

Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments,

on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of

Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 21, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, alphabetically add the following inert ingredients to the table to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *		
N-alkyl(C ₈ -C ₁₈) dimethylamidopropylamines where the alkyl group is linear and may be saturated and/or unsaturated (CAS Reg. Nos. 109-28-4, 3179-80-4, 7651-02-7, 22890-10-4, 22890-11-5, 39669-97-1, 45267-19-4, 68140-01-2, 1147459-12-8, 146987-98-6).	Not to exceed 20% by weight in herbicide formulations.	Surfactants, related adjuvants of surfactants.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8
RIN 0930-AA14

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Proposed Modification of Dispensing Restrictions for Buprenorphine and Buprenorphine Combination as Used in Approved Opioid Treatment Medications

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

ACTION: Final rule.

SUMMARY: This final rule amends the federal opioid treatment program regulations by modifying the dispensing requirements for buprenorphine and buprenorphine combination products approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs. In particular, this rule would allow opioid treatment programs more flexibility in dispensing take-home supplies of buprenorphine—removing restrictions on the time a patient needs to be in treatment in order to receive take-home supplies—after the assessment and documentation of a patient’s responsibility and stability to receive opioid addiction treatment medication. Opioid treatment programs that use these products in the treatment of opioid dependence will continue to

adhere to all other federal treatment standards established for methadone.

DATES: This rule is effective January 7, 2013.

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, email: Nicholas.Reuter@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Purpose of the Regulatory Action

This final rule will modify the way that the narcotic treatment medication buprenorphine will be dispensed by treatment programs to individuals who are dependent on heroin or on certain prescription pain relievers by reducing

the requirements for dispensing treatment medications for “take home” use. Currently, patients in treatment must wait one year before treatment programs may dispense a two week supply of medication. These types of requirements impart a burden on patients and may affect their adherence to treatment. This final rule will provide flexibility to programs in matching patient needs.

There are approximately 1,270 facilities in the U.S. that are specially authorized to use narcotic medications like methadone and buprenorphine to treat addiction. The special authorization is required under federal law because these medications can be abused, and can also produce dependence. To obtain the special authorization, the programs must adhere to requirements that relate to the way patients are selected for treatment, how they receive treatment, and how the treatment medications are dispensed. The Secretary has the authority under 21 U.S.C. 823(g) to establish standards for the quantity of narcotic treatment medications, like buprenorphine, that may be provided by authorized programs for unsupervised use. This rulemaking changes these regulatory standards for buprenorphine.

B. Summary of the Major Provisions of the Regulatory Action in Question

This final rule changes the way one narcotic treatment medication, buprenorphