate user.

(~~e~~f) Controlled substances dispensed by means of the Internet

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

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Part D -- Offenses and Penalties

Section 842. Prohibited Acts B

(a) Unlawful acts

It shall be unlawful for any person--

(1) who is subject to the requirements of part C to distribute, prescribe or dispense a controlled substance in violation of section 829 of this title;

(2) who is a registrant to distribute, prescribe, or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;

...

Section 843. Prohibited Acts C

(a) Unlawful acts

It shall be unlawful for any person knowingly or intentionally --

(1) who is a registrant to distribute a controlled substance classified in schedule I or II,in the course of his legitimate business, except pursuant to an order or an order form as required by section 828 of this title;

(2) to use in the course of the manufacture, distribution, prescribing, or dispensing of a controlled substance, or to use for the purpose of acquiring or obtaining a controlled substance, a registration number which is fictitious, revoked, suspended, expired, or issued to another person;

…

(c) Advertisement

…

(2)(A) It shall be unlawful for any person to knowingly or intentionally use the Internet, or cause the Internet to be used, to advertise the sale of, or to offer to sell, distribute, prescribe, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized by this subchapter or by the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

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Part E -- Administrative And Enforcement Provisions

Section 871. Attorney General

(a) Delegation of functions

The Attorney General may delegate any of his functions under this subchapter to any officer or employee of the Department of Justice.

(b) Rules and regulations

The Attorney General may promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter. Such rules, regulations, and procedures shall be reviewed every 10 years and public comments shall be solicited as part of that review process.

(c) Acceptance of devises, bequests, gifts, and donations

The Attorney General may accept in the name of the Department of Justice any form of devise, bequest, gift, or donation where the donor intends to donate property for the purpose of preventing or controlling the abuse of controlled substances. He may take all appropriate steps

to secure possession of such property and may sell, assign, transfer, or convey any such property other than moneys.

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Sec. 872. Education and research programs of Attorney General

(a) Authorization

The Attorney General is authorized to carry out educational and research programs directly related to enforcement of the laws under his jurisdiction concerning drugs or other substances which are or may be subject to control under this subchapter. Such programs may include--

…

(e) Use of controlled substances in research

The Attorney General, on his own motion or at the request of the Secretary, may authorize the possession, distribution, prescribing, and dispensing of controlled substances by persons engaged in research. Persons who obtain this authorization shall be exempt from State or Federal prosecution for possession, distribution, prescribing, and dispensing of controlled substances to the extent authorized by the Attorney General.

…

Section 886a. Diversion Control Fee Account

(1) In general

There is established in the general fund of the Treasury a separate account which shall be known as the Diversion Control Fee Account. For fiscal year 1993 and thereafter:

…

(2) Definitions

In this section:

(A) Diversion control program

The term "diversion control program" means the controlled substance and chemical diversion control activities of the Drug Enforcement Administration.

(B) Controlled substance and chemical diversion control activities

The term "controlled substance and chemical diversion control activities" means those activities related to the registration and control of the manufacture, distribution, prescribing, dispensing, importation, and exportation of controlled substances and listed chemicals.

Part F -- General Provisions

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Subchapter II -- Import and Export

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Background:

The task force members reviewed the 2010-2011 Report of the Task Force to Review and Recommend Revisions to the Controlled Substances Act and determined they would focus on recommending revisions only to the CSA so as to follow federal procedure. Members determined that once the CSA is revised, the relevant Code of Federal Regulations (CFR) can then be addressed. The task force discussed the CSA sections that required revisions and the recommendations agreed upon are summarized below:

- **Section 802. Definitions**
  - "Addict" – agreed with the 2010-2011 task force recommendation;
  - "Administer" – agreed with the 2010-2011 task force recommendation in that "administer," "dispense," and "prescribe" should be separate practitioner functions;
  - "Agent" – added "prescriber" and "ultimate user" to expand the definition;
  - "Dispense" – agreed with the 2010-2011 task force recommendation but determined that "ultimate user's agent" needed to be included in the definition and also determined that wherever "dispense" appeared in the CSA, revision may be necessary to add "prescribing" as a separate function;
  - "Practitioner" – agreed with the 2010-2011 task force recommendation that "pharmacist" should be added;
  - "Prescribe" – agreed with the 2010-2011 task force recommendation;
  - "Prescription" – added new definition for clarity; and
  - "Ultimate User" – revised to reflect revisions to "agent."
- **Section 821. Rules and Regulations**
  - Added "prescribing" as a separate practitioner function.
- **Section 822. Persons Required to Register**
  - Added "prescribe" and "prescribing" as a separate practitioner function, where necessary, throughout entire section.
- **Section 823. Registration Requirements**
  - Added "prescribing" as a separate practitioner function, where necessary, throughout entire section.
- **Section 824. Denial, Revocation, or Suspension of Registration**
  - Added "prescribe" as a separate practitioner function.

