

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.