status available to the public for comment. APHIS will announce the availability of this information by publishing a notice in the **Federal Register**.

(c) *Determination.* Based on the reassessment conducted in accordance with paragraph (b) of this section, including comments regarding the reassessment information, APHIS will take one of the following actions:

(1) Publish a final rule that reinstates the disease-free status of the region, or a portion of the region, covered by the interim rule;

(2) Publish an affirmation of the interim rule that imposed prohibitions or restrictions on the imports of animals and animal products from that region; or

(3) Publish another document in the **Federal Register** for comment.

Done in Washington, DC, this 19th day of June, 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03–15907 Filed 6–23–03; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 63

[Docket No. PRM–63–1]

State of Nevada; Denial of a Petition for Rulemaking; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking: denial; correction.

SUMMARY: On February 27, 2003 (68 FR 9023), the U.S. Nuclear Regulatory Commission (NRC) published a notice of denial of a petition for rulemaking. The petition for rulemaking, dated July 12, 2002, had been filed with the Commission by the State of Nevada, and assigned Docket No. PRM–63–1. The petitioner had requested that the NRC amend its regulations governing the disposal of high-level radioactive waste in a proposed geologic repository at Yucca Mountain, Nevada. This action corrects a sentence in the notice of denial by restoring a word that was mistakenly omitted from the published document. This action also corrects an erroneous citation and a typographical error in the body of the notice.

FOR FURTHER INFORMATION CONTACT: Timothy McCartin, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7285 or Toll Free: 1–800–368–5642, e-mail: *tjm3@nrc.gov;* or Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7163 or Toll Free: 1–800–368–5642, e-mail: *MTL@nrc.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–4625, published on February 27, 2003 (68 FR 9023), the following corrections are made.

1. On page 9025, in the third column, the second heading is corrected to read as follows:

a. 10 CFR part 63 Is in Accord With NWPA Requirements.

2. On page 9026, in the third column, the third sentence from the bottom of the column is corrected to read as follows:

The Commission decided to reexamine its implementation of a multiple barrier approach and propose a regulation which required a system of multiple barriers, but which did not set numerical goals for the performance of individual barriers.

3. On page 9032, in the fifth line, the words ''Swedish Nuclear Power Inspectorate'' are replaced by the words ''Swedish Nuclear Fuel and Waste Management Company''.

Dated at Rockville, Maryland, this 18th day of June, 2003.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 03–15861 Filed 6–23–03; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301, 1306

[Docket No. DEA–202P]

RIN 1117–AA68

Authority for Practitioners To Dispense or Prescribe Approved Narcotic (Opioid) Controlled Substances for Maintenance or Detoxification Treatment

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA proposes to amend its regulations to allow qualified practitioners to dispense and prescribe to narcotic (opioid) dependent persons Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. These practitioners would not need to obtain a separate DEA registration as a narcotic treatment program to legally dispense or prescribe these drugs. Such practitioners, however, must be deemed ''qualifying physicians'' by the Secretary, Department of Health and Human Services. This notice of proposed rulemaking is in response to the recent amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA), title XXXV of the Children's Health Act of 2000 (Pub. L. 106–310), that are designed to expand and improve treatment of opioid addiction. The proposed regulations are intended to accomplish the goals of DATA while preventing the diversion of Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration specifically for maintenance/detoxification treatment.

DATES: Written comments must be postmarked on or before September 22, 2003.

ADDRESSES: Comments should be submitted to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

What Change in the Current Regulations Is This Notice Proposing?

With passage of the Drug Addiction Treatment Act of 2000 (DATA), title XXXV of the Children's Health Act of 2000 (Pub. L. 106–310; 116 Stat. 1222), this notice of proposed rulemaking proposes to amend the regulations affecting maintenance and detoxification treatment for narcotic (opioid) addiction. The Controlled Substances Act (CSA) and current regulations require that practitioners who want to conduct maintenance or detoxification treatment using narcotic (opioid) controlled drugs be registered with DEA as narcotic treatment programs (NTPs) in addition to the practitioners' personal registrations. The separate NTP registrations authorize the practitioners to dispense or administer, but not prescribe, narcotic (opioid) controlled drugs.

