October 3, 1996, and will remove the exemption from regulation for pseudoephedrine and phenylpropanolamine drug products effective October 3, 1997, making persons who distribute the respective products subject to the registration requirement on those dates. Determination of the appropriate procedures and amendment of the regulations to set the new fees will extend well beyond those deadlines for registration. Therefore, DEA is waiving a portion of the application fee for new registration. It would be inconsistent with the principles of OMB Circular A–25 to charge a fee for a specific service, e.g., completing the processing of the application and the pre-registration investigation, knowing that the costs and resources to be expended in providing that service will change. Persons who have already applied for registration to distribute regulated drug products and paid the existing fee will be refunded the amount of fee that is being waived.

The Acting Deputy Administrator of DEA is, therefore, waiving that portion of the fee for registration as a non-retail distributor of regulated drug products associated with the 12 hours of investigator time allocated for the on-site visit and travel time, which, at $39.92 per hour, amounts to $479.00 (See 59 FR 51892). The remaining administrative costs and time allotted for background checks and reports will continue. Thus the fee for an initial application for registration as a non-retail distributor of regulated drug products is $116.00. That fee will remain in effect until the review of the registration procedures has been completed and a determination has been made regarding how the processing of such applications and the pre-registration investigation will be carried out. At that time, a notice will be published in the **Federal Register** regarding the procedures to be followed and fee that will be required for future applications.

This waiver applies only to applicants for registration as non-retail distributors of regulated drug products. All other applicants remain subject to the full fees, as set forth in Title 21, Code of Federal Regulations, Section 1309.11. As noted earlier, persons who have already submitted an application for registration as a non-retail distributor of regulated drug products and paid the full fee will be provided with a $479.00 refund.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27452 Filed 10–16–97; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[DEA Number 168I]

RIN 1117–AA46

Temporary Exemption From Chemical Registration for Distributors of Pseudoephedrine and Phenylpropanolamine Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim Rule with request for comments.

SUMMARY: DEA is amending its regulations to provide a temporary exemption from registration for persons who distribute pseudoephedrine and phenylpropanolamine drug products. The Comprehensive Methamphetamine Control Act of 1996 (MCA) amends the Controlled Substances Act of 1970 (CSA) to require that, effective October 3, 1997, persons who distribute these drug products shall be subject to the chemical registration requirement. To avoid interruption in the legitimate distribution of the drug products pending promulgation of final regulations and issuance of registrations, DEA is amending its regulations to provide certain temporary exemptions from the registration requirement.

DATES: October 17, 1997. Persons required to register to handle pseudoephedrine or phenylpropanolamine must submit an application on or before December 3, 1997, in order to continue their activities pending final action by DEA on their application. Written comments or objections must be submitted on or before December 16, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

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

SUPPLEMENTARY INFORMATION: The Comprehensive Methamphetamine Control Act of 1996 (MCA) requires that, effective October 3, 1997, pseudoephedrine and phenylpropanolamine drug products (regulated drug products) will become subject to regulation as List I chemicals. Under this new requirement, any person who wishes to distribute, import, or export these products must first obtain a DEA chemical registration. Because full implementation of this provision and issuance of the registrations will not be possible prior to the October 3, 1997 deadline, DEA is establishing temporary exemptions from the registration requirement for persons handling regulated drug products to allow for continuation of legitimate commerce in the products. In addition, the existing exemptions from chemical registration for persons registered with DEA to handle controlled substances, which is contained in 21 CFR 1309.25, and for distributors of prescription drug products, which is contained in 21 CFR 1309.28, will also apply to the regulated drug products.

The first exemption applies to retail distributors of regulated drug products. A single transaction limit of 24 grams has been established by the MCA for retail distributions of regulated drug products. Consistent with previous proposals regarding the regulation of retail distributions of drug products that contain List I chemicals, DEA is temporarily exempting retail distributors from the registration requirement. Under this exemption, retail distributors will not be required to obtain a registration if they engage exclusively in distributions of regulated drug products below the 24-gram limit in a single transaction for legitimate medical use, either directly to walk-in customers or in face-to-face transactions by direct sales. This exemption is set out in 21 CFR 1309.29(b).

The second exemption applies to those persons who are required to obtain a registration. Any such person who submits an application for registration for activities involving regulated drug products on or before December 3, 1997 will be exempt from the registration requirement for their lawful activities with regulated drug products until the Administration has taken final action with respect to that application. This exemption is set out in 21 CFR 1310.09.

DEA recognizes that, unlike the second exemption, which provides a general benefit to all affected persons, the first exemption is limited in its application. Therefore, while the regulatory changes in this notice take

effect upon publication, the notice is open for public comment or objection until December 16, 1997. Further, the exemptions are temporary and may be subject to change, based on the comments or objections received.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this interim rulemaking will not have a significant economic impact upon a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This interim rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration pending promulgation, through notice and comment, of the regulations necessary to implement the provisions of the MCA pertaining to regulated drug products. Further, since this is a temporary action which provides affected persons with a means to comply with the law pending promulgation of regulations implementing the MCA, this action is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this interim rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR parts 1309 and 1310 are amended to read as follows:

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.29 is revised to read as follows:

§ 1309.29 Exemption of retail distributors of regulated drug products.

The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are restricted to the distribution of below-threshold quantities of a drug product that contains a List I chemical that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter to an individual for legitimate medical use.

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.09 is amended by redesignating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27453 Filed 10–16–97; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH72

Informed Consent for Patient Care

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends VA medical regulations concerning informed consent for patient care. It describes the requirements for obtaining and documenting informed consent. It also describes the types of treatments or procedures for which the patient's or surrogate's signature on a VA-authorized form is required and establishes a list and priority of surrogates authorized to act on behalf of patients who lack decision-making capacity. Further, it establishes an internal decision-making process for patients who lack decision-making capacity and who have no authorized surrogate. This is intended to protect patient rights and ensure that the patient (or the patient's surrogate or representative) receives sufficient information to make an informed health-care decision.

DATES: *Effective Date:* November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Ruth-Ann Phelps, Ph.D., Veterans Health Administration, Patient Care Services (11B), 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–8473.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on August 7, 1996 (61 FR 41108), we proposed to amend our regulations concerning informed consent for patient care. Interested parties were invited to submit written comments on or before October 7, 1996. We received comments from one commenter, the American Psychiatric Association.

Comments

The commenter suggested that whenever the word ''patient'' appears in the document, the phrase ''or patient surrogate'' should be added. In response, we have added the words ''or surrogate'' wherever appropriate. This is intended to clarify, consistent with the intent of the proposal, that a surrogate may give informed consent on behalf of a patient who lacks decision-making capacity.

With respect to requirements regarding the administration of psychotropic medication to an involuntarily committed patient, the commenter asserted that the prescribing of such medications should be limited to psychiatrists, and further asserted that the multi-disciplinary review committee constituted for purposes of review of the decision to administer or continue the administration of such medications should be required to include a psychiatrist. We do not believe that psychotropic medication should be prescribed only by psychiatrists. We believe that patients are adequately served as long as the prescribing physician is privileged to prescribe such medication. Also, we have added the requirement that the committee must include a psychiatrist or a physician who has