Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. This proposed rule involves the establishment of safety zones and as such should be categorically excluded, under figure 2–1, paragraph 34(g) of the Instruction from further environmental documentation.

We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

2. In § 165.939 revise paragraph (a) introductory text and add paragraphs (a)(27) through (32) to read as follows:

§ 165.939 Safety Zones; Annual Fireworks Events in the Captain of the Port Buffalo Zone.

(a) *Safety Zones:*

* * * * *

(27) *Independence Celebration Fireworks, Lake Ontario, Oswego Harbor, Oswego, NY*—(i) *Location.* All waters of Lake Ontario at within an 800-foot radius of position 43°28′05″ N, 076°31′01″ W; in Oswego Harbor, Oswego, NY. (DATUM: NAD 83).

(ii) *Enforcement date.* One day in the first week of July.

(28) *Rochester Harborfest, Lake Ontario at the Genesee River, Rochester, NY*—(i) *Location.* All waters of Lake Ontario at Genesee River, within a 500-foot radius of position 43°15′21″ N, 077°36′19″ W; in Rochester, NY. [DATUM: NAD 83]. Located on the Ontario Beach West pier.

(ii) *Enforcement date.* One weekend after Fathers Day weekend in June.

(29) *A Salute to Our Hero's, Lake Ontario, Hamlin, NY*—(i) *Location.* All waters of Lake Ontario within a 300-foot radius of position 43°16′27″ N, 076°58′27″ W; off Hamlin Beach State Park Area 1. (DATUM: NAD 83).

(ii) *Enforcement date.* One day in the first week of July.

(30) *Olcott NY Fireworks, Lake Ontario, Olcott, NY*—(i) *Location.* All waters of Lake Ontario within a 600-foot radius of position 43°20′24″ N, 078°43′09″ W; located on the West Federal Pier in Olcott, NY. (DATUM: NAD 83).

(ii) *Enforcement date.* One day in the first week of July.

(31) *Erie Summer Festival of the Arts, Lake Erie, Presque Isle Bay, Erie, PA*—(i) *Location.* All waters of Lake Erie, Presque Isle Bay within a 420-foot radius of position 42°07′45″ N, 080°06′20″ W; in Erie, PA (DATUM: NAD 83).

(ii) *Enforcement date.* One day in the last week of June.

(32) *Mercyhurst College ''Old Fashion 4th of July,'' Lake Erie, Presque Isle Bay, Erie, PA*—(i) *Location.* All waters of Lake Erie, Presque Isle Bay 1,000 feet NW of the Chestnut Street Boat Launch in a 400-foot radius of position 42°08′41″ N, 080°06′40″ W; in Erie, PA. (DATUM: NAD 83).

(ii) *Enforcement date.* One day in the first week of July.

Dated: June 4, 2009.

R.S. Burchell,

Captain, U.S. Coast Guard, Captain of the Port Buffalo.

[FR Doc. E9–14381 Filed 6–18–09; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8

RIN 0930–AA14

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Buprenorphine and Buprenorphine Combination; Approved Opioid Treatment Medications Use

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule amends the Federal opioid treatment program regulations by modifying the dispensing requirements for buprenorphine and buprenorphine combination products approved by FDA for opioid dependence and used in federally certified and registered opioid treatment programs. Opioid treatment programs that use these products in the treatment of opioid dependence will adhere to all other Federal treatment standards established for methadone.

DATES: Written comments must be received by the Substance Abuse and Mental Health Services Administration (SAMHSA) on or before August 18, 2009.

ADDRESSES: To assure proper handling of comments, please reference ''Docket No. CSAT 001'' on all written and electronic correspondence. Written comments may be submitted to the Division of Pharmacologic Therapies, Center for Substance Abuse Treatment, 1 Choke Cherry Road, Room 2–1063, Rockville, MD 20857; Attention: DPT Federal Register Representative. Alternatively, comments may be submitted directly to SAMHSA by sending an electronic message to *dpt_interimrule@samhsa.hhs.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.regulation.gov* Web site. 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. SAMHSA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. SAMHSA will not accept any file formats other than those specifically listed here.