Proposed § 1301.27 would establish an exemption from the separate registration requirement for qualified

practitioners dispensing or prescribing Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment (see also proposed amendments to §§ 1306.04(c) and 1306.07). This NPRM would allow ''qualifying physicians,'' whether they are already registered as NTPs or not, to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs or combinations of controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment. (On October 8, 2002, FDA approved two products containing buprenorphine, subutex and suboxone, Schedule III controlled drugs, for use in maintenance and detoxification treatment.) Under this proposed rule, practitioners permitted to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment would not be required to have separate DEA registrations as NTPs. DEA is taking this proposed action in conjunction with the Department of Health and Human Services' (HHS) adoption of the concept of Office-Based Opioid Treatment. Proponents believe that the changes proposed here would provide greater access to narcotic (opioid) addiction treatment, and permit expanded treatment services. This action also responds to the recent amendment to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000. This proposed rule would not affect the existing prohibition against prescribing any Schedule II narcotic (opioid) controlled drugs for maintenance or detoxification treatment.

The proposed rule would:

(1) Permit qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment;

(2) Permit opioid dependent patients to have one-on-one consultations with a practitioner in a private practice setting;

(3) Permit pharmacies to fill prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment; and

(4) Permit practitioners to offer maintenance and detoxification treatment in their private practices without having a second registration as a NTP.

This proposed rule would apply to individual practitioners working in traditional NTPs or any other practice setting.

What Is the Legal Basis for Providing Maintenance or Detoxification Treatment?

Congress passed the Harrison Narcotic Act of 1914 to fulfill U.S. obligations to uphold the international Opium Convention signed at the Hague in 1912. The Act was the first comprehensive federal legislation to place controls on licit pharmaceuticals and allowed practitioners to prescribe narcotics (opioids) only for legitimate medical purposes in the course of their professional practice. It did not permit the prescribing of narcotics (opioids) simply to support or maintain an addiction.

During the late 1960s and the early 1970s, drug substitution therapy for addiction treatment using methadone was introduced as a medical modality and was considered ''research,'' that is, still outside the scope of ''medical treatment.'' At that time, medical and legal standards governing the use of methadone in addiction treatment programs did not exist. In effect, there were no clear means for differentiating legitimate treatment efforts using the drug as part of a comprehensive program of treatment services from bogus clinics or unethical practitioners distributing methadone to addicts under the guise of treatment. As a result the diversion of methadone was occurring on a large-scale basis.

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (Pub. L. 91–513), which consolidated existing Federal drug control statutes, and created new laws regarding activities pertaining to controlled drugs. Title II of this legislation, also known as the Controlled Substances Act, regulates the manufacture and distribution of controlled drugs. However, the issues of maintenance treatment and detoxification treatment were not addressed.

In the mid-1970s, methadone maintenance treatment became the subject of intense policy debate, and Congress passed the Narcotic Addict Treatment Act of 1974. This amendment to the Controlled Substances Act required practitioners who wished to conduct maintenance/detoxification treatment to obtain separate registration as NTPs. To be registered as NTPs, practitioners must comply with DEA requirements for secure drug storage and record keeping; must be qualified under the treatment standards established by the Department of Health and Human Services (HHS); and must comply with standards established by HHS (after consultation with DEA) regarding quantities of narcotic (opioid) drugs for unsupervised take-home use by persons undergoing addiction treatment (21 U.S.C. 823(g)). Since the mid-1970s, products containing methadone and, by the 1990's products containing levo-alpha-acetyl-methadol (LAAM), which are Schedule II controlled substances, have been approved by FDA specifically for use in maintenance or detoxification treatment. (On October 8, 2002, FDA approved buprenorphine products, Schedule III controlled drugs, for use in maintenance and detoxification treatment.)

The Narcotic Addict Treatment Act allows practitioners to dispense narcotic (opioid) drugs for maintenance or detoxification treatment. Under this legislation the term dispense means to deliver a controlled drug to an ultimate user under a lawful order of a practitioner, including the prescribing and administering of a controlled drug. However, as drug replacement therapy was considered research at that time, and to ensure public health and safety, practitioners were restricted to administering and dispensing (other than by prescription) controlled drugs for maintenance or detoxification treatment. After passage of the Narcotic Addict Treatment Act, such drug replacement therapy was no longer considered research.

Today treatment experts view addiction as a medical condition, which should be treated as a chronic disease, and believe that drug replacement therapy is a viable form of medical treatment for opioid dependent individuals. On October 17, 2000, Congress passed DATA, amending the Controlled Substances Act to establish ''waiver authority for physicians who dispense or prescribe certain narcotic (opioid) drugs for maintenance treatment or detoxification treatment'' (Pub. L. 106–310, title XXXV; 116 Stat. 1222). When the DATA bill was introduced in the United States Senate, it was described as follows:

> The goal of the DATA provisions is simple but it is important: The DATA bill attempts to make drug treatment more available and more effective to those who need it. This legislation focuses on increasing the availability and effectiveness of drug treatment. The purpose of the Drug Addiction Treatment Act is to allow qualified physicians, as determined by the Department of Health and Human Services, to prescribe schedule III, IV and V anti-addiction medications in physicians' offices without an additional Drug Enforcement Administration, DEA, registration if certain conditions are met.