- **Section 829. Prescriptions**
  - Added "ultimate user's agent" for consistency throughout the CSA, limited the time in which a schedule II controlled substance can be filled to six months, and clarified that a controlled substance may be dispensed directly to a practitioner for administration to an ultimate user.
- **Section 842. Prohibited Acts B**
  - Added "prescribe" as a separate practitioner function.
- **Section 843. Prohibited Acts C**
  - Added "prescribe" and "prescribing" as a separate practitioner function.
- **Sec. 872. Education and research programs of Attorney General**
  - Added "prescribing" as a separate practitioner function.
- **Section 886a. Diversion Control Fee Account**
  - Added "prescribing" as a separate practitioner function.
- **Section 871. Attorney General**
  - Added provision that mandates a 10-year review for all rules, regulations, and procedures.

Recommendation 2: NABP Introduce the Proposed Revisions to the CSA to the US Congress

The task force recommends that NABP take the necessary steps in order to introduce the proposed revisions to the CSA to the appropriate members of the US Congress.

Background:

The task force chairperson informed the members that legislation must be introduced in Congress in order to have the task force's recommended revisions to the CSA considered by DEA. The task force determined that the most appropriate sponsor who could accomplish this would be a member of the Senate Committee on the Judiciary.

Recommendation 3: NABP Send a Letter to Drug Enforcement Administration (DEA) Requesting a Review of 21 CFR 1304.04, 21 CFR 1306.25, and 21 CFR 1306.26 and Consider Revising According to the 2010-2011 Task Force's Recommendations

The task force recommends that NABP send a letter to DEA requesting a review of certain provisions in the CFR, specifically, 21 CFR 1304.04, 21 CFR 1306.25, and 21 CFR 1306.26, which pertain to prescription transfers and electronic storage of records, and requesting that DEA consider revising them according to the recommendations made by the 2010-2011 task force.

Background:

Although the task force agreed to first address the CSA, members decided that several CFR provisions, which the 2010-2011 task force recommended revising pertaining to prescription transfers and electronic storage of records, could possibly be addressed sooner. The task force opined that DEA has the ability to revise the CFR without a congressional directive and recommended that NABP not provide specific language but rather request that DEA strongly consider allowing for all records to be stored electronically at a central location, including executed order forms and inventories; removing the requirement that prescription transfers must be communicated directly between two licensed pharmacists where the pharmacies share an electronic, real-time, online database; as well as allowing for an electronic record for the dispensing of nonprescription controlled substances. Members concurred that the letter should encourage that revisions such as these, which reflect technological advances, be implemented in a timely manner.

Recommendation 4: NABP Send a Letter to the Department of Health and Human Services Requesting a Review of 21 CFR 290.5, which Contains the Required Prescription Label Warning Statement for Schedule II through IV Controlled Substances Prescriptions, and Recommend Removing or Revising

The task force recommends that NABP send a letter to the Secretary of the Department of Health and Human Services (HHS) requesting that 21 CFR 290.5, which contains the warning statement that is required on the prescription label for Schedule II through IV controlled substance prescriptions, be reviewed and revised according to the 2010-2011 task force's recommendation.

Background:

The task force agreed this was another CFR provision that currently warranted review and possible revision by the appropriate entity. The 2010-2011 task force "realized that the spirit of the warning label is to decrease rampant drug abuse and addiction, but believed that the label should only contain important patient information." Members agreed with the previous task force's recommendation that the warning statement should be removed; however, if HHS determines that the current statement should remain, NABP should urge that it be reworded for increased understandability to "It is unlawful to share this medication."

Recommendation 5: NABP Staff Review the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (*Model Act)* and Suggest Amendments to Reflect the Recommended Revisions to the CSA and CFR

The task force recommends that NABP staff review and suggest appropriate amendments to the *Model Act* that incorporate the recommended revisions to the CSA and CFR.