DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–275P]

RIN 1117–AA99

Changes to Patient Limitation for Dispensing or Prescribing Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment by Qualified Individual Practitioners

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to conform its regulations to recent statutory amendments to the Controlled Substances Act that changed certain patient limitations for practitioners who dispense or prescribe certain narcotic drugs for maintenance or detoxification treatment.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before November 19, 2007.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–275'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent directly to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and posted online and placed in the Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

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

SUPPLEMENTARY INFORMATION:

Overview

On August 2, 2005, the President signed amendments to the Controlled Substances Act to increase the patient limitation on prescribing drug addiction treatments by qualified medical practitioners in group practices from 30 patients for each group to 30 patients for each qualified practitioner in a group (Pub. L. 109–56; 119 Stat. 591) (21 U.S.C. 823(g)(2)).

On December 29, 2006, the President signed amendments to the Controlled Substances Act to permit certain qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic controlled substances approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to up to 100 patients at any one time, after the practitioner submits to the Secretary of Health and Human Services a notification of the practitioner's need and intent to treat the increased number of patients. The amendment was made as part of the Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) (§ 1102 of Pub. L. 109–469, 120 Stat. 3502).

This Notice of Proposed Rulemaking (NPRM) would conform DEA regulations to Pub. L. 109–56 by removing the requirement in 21 CFR 1301.28(b)(iv) that limits to 30 the number of patients that could receive maintenance or detoxification treatment through a group practice. This change means that each qualifying practitioner whether working individually or in a group practice may offer maintenance and detoxification treatment to 30 patients at any one time. This NPRM would also conform DEA regulations to § 1102 of Pub. L. 109–469 by permitting certain qualifying physicians to treat up to 100 patients. To qualify to treat the additional patients, not sooner than one year after the practitioner submitted the initial notification, the practitioner must submit a second notification to the Secretary of Health and Human Services of the need and intent of the practitioner to treat up to 100 patients. Further, the practitioner must be a ''qualifying physician'' under 21 U.S.C. 823(g)(2)(G) and must have the capacity to refer the patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs for appropriate counseling and other appropriate ancillary services (21 CFR 1301.28(b)(1)(i) and (ii)). These proposed amendments would not change the requirement that each practitioner must first qualify to prescribe and dispense these medications for maintenance and detoxification treatment, or must be prescribing these approved substances using the ''good faith'' exception, found within current regulations at 21 CFR 1301.28(e).

Background

On October 17, 2000, Congress passed the Drug Addiction Treatment Act of 2000 (DATA), amending the Controlled Substances Act (CSA) (21 U.S.C. § 801 *et seq.*) to establish ''waiver authority for physicians who dispense or prescribe certain narcotic drugs for maintenance

treatment or detoxification treatment'' (Pub. L. 106–310, title XXXV; 114 Stat. 1222, codified at 21 U.S.C. 823(g)(2)). Prior to DATA, the Controlled Substances Act and DEA regulations required practitioners who wanted to conduct maintenance or detoxification treatment using narcotic controlled drugs to be registered as a Narcotic Treatment Program (NTP) in addition to the practitioner's individual registration. The separate NTP registration authorized the practitioner to dispense or administer, but not prescribe, narcotic drugs.

With passage of DATA, DEA published a NPRM (68 FR 37429; June 24, 2003) proposing to amend the regulations affecting maintenance and detoxification treatment for narcotic treatment by establishing an exemption from the separate registration requirement. After consideration of the comments received on the NPRM, DEA published a Final Rule on June 23, 2005 (70 FR 36338). The June 23, 2005, Final Rule permitted the following:

(1) Qualifying physicians to dispense and prescribe Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(2) Narcotic-dependent patients to have one-on-one consultations with a practitioner in a private practice setting.

(3) Pharmacies to fill prescriptions for Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

(4) Practitioners to offer maintenance and detoxification treatment with Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment to no more than 30 patients in their private practices without having a second registration as a NTP.

The exemption and other amendments established by the Final Rule apply to individual practitioners working in traditional NTPs as well as any other practice setting. The rule does not affect the existing prohibition against prescribing any Schedule II narcotic controlled drugs for maintenance or detoxification treatment.

Under the provisions of DATA implementing regulations as codified in 21 CFR 1301.28(b)(1)(iii) and (iv), the 30-patient limitation applied equally to individual practices and to group practices (i.e., 30 patients per group), severely limiting the number of patients that could be treated by physicians in group practices.

Pursuant to Pub. L. 109–56 effective on August 2, 2005, and § 1102 of Pub. L. 109–469 effective on December 29, 2006, this NPRM would make conforming changes to DEA's regulations at 21 CFR 1301.28(b)(1)(iii) and (iv). Specifically, paragraph (b)(1)(iii) is proposed to be amended to permit the treatment of up to 100 patients by a qualifying practitioner if the necessary criteria are met and notification is submitted to the Secretary of Health and Human Services. Further, paragraph (b)(1)(iii) is proposed to be amended by removing the phrase ''Where the individual practitioner is not a member of a group practice,'' since there is no longer a distinction between practitioners in group practices and those practicing independently. Finally, paragraph (b)(1)(iv) is proposed to be deleted to remove language regarding members of group practices.