146 Cong. Rec. S9262 (daily ed. Sept. 26, 2000).

What Are the Conditions for Qualifying for the Proposed § 1301.27 Exemption From Separate Registration for Practitioners Dispensing or Prescribing Schedule III, IV, and V Narcotic Drugs Approved by FDA Specifically for Use in Maintenance or Detoxification Treatment?

There are two main sets of conditions involved in the proposed exemption: Conditions with respect to the practitioner and conditions with respect to the Schedule III, IV, or V narcotic (opioid) drugs approved by FDA specifically for use in maintenance or detoxification treatment. To qualify for the proposed exemption, a practitioner would have to submit notification to HHS stating his or her intent to dispense or prescribe narcotic (opioid) controlled drugs to opiate-dependent patients and certifying that all of following are true:

(1) The practitioner is a ''qualifying physician.'' A practitioner is a ''qualifying physician'' if he or she is licensed under State law and has specific medical certification, training or experience in maintenance or detoxification treatment. The Secretary of HHS will establish criteria to be used for determining whether a practitioner is a ''qualifying physician.''

(2) The practitioner has the capacity to refer the patients, to whom the practitioner will provide specifically approved narcotic (opioid) drugs or combinations of narcotic (opioid) drugs, for appropriate counseling and other appropriate ancillary services.

(3) The total number of patients treated for opiate dependence by the practitioner who is not a member of a group practice will not exceed 30 at any one time, unless modified by regulation by the Secretary of HHS.

(4) If the practitioner is a member of a group practice, the total number of patients treated for opiate dependence by the group practice of which the practitioner is a member will not exceed 30 at any one time, unless modified by regulation by the Secretary of HHS.

Schedule III, IV and V narcotic (opioid) drugs to be dispensed or prescribed must meet the following two conditions:

(1) They must have been approved by FDA specifically for use in maintenance treatment or detoxification treatment.

(2) They cannot have been the subject of an adverse determination by HHS that their use requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

What Will Happen After the Practitioner Submits to HHS the Notification Under Proposed § 1301.27 of Intent To Dispense or Prescribe Narcotic Drugs?

When HHS receives a notification of intent to dispense or prescribe narcotic (opioid) controlled drugs for maintenance or detoxification treatment it will forward a copy of the notification to DEA. From the date HHS receives the notification it will have up to 45 days to review the practitioner's qualifications and make a determination whether the practitioner meets all of the requirements for the exemption. While HHS is conducting its determination, DEA will conduct its own review to determine if the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(a) and if there are any adverse determinations.

Once HHS has made its determination, it will send the findings to DEA. If DEA determines that the practitioner has the appropriate DEA registration in accordance with 21 U.S.C. 823(a) and if there are no adverse determinations, then DEA will issue the practitioner an identification number as soon as either of the following conditions occurs: (1) DEA receives the positive determination from HHS before the conclusion of the 45 day review period, or (2) the 45 day review period has concluded and no determination by HHS has been received. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued. Under proposed § 1301.27(d) the practitioner would be required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedule III, IV or V narcotic (opioid) controlled drugs for use in maintenance or detoxification treatment.

Would Practitioners Have To Wait Until They Receive an Identification Number From DEA Before They Could Dispense or Prescribe Schedule III, IV or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Use in Maintenance Treatment or Detoxification Treatment?

The practitioner would not have to wait if the practitioner was in compliance with proposed § 1301.27(e). As proposed, the practitioner could begin dispensing or prescribing during the 45-day review period if all of the following requirements are met:

(1) The practitioner has submitted, in good faith, a written notification under § 1301.27(b).

(2) The practitioner reasonably believes that the conditions specified in §§ 1301.27(b) and (c), regarding the practitioner and the narcotic (opioid) drugs, have been met.

(3) Prescribing or dispensing the narcotic (opioid) drugs would facilitate the treatment of an individual patient.

(4) The practitioner has notified both the Secretary of HHS and DEA of the intent to do so.

(5) The Secretary has not issued an order indicating that the registrant is not a qualified physician.

(6) The practitioner has the appropriate DEA registration under 21 CFR 1301.13.