Please note that SAMHSA is requesting that electronic comments be submitted before midnight Eastern time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern time on the day the comment period closes. Commenters in time zones other than Eastern time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

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 SAMHSA'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 the comment, in redacted form, will be posted online and placed in the SAMHSA's public docket file. Please note that the Freedom of Information Act applies to all comments received. 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: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapies, SAMHSA, 1 Choke Cherry Road, Room 2–1063, Rockville, MD 20857, (240) 276–2716, e-mail: *Nicholas.Reuter@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of January 17, 2001 (66 FR 4076, January 17, 2001), SAMHSA issued final regulations for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. That final rule established an accreditation-based regulatory system under 42 CFR part 8 (''Certification of Opioid Treatment Programs (OTPs)''). The regulations also established (under § 8.12) the Secretary's standards for the use of opioid medications in the treatment of addiction, including standards regarding the quantities of opioid drugs which may be provided for unsupervised use. The SAMHSA regulations establish the standards for determining that practitioners (programs) are qualified for Drug Enforcement Administration (DEA) registration under 21 U.S.C. 823(g)(1).

Section 8.12(h) sets forth the standards for medication administration, dispensing and use. Under this Section, OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. The regulation listed methadone and levomethadyl acetate (''ORLAAM'') as the opioid agonist treatment medications considered to be approved by the FDA for use in the treatment of opioid addiction.

A. Interim Final Rule—SAMHSA/CSAT expanded the list of approved medications for use in certified opioid treatment programs by issuing an Interim Final Rule on May 22, 2003 (68 FR 27937, May 22, 2003, ''Interim Final Rule''). This document was preceded by the Food and Drug Administration's approval of two buprenorphine products (Subutex® and Suboxone®) on October 8, 2002, and the Drug Enforcement Administration's (DEA) rescheduling of bulk buprenorphine, as well as all approved medical products containing buprenorphine from Schedule V to Schedule III (see Federal Register of October 7, 2002 (67 FR 62354)).

The May 22, 2003, Interim Final Rule added the two FDA-approved buprenorphine addiction treatment products to the previous list of approved opioid treatment medications under 42 CFR 8.12(h)(2). Effective upon publication, the Interim Final Rule allowed OTPs to use buprenorphine and buprenorphine combination for the treatment of opioid addiction. In addition, the Interim Final Rule required OTPs to apply the same treatment standards that were finalized on January 17, 2001, for methadone and ORLAAM. These requirements included the restrictions for treatment medications dispensed for unsupervised use, e.g., ''take-home'' medication. Finally, the Interim Final Rule solicited comments on the new provisions.

The ''take-home'' provisions are intended to reduce the risk of abuse and diversion of opioid treatment medications that have abuse potential. The rules tie the amount of ''take home'' medication that a program may dispense to patient characteristics, such as their stability, responsibility and time in treatment. For example, under 42 CFR 8.12(i)(3), a patient would have to be stable in treatment for 9 months to be eligible for a 6-day supply of medication

(either methadone or buprenorphine). In addition to the time in treatment eligibility, program physicians must still evaluate and document every patient's stability for take-home medication by applying the factors set forth under 42 CFR 8.12(i)(2).

B. Buprenorphine in Office-Based Opioid Treatment—The Drug Addiction Treatment Act of 2000, (Section 3502 of the Children's Health Act of 2000, Public Law 106–310, 21 U.S.C. 823(g)(2)), ''DATA 2000'') permits qualified physicians to dispense certain opioid treatment medications for the treatment of opioid dependence. Under DATA 2000, qualifying physicians are ''certified'' to obtain waivers from the requirement to obtain approval from SAMHSA as OTPs. Qualifying physicians are permitted to dispense, including prescribe, Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for maintenance or detoxification treatment without being separately registered as a narcotic treatment program by DEA (21 U.S.C. 823(g)(2)(A)).

Certified physicians are subject to certain limits. For example, certified physicians are authorized to prescribe only opioid medications that are specifically approved by FDA for dependence or addiction treatment. These medications must be controlled in Schedules III through V. This excludes the Schedule II medication methadone. Physicians must be ''qualified'' by credentialing or experience. In addition, physicians are subject to limits on how many patients they can treat at any one time. Importantly, DATA 2000 did not include restrictions on the amount of an approved drug that may be prescribed to a patient at any one time.

DATA 2000 assigned new responsibilities to both the Department of Health and Human Services (HHS) and the Department of Justice (DOJ). The DEA issued regulations to carry out the DOJ responsibilities, while HHS delegated implementation responsibilities to SAMHSA. SAMHSA has implemented the Department's new responsibilities without new rules. The DEA's final regulation removed the regulatory prohibition on prescribing narcotic treatment drugs, outlined the process for the interagency review of ''notifications'' under the new law and how the ''unique identification number'' will be assigned, and established recordkeeping requirements for certified physicians. The DEA rule did not establish new requirements or limits for dispensing or prescribing buprenorphine products (70 FR 36338, June 23, 2005).