Relevant to the change regarding the treatment of up to 100 patients, the Director of the Center for Substance Abuse Treatment in the Department of Health and Human Services issued a letter announcing the statutory change as follows:

> Under ONDCPRA (effective December 29, 2006), physicians who meet the following criteria may notify the Secretary of Health and Human Services (HHS) of their need and intent to treat up to 100 patients at any time: (1) The physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify their capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DEA emphasizes that practitioners must meet these HHS criteria before prescribing a Schedule III, IV, or V controlled substance for narcotic maintenance or detoxification treatment to more than 30 patients at any one time.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, has reviewed this regulation and hereby certifies that it has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) and that it will not have a significant economic impact on a substantial number of small entities. This NPRM would relieve a restriction on practitioners desiring to treat narcotic dependent patients by removing the 30 patient limit for group practices and by permitting certain qualifying physicians to treat up to 100 patients after certain criteria are met. Thus the changes would provide greater access to care for patients due to increased patient limits.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rule has been drafted in accordance with the principles in Executive Order 12866 § 1(b). It has been determined that this is a significant regulatory action and, therefore, this action has been reviewed by the Office of Management and Budget. This rule will not impose additional costs on practitioners as it simply increases the number of patients that a practitioner may treat for narcotic dependence. As previously noted, this change would provide greater access to care for patients due to the increased patient limits.

Executive Order 12988

This rule meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rule 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 $120,000,000 or more (adjusted for inflation) 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.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). 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 in 21 CFR Part 1301

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

For the reasons set out above, 21 CFR part 1301 is proposed to be amended as follows:

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

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, 886a, 951, 952, 953, 956, 957.

2. § 1301.28 is proposed to be amended by revising paragraph (b)(1)(iii) and removing paragraph (b)(1)(iv) to read as follows:

§ 1301.28 Exemption from separate registration for practitioners dispensing or prescribing Schedule III, IV, or V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment.

* * * * *

(b)(1) * * *

(iii) The total number of patients to whom the individual practitioner will provide narcotic drugs or combinations of narcotic drugs under this section will not exceed 30 at any one time unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification to the Secretary of Health and Human Services, 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 subparagraph shall contain the certifications required by subparagraphs (i) and (ii) of this paragraph. The Secretary of Health and Human Services may promulgate regulations to change the total number of patients.

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Dated: September 13, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E7–18531 Filed 9–19–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 950

[FHWA Docket No. FHWA–06–23597]

RIN 2125–AF07

Interoperability Requirements, Standards, or Performance Specifications for Automated Toll Collection Systems

AGENCY: Federal Highway Administration (FHWA); DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: As required under section 1604(b)(6) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), this proposed rule specifies the interoperability requirements for automated toll collection systems for the facilities that are tolled under any of the tolling programs contained in section 1604 of SAFETEA–LU. Specifically, this notice proposes to require facilities operating with authority under section 1604 of SAFETEA–LU to use electronic toll collection systems and for these systems to address their interoperability with other toll facilities. Although a nationwide interoperability standard has not yet been established, this proposed rule seeks to accelerate progress toward achieving nationwide interoperability by requiring these facilities to upgrade their electronic toll collection systems to the national standards whenever adopted. This document also provides notice of public meetings on this proposed regulation.

DATES: The public meeting will be held on Thursday, October 11, 2007, from 1:30 p.m. to 5 p.m., at the U.S. Department of Transportation headquarters conference center. Comments must be received on or before November 19, 2007. Late-filed comments will be considered to the extent practicable, but the FHWA may issue a final rule at any time after the close of the comment period.

ADDRESSES: The October 11, 2007, public meeting will be held at the U.S. Department of Transportation headquarters conference center, 1200 New Jersey Avenue, SE., Washington, DC 20590.

Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, Room PL–401, 1200 New Jersey Avenue, SE., Washington, DC 20590, or submit electronically at *http://dmses.dot.gov/submit* or fax comments to (202) 493–2251. Alternatively, comments may be submitted to the Federal eRulemaking portal at *http://www.regulations.gov*.

All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone is able to search the electronic form of all comments in any one of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, or labor union). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70, Pages 19477–78) or you may visit *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: For technical questions or information about this notice of proposed rulemaking, contact Mr. Robert Rupert, FHWA Office of Operations, (202) 366–2194. For legal questions, please contact Mr. Michael Harkins, Attorney Advisor, FHWA Office of the Chief Counsel, (202) 366–4928, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours for the FHWA are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or retrieve comments online through the Document Management System (DMS) at: *http://dmses.dot.gov/submit*. Electronic submission and retrieval help and guidelines are available under the help section of the Web site. Alternatively, internet users may access all comments received by the DOT Docket Facility by using the universal resource locator (URL) *http://dms.dot.gov*. It is available 24 hours each day, 365 days each year. Please follow the instructions. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's home page at: *http://www.archives.gov* or the Government Printing Office's Web page at *http://www.gpoaccess.gov/nara*.

Introduction

Section 1604 of SAFETEA–LU (Pub. L. 109–59, 119 Stat. 1144) includes provisions related to tolling of highways