The practitioner would be able to satisfy the fourth requirement by including within the notification required by proposed § 1301.27(b) a statement of his or her intent to immediately commence prescribing or dispensing. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued.

What Happens if a Practitioner Dispenses or Prescribes Schedule III, IV, or V Narcotic (Opioid) Drugs in Violation of One of the Conditions in Proposed § 1301.27(b)?

If a practitioner dispenses or prescribes Schedule III, IV, or V narcotic (opioid) drugs in violation of any of the conditions specified in proposed § 1301.27(b), then DEA may revoke the practitioner's DEA registration in accordance with § 1301.36.

Due to the potential for diversion and in an effort to verify compliance with these regulations, DEA intends to conduct at least two regulatory investigations per field office per year of practitioners dispensing and prescribing to narcotic (opioid) dependent persons Schedule III, IV, and V narcotic (opioid) controlled drugs approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment.

Would the Proposed Requirements Be Applied Differently to Practitioners Working in Traditional NTPs as Opposed to Practitioners in Other Practice Settings?

The proposed regulation would affect practitioners working in traditional NTPs the same as any other practitioners. If a ''qualifying physician'' working in a NTP wants to dispense or

prescribe Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment, then he or she would have to comply with the proposed regulations.

What Additional Requirements Would Apply When a ''Qualifying Physician'' Writes a Prescription for Schedule III, IV, and V Narcotic (Opioid) Drugs Approved by FDA Specifically for Maintenance or Detoxification Treatment?

Proposed changes to § 1306.05(a) require the practitioner to include on the prescription the identification number (issued under proposed § 1301.27(d)) or written notice that the practitioner is acting under the good faith exception of proposed § 1301.27(e). These prescriptions would be subject to all of the existing requirements of Part 1306 that apply to prescriptions for controlled drugs. To be valid, a prescription must be written for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice (§ 1306.04(a)). The prescription must be dated and signed on the day issued, must contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner (§ 1306.05(a)).

Under current law practitioners are not normally required to keep records of prescriptions issued. However, DEA regulations (§ 1304.03(c)) do require records to be kept by practitioners prescribing controlled drugs listed in any schedule for maintenance or detoxification treatment of an individual.

For conformity §§ 1306.04, Purpose of issue of prescription, and 1306.07, Administering or dispensing of narcotic (opioid) controlled drugs, would also be amended by this NPRM. Section 1306.04(c) currently prohibits the issuance of prescriptions for narcotic (opioid) drugs listed in any schedule for ''detoxification treatment'' or ''maintenance treatment.'' Under this NPRM, the prohibition against prescriptions in § 1306.04(c) would be amended to permit prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for maintenance or detoxification treatment by practitioners who are in compliance with proposed § 1301.27.

Section 1306.07(a) currently permits the administering and dispensing (but not prescribing) of narcotic (opioid) drugs for detoxification or maintenance treatment only by practitioners who are separately registered as a Narcotic Treatment Program. This proposed rule would add paragraph (d) to § 1306.07 to permit a practitioner to administer or dispense (including prescribe) any Schedule III, IV, or V narcotic (opioid) controlled drug approved by FDA specifically for use in maintenance or detoxification treatment if the practitioner is in compliance with proposed § 1301.27. This NPRM would also revise § 1306.07(a) to improve the clarity of the language, but not to change the drug of the paragraph.

Could a Practitioner Authorize Refills of Prescriptions for Schedule III, IV, or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Use in Maintenance or Detoxification Treatment?

DEA regulations allow practitioners to authorize refills for Schedule III, IV, or V controlled drug prescriptions. Prescriptions for Schedule III, IV and V controlled drugs are subject to the requirements in §§ 1306.22 and 1306.23, regarding the refilling and partial filling of prescriptions. In addition, practitioners prescribing Schedule III, IV, or V narcotic (opioid) drugs for use in maintenance or detoxification treatment would be subject to all relevant state and federal requirements that apply to prescriptions for controlled drugs.

Under Current Regulations, What Other Requirements Would Apply When a Practitioner Administers or Dispenses Schedule III, IV, or V Narcotic (Opioid) Drugs Approved by FDA Specifically for Maintenance or Detoxification Treatment?

Practitioners who administer or dispense (other than by prescription) Schedule III, IV, or V narcotic (opioid) drugs approved by FDA specifically for maintenance or detoxification treatment must maintain records and provide security for the controlled drugs in their possession. Records required to be maintained include inventories, records of receipt, reports of theft or loss, destruction of controlled drugs, and records of dispensation. These records must be maintained for two years.

The regulations also require practitioners to safeguard controlled drugs (§ 1301.75(b)). The Schedule III, IV, or V narcotic (opioid) controlled drugs approved by FDA specifically for maintenance or detoxification treatment must be stored in a securely locked, substantially constructed cabinet.

Current regulations on prescribing permit the use of a written prescription signed by a practitioner. Current regulations also permit a practitioner, or the practitioner's agent, to transmit a facsimile of a written signed prescription to a pharmacy (§ 1306.21). In addition, a practitioner may telephone the pharmacy with an oral prescription. The pharmacist must immediately reduce the oral prescription to writing, including all information required in § 1306.05, except for the signature of the practitioner (§ 1306.21(a)).

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, has reviewed this proposed regulation and hereby certifies that it has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and that it will not have a significant economic impact on a substantial number of small entities. This proposed rulemaking would permit practitioners to prescribe Schedule III, IV and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP. Although virtually all entities affected would be small, the cost of determining eligibility and applying for a waiver is negligible.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this proposed rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. As noted above, this proposed rulemaking would permit practitioners to prescribe Schedule III, IV and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment without being separately registered with DEA as a NTP.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have Federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

For the reasons set out above, 21 CFR Parts 1301 and 1306 are proposed to be amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES—[AMENDED]

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 956.

2. Part 1301 is proposed to be amended by adding §1301.27 to read as follows:

§ 1301.27 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.

(a) A practitioner may dispense or prescribe Schedule III, IV, or V narcotic (opioid) controlled drugs or combinations of narcotic (opioid) controlled drugs which have been approved by the Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment without obtaining the separate registration required by § 1301.13(e) so long as all of the following conditions are met:

(1) The practitioner meets the conditions specified in paragraph (b) of this section.

(2) The narcotic (opioid) drugs or combination of narcotic (opioid) drugs meet the conditions specified in paragraph (c) of this section.

(3) The practitioner is in compliance with either paragraph (d) or paragraph (e) of this section.

(b)(1) The practitioner must submit notification to the Secretary of Health and Human Services stating the practitioner's intent to dispense or prescribe narcotic (opioid) drugs under paragraph (a) of this section. The notice must contain all of the following certifications:

(i) The practitioner is registered under § 1301.13 and is a ''qualifying physician'' as defined in section 303(g)(2)(G) of the Act (21 U.S.C. 823(g)(2)(G)).

(ii) The practitioner has the capacity to refer the patients to whom the practitioner will provide narcotic (opioid) drugs or combinations of narcotic (opioid) drugs for appropriate counseling and other appropriate ancillary services.

(iii) Where the practitioner is not a member of a group practice, the total number of such patients of the practitioner will not exceed 30 at any one time, unless regulations promulgated by the Secretary of Health and Human Services are modified.

(iv) Where the practitioner is a member of a group practice, the total number of such patients of the group practice will not exceed 30 at any one time, unless regulations promulgated by the Secretary of Health and Human Services are modified.

(2) In addition, if a practitioner wishes to prescribe or dispense narcotic (opioid) drugs pursuant to paragraph (e) of this section, the practitioner must provide the following:

(i) Notification as required under subparagraph (1) of this paragraph must be provided in writing, and must state the name of the practitioner and the registration number of the practitioner issued under § 1301.13.

(ii) If the practitioner is a member of a group practice, the names of the other practitioners in the group and the registration numbers issued to the other practitioners under § 1301.13 shall be provided.

(c) The narcotic (opioid) drugs or combination of narcotic (opioid) drugs to be dispensed or prescribed under this section must meet all of the following conditions:

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

(2) The drugs or combination of drugs have not been the subject of an adverse determination by the Secretary of Health and Human Services, after consultation with the Attorney General, that the use of the drugs or combination of drugs requires additional standards respecting the qualifications of practitioners or the quantities of the drugs that may be provided for unsupervised use.

(d) After receiving the notification submitted under paragraph (b) of this section, the Secretary of Health and Human Services will forward a copy of the notification to the Administrator. The Secretary of Health and Human Services will have 45 days from the date of receipt of the notification to make a determination of whether the practitioner involved meets all requirements for a waiver under § 823(g)(2)(B) of the Act (21 U.S.C. 823(g)(2)(B)). HHS will notify DEA of its determination regarding the practitioner. If the practitioner has the appropriate registration under § 1301.13 of this chapter, then the Administrator will issue the practitioner an identification number as soon as one of the following conditions occurs:

(1) The Administrator receives a positive determination from the Secretary of Health and Human Services before the conclusion of the 45-day review period, or

(2) The 45-day review period has concluded and no determination by the Secretary of Health and Human Services has been made. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued. The practitioner must include the identification number on all records when dispensing and on all prescriptions when prescribing narcotic (opioid) drugs under this section.

(e) A practitioner may begin to prescribe or dispense narcotic (opioid) drugs under this section before receiving an identification number from the Administrator so long as the following conditions are met:

(1) The practitioner has submitted a notification under paragraph (b) of this section in good faith to the Secretary of Health and Human Services.

(2) The practitioner reasonably believes that the conditions specified in paragraphs (b) and (c) of this section have been met.

(3) The practitioner reasonably believes that prescribing or dispensing narcotic (opioid) drugs under this section before the sooner of:

(i) Receipt of an identification number from the Administrator, or

(ii) Expiration of the 45-day period would facilitate the treatment of an individual patient.

(4) The practitioner has notified both the Secretary of Health and Human Services and the Administrator of his or her intent to begin prescribing or dispensing the narcotic (opioid) drugs before expiration of the 45-day period.

(5) The Secretary has not issued an order indicating that the registrant is not qualified under paragraph (d) of this section.

(6) The practitioner has the appropriate registration under § 1301.13 of this chapter. If HHS refuses to certify a practitioner or withdraws such certification once it is issued, then DEA will not issue the practitioner an identification number, or will withdraw the identification number if one has been issued.

(f) If a practitioner dispenses or prescribes Schedule III, IV, or V narcotic (opioid) drugs approved by FDA specifically for maintenance or detoxification treatment in violation of any of the conditions specified in § 1301.27(b) or (c), the Administrator may revoke the practitioner's registration in accordance with § 1301.36.

PART 1306—PRESCRIPTIONS—[AMENDED]

3. The authority citation for Part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

4. Section 1306.04 is amended by revising paragraph (c) to read as follows:

§ 1306.04 Purpose of issue of prescription.

* * * * *

(c) A prescription may not be issued for ''detoxification treatment'' or ''maintenance treatment,'' unless the prescription is for a Schedule III, IV, or V narcotic (opioid) drug approved by FDA specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.27 of this chapter.

5. Section 1306.05 is amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. In addition, a prescription for a Schedule III, IV, or V narcotic (opioid) drug approved by FDA specifically for ''detoxification treatment'' or ''maintenance treatment'' must include the identification number issued by the Administration under § 1301.27(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.27(e). A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.,* J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

* * * * *

6. Section 1306.07 is amended by revising the section heading and paragraph (a) and adding paragraph (d) to read as follows:

§ 1306.07 Administering or dispensing of narcotic (opioid) drugs.

(a) A practitioner may administer or dispense directly (but not prescribe) a narcotic (opioid) drug listed in Schedule II if the practitioner meets both of the following conditions:

(1) The practitioner is separately registered with DEA as a narcotic treatment program.

(2) The practitioner is a qualifying physician under §1301.27 of this chapter and in compliance with DEA regulations regarding security, and records.

* * * * *

(d) A practitioner may administer or dispense (including prescribe) any Schedule III, IV or V narcotic (opioid) drug specifically approved by the Food and Drug Administration for use in maintenance or detoxification treatment to a narcotic (opioid) dependent person if the practitioner complies with the requirements of § 1301.27 of this chapter.

Dated: June 17, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106736–00]

RIN 1545–AX93

Assumption of Partner Liabilities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of proposed rulemaking by cross-reference to temporary regulations; and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the definition of liabilities under section 752 of the Internal Revenue Code. These regulations provide rules regarding a partnership's assumption of certain fixed and contingent obligations in exchange for a partnership interest and provide conforming changes to certain regulations. These regulations also provide rules under section 358(h) for assumptions of liabilities by corporations from partners and partnerships. In addition, this document provides notice that the IRS and Treasury intend to issue supplemental guidance that may apply certain of the rules outlined in these proposed regulations to transactions involving corporations. This document also provides notice of public hearing on the proposed regulations.

DATES: Written or electronic comments and requests to speak at the public hearing scheduled for Tuesday, October 14, 2003, must be received by September 22, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG–106736–00), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered between the hours of 8 a.m. and 4 p.m. to CC:PA:RU (REG–106736–00), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC or sent electronically, via the IRS Internet site at: *www.irs.gov/regs.* The public hearing will be held in the auditorium, Internal