In sum, DEA, FDA and SAMHSA actions to implement DATA 2000 and SAMHSA's May 22, 2003 Interim Final Rule distinguished how the same medications (buprenorphine and buprenorphine combination products) are dispensed in different settings (OTP versus certified physician. (Ref 1)).

C. Analysis of Comments—In response to the Interim Final Rule, SAMHSA received two comments from individuals representing hundreds of OTPs providing treatment in several States. While the comments support the Secretary's immediate action to make the new treatment medication available to OTPs expeditiously, the comments questioned the rationale for applying the treatment standards in place for methadone to the new buprenorphine products. One commenter noted that buprenorphine has the same pharmacological properties whether administered by OTPs or ''waived physicians.''

The commenter did not believe that the regulations should preclude OTPs from dispensing buprenorphine in the same manner as private physicians. They stated that it was an error to impose uniquely stringent treatment standards on those clinics best placed to administer buprenorphine products to treat addiction. Because of these dispensing restrictions, the interim final rule ''in short, will significantly limit if not completely suppress the availability of buprenorphine therapy in OTPs.''

The comments also suggested that the restriction would impact patient care. Whether used in an OTP or in a private office, buprenorphine therapy should not be subject to the dispensing restrictions developed to deal with the special risks posed by Schedule II methadone. From the patient's perspective, the critical advantage of buprenorphine is the possibility of avoiding the long-term daily attendance for dosing that is required with methadone therapy. The commenters stated that ''OTPs have substantial experience in treating a particularly challenging population of patients. Requiring Schedule II type procedures for OTP-based buprenorphine treatment—and by precluding OTPs from administering buprenorphine in the same manner that the drug is available to private physicians—risks suppression of addicts entering treatment.''

The commenters requested that SAMHSA provide OTPs with the same take-home prescribing authority which is currently in force for qualified physicians under DATA 2000. In this way, there will be no artificial difference in how OTPs prescribe buprenorphine as compared to qualified physicians under DATA 2000. The comments did not suggest changing the OTP dispensing restriction for methadone.

The Secretary agrees with the comments supporting the modification of the dispensing regime for buprenorphine in OTPs. Based on the information available, the Department believes that the experience with buprenorphine use in addiction treatment over the last several years, together with the pharmacological properties of the approved buprenorphine treatment products, distinguishes Schedule III buprenorphine products from Schedule II methadone products. These distinctions strongly support the establishment of a less restrictive distribution scheme for Schedule III buprenorphine products approved to treat opioid dependence.

D. Discussion—In contrast to 2003, there is now extensive experience with buprenorphine in the treatment of opioid dependence. Since 2002, over 16,000 physicians have sought and obtained the Federal certification to prescribe buprenorphine products. Over 73 million dosage units were distributed to pharmacies in 2007, millions of prescriptions have been issued, and hundreds of thousands of patients have been treated. Almost all the buprenorphine used in addiction treatment has come from physician prescriptions. These prescriptions have been issued without the mandatory time in treatment schedule currently in place for methadone products.

The Secretary has assessed the public health implications associated with physician prescribed buprenorphine as part of a formal ''Determinations Report.'' That report indicates that the DATA 2000 physician waiver program has expanded access to treatment and produced effective treatment outcomes without producing negative public health issues (Ref. 2). According to the DEA's Automation of Reports and Consolidated Orders System (ARCOS), the amount of buprenorphine distributed each year has increased from 3 million dosage units in 2003 to over 70 million dosage units in 2007 (Ref. 3).

While buprenorphine products are abused and diverted, according to information from published literature reports and from long-standing monitoring systems maintained by FDA, SAMHSA, and DEA, the scope and nature of abuse and diversion are considerably less than that of methadone and other Schedule II opioid

drug products. FDA, SAMHSA, and DEA will continue to monitor the abuse and diversion of buprenorphine products and intervene if needed to address increases.

The FDA Adverse Drug Monitoring System—MedWatch, is in place to receive and review adverse drug events on marketed prescription drugs. Since the buprenorphine addiction treatment products were approved in late 2002, FDA has received approximately 50 buprenorphine-associated fatal adverse events. Similar numbers have been reported by the drug manufacturer.

Another monitoring system is SAMHSA's Drug Abuse Warning Network (DAWN). DAWN is a public health surveillance system that monitors drug-related visits to hospital emergency departments (EDs). Hospital emergency department (ED) visits involving the nonmedical use (or misuse/abuse) of buprenorphine are increasing with the increased availability of buprenorphine products; however, ED visits involving the nonmedical use (or misuse/abuse) of buprenorphine are relatively rare. According to the 2006 DAWN report, out of an estimated 741,425 drug-related ED visits involving the nonmedical use of pharmaceuticals in 2006, there were an estimated 4,440 (95 percent confidence interval [CI] 823 to 8,057) visits involving buprenorphine/combinations. DAWN estimates for 2004 and 2005 could not be published for buprenorphine because the estimates for buprenorphine were too imprecise for publication. The wide confidence interval for 2006 illustrates the relative imprecision of a national estimate based on few reports (Ref. 4). In contrast, the ED visits for other opioids for 2006 are as follows: Oxycodone/combinations—64,888 visits (95 percent C.I. 49,746–80,030); Hydrocodone/combinations—57,550 visits (95 percent C.I. 43,701–71,398); Fentanyl/combinations—16,012 visits (95 percent C.I. 7,441–24,582); Hydromorphone/combinations—6,780 (95 percent C.I. 3,649–9,911); and, Methadone 45,130 (95 percent C.I. 35,870–54,389).

In contrast, DAWN estimates from 2006 revealed that methadone was one of the top three opioid analgesics (along with hydrocodone/combinations and oxycodone/combinations) associated with ED visits involving the nonmedical use of pharmaceuticals. Opioid analgesics were involved in 32 percent of visits involving nonmedical use of pharmaceuticals. According to the 2006 DAWN ED publication, methadone was associated with an estimated 45,000 ED visits involving nonmedical use. The consequences of methadone abuse, misuse, and diversion can be severe. Methadone-associated deaths [between 2001 and 2003] increased in many States including Maine, Florida, and North Carolina. Methadone-detected deaths in Maine doubled between 1999 and 2000, while North Carolina noted a 5-fold increase between 1997 and 2001. Data from the National Center for Health Statistics (NCHS), National Vital Statistics System indicate that the rate at which methadone was listed on death certificates as contributing to deaths increased almost 4-fold between 1999 and 2003 (Ref. 5).

Finally, a DAWN medical examiner report from 2005 indicates that methadone contributed to deaths more frequently than other prescribed opioid medications in 5 out of 6 States (Ref 6). DAWN–Medical Examiner (DAWN–ME) collects data on all deaths where drugs played a role, either directly (such as an overdose) or indirectly (such as a fatal car crash where drugs were involved). A drug misuse death is defined as a drug-related death caused by homicide by drugs, overmedication, all other accidental causes, and where the cause could not be determined. There are limitations with the DAWN–ME system. For example, the drugs acquired through legitimate prescriptions cannot be differentiated from diverted prescription medications or illicit drugs because information on the source is not available.

It is imperative to note, however, that following an extensive national assessment, a 2003 SAMHSA Methadone-Associated Mortality report did not associate increases in methadone distribution, diversion, morbidity and mortality with methadone administered and dispensed by OTPs. Indeed, the report indicated that Federal OTP regulations reduce the risk of methadone in-treatment mortality (Ref. 7). While the Secretary has no immediate plans to revise methadone ''take-home'' regulations, it may be appropriate to revisit the methadone dispensing restrictions under 42 CFR 8.12(i) at some point in the future.

The differences between buprenorphine and methadone are also evident in their international and domestic control status. While buprenorphine is controlled under Schedule III of the Convention on Psychotropic Substances (1971), methadone is controlled in Schedule II of the Single Convention on Narcotic Drugs, the same level of control as morphine, cocaine, hydrocodone, and oxycodone. The international control status of buprenorphine was reaffirmed in September 2006 by the World Health Organization's 34th Expert Committee on Drug Control. The Committee, after reviewing evidence ''demonstrating unique pharmacological actions of buprenorphine, which distinguish it from other opioids'' such as methadone, concluded that buprenorphine's unique spectrum of pharmacological actions, did not warrant control under the Single Convention (Ref. 8).

Domestically, buprenorphine is controlled in Schedule III of the Controlled Substances Act (CSA). Methadone is controlled domestically in Schedule II, along with cocaine, morphine, oxycodone and other potent narcotic substances. Under the CSA, Schedule III substances must be found to have less abuse potential and less potential to produce dependence when compared to Schedule II substances (21 U.S.C. 812(b)(3)). Specifically, in controlling buprenorphine in Schedule III, the DEA found, based upon a recommendation from the Department of Health and Human Services, that buprenorphine has a potential for abuse less than the drugs or other substances in Schedules I and II. These important pharmacologic differences support a different regulatory distribution scheme for buprenorphine products (Ref. 9).

Based upon the discussion above, the Secretary is proposing to eliminate the take-home dispensing schedule for buprenorphine products as set forth in Section III.

II. References

1. Food and Drug Administration, approved product labeling, Suboxone and Subutex, October 2002, *http://www.fda.gov/cder/foi/label/2002/20732lbl.pdf.*

2. Substance Abuse and Mental Health Services Administration, The Determinations Report: A Report On the Physician Waiver Program Established by the Drug Addiction Treatment Act of 2000. Submitted by the Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, U.S. Department of Health and Human Services, March 30, 2006.

3. Drug Enforcement Administration Automation of Reports and Consolidated Order System, 2006, Special Report.

4. Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, *http://DAWNinfo.samhsa.gov,* 2006.

5. Fingerhut, L.A., Increases in Methadone-Related Deaths: 1999–2004,

National Center for Health Statistics, Office of Analysis and Epidemiology.

6. Substance Abuse and Mental Health Services Administration, Drug Abuse Warning Network, Opiate-Related Drug Misuse Deaths in Six States: 2003, Issue 19, 2006.

7. Center for Substance Abuse Treatment, Methadone-Associated Mortality: Report of a National Assessment, May 8–9, 2003. SAMHSA Publication No. 04–3904. Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, 2004.

8. WHO Technical Report Series, 942, WHO Expert Committee On Drug Dependence, Thirty-Fourth Report, 2006, p 6.

9. Drug Enforcement Administration, 67 FR 62354, October 7, 2002, Schedules of Controlled Substances: Rescheduling of Buprenorphine From Schedule V to Schedule III, Final rule.

III. Summary of Proposed Regulation

The opioid treatment program regulations (42 CFR part 8) establish the procedures by which the Secretary will determine whether a practitioner is qualified under Section 303(g) of the CSA (21 U.S.C. 823(g)(1)) to dispense certain therapeutic narcotic drugs in the treatment of individuals suffering from narcotic addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of narcotic drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)(c)). (See also 42 U.S.C. 257a.)

SAMHSA is not proposing at this time to change any of the provisions in Subpart A (Accreditation) or Subpart C (Procedures for Review of Suspension or Proposed Revocation of OTP Certification and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body). Instead, SAMHSA is proposing a minor amendment to subpart B, Certification and Treatment Standards. If finalized, the rule would amend only one section of subpart B, § 8.12(i). Unsupervised or ''take-home'' use.

Under 42 CFR 8.12(i), OTPs must adhere to requirements for dispensing treatment medications for unsupervised or ''take-home'' use. These restrictions are in place to limit or reduce the potential for diversion of these medications to the illicit market. The effect of this proposed rule is to remove the restrictions for dispensing buprenorphine and buprenorphine combination products for unsupervised or ''take-home'' use while retaining those requirements for methadone products. This proposed change would be incorporated by adding the following language to 42 CFR 8.12(i)(3): ''The dispensing restrictions set forth in paragraphs (i) through (vi) do not apply to buprenorphine and buprenorphine products listed under 42 CFR section 8.12(h)(2)(iii).''

It should be noted that OTPs would still be required to assess and document each patient's responsibility and stability to handle opioid drug products for unsupervised use set forth under 42 CFR 8.12(i)(2) and 8.12(i)(3).

IV. Request for Comments

Under the rulemaking provisions of the Administrative Procedure Act (APA), an agency must provide the public with notice of certain proposed rules it wishes to promulgate (through publication in the **Federal Register**), and must afford the public an opportunity to comment on those proposed rules before they become final [5 U.S.C. 553(b)].

Instructions for submitting comments to this proposed rule are discussed above. SAMHSA will consider comments submitted during the 60-day comment period. All comments are welcome; however, information and evidence specific to this issue of buprenorphine and buprenorphine dispensing by certified OTPs will be especially useful.

V. Analysis of Economic Impacts

The Secretary has examined the impact of this proposed rule under Executive Order 12866, which directs Federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). This proposed rule does not establish additional regulatory requirements; it allows an activity that is otherwise prohibited. According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. A detailed discussion of the Secretary's analysis is contained in the opioid treatment Final Rule published in the **Federal Register** of January 17, 2001 (66 FR 4086–4090). That document described the impact of the opioid treatment regulations, analyzed alternatives, and considered comments from small entities. In addition, a **Federal Register** notice published April 17, 2006, offered the opportunity for comments on this information collection activity.

The Secretary also finds that this proposed rule is not a significant regulatory action as defined by Executive Order 12866. The rule merely permits OTPs to dispense buprenorphine and buprenorphine combination products without adhering to the dispensing schedule established for Schedule II medications like methadone. If opioid treatment programs choose to use these products, the new medications will be used in accordance with all other standards set forth in the January 17, 2001, Final Rule (66 FR 4090). No new regulatory requirements are imposed by this proposed rule; however, some regulatory requirements will be reduced.

The Secretary anticipates that there will be an overall reduction in societal costs if treatment is expanded under this proposal. Indeed, the National Institutes of Health estimates conservatively that every $1 invested in addiction treatment programs yields a return of between $4 and $7 in reduced drug-related crime, criminal justice costs, and theft. When savings related to health care are included, total savings can exceed costs by a 12 to 1 ratio.

For the reasons outlined above, the Secretary has determined that this proposed rule will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 605(b)). Therefore, an initial regulatory flexibility analysis is not required for this proposed Rule.

The Secretary has determined that this rule is not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

The Secretary has examined the impact of this rule under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This rule does not trigger the requirement for a written statement under section 202(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million (adjusted annually for

inflation) or more by either State, local, and tribal governments in the aggregate or by the private sector in any 1 year.

Environmental Impact

The Secretary has previously considered the environmental effects of this rule as announced in the Final Rule (66 FR 4076 at 4088). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed this proposed rule in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law. As defined in the Order, ''policies that have federalism implications'' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

The Secretary is publishing this proposed rule to modify treatment regulations that provide for the use of approved opioid agonist treatment medications in the treatment of opiate addiction. The Narcotic Addict Treatment Act (NATA, Pub. L. 93–281) modified the Controlled Substances Act (CSA) to establish the basis for the Federal control of narcotic addiction treatment by the Attorney General and the Secretary. Because enforcement of these Sections of the CSA is a Federal responsibility, there should be little, if any, impact from this rule on the distribution of power and responsibilities among the various levels of government. In addition, this proposed rule does not preempt State law. Accordingly, the Secretary has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.

Paperwork Reduction Act of 1995

This proposed rule modifies 42 CFR 8.12(i) by reducing regulatory dispensing requirements for buprenorphine and buprenorphine combination products that may be used in SAMHSA-certified opioid treatment programs. The proposed rule establishes no new reporting or recordkeeping requirements beyond those discussed in the January 17, 2001, Final Rule (66 FR 4076 at 4088). On January 10, 2007, the Office of Management and Budget approved the information collection requirements of the Final Rule under control number 0930–0206.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires us to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

Dated: May 1, 2009.

Eric B. Broderick,

Acting Administrator, SAMHSA, Assistant Surgeon General.

Dated: May 13, 2009.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 8

Health professions, Levo-Alpha-Acetyl-Methadol (LAAM), Methadone, Reporting and recordkeeping requirements.

For the reasons set forth above, part 8 of Title 42 of the Code of Federal Regulations is proposed to be amended as follows:

1. The authority citation for part 8 continues to read as follows:

Authority: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

2. Section 8.12(i)(3) introductory text is revised to read as follows:

§ 8.12 Federal opioid treatment standards.

* * * * *

(i) * * *

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under 42 CFR 8.12(h)(2)(iii).

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 300 and 665

[Docket No. 080225267–9319–02]

RIN 0648–AW49

International Fisheries Regulations; Fisheries in the Western Pacific; Pelagic Fisheries; Hawaii-based Shallow-set Longline Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would remove the annual limit on the number of fishing gear deployments (sets) for the Hawaii-based pelagic longline fishery. The rule would also increase the current limit on incidental interactions that occur annually between loggerhead sea turtles and shallow-set longline fishing. The proposed rule is intended to increase opportunities for the shallow-set fishery to sustainably harvest swordfish and other fish species, without jeopardizing the continued existence of sea turtles and other protected resources. This proposed rule would also make several administrative clarifications to the regulations.

DATES: Comments on the proposed rule must be received by August 3, 2009.

ADDRESSES: Comments on this proposed rule, identified by 0648–AW49, may be sent to either of the following addresses:

• Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal *www.regulations.gov*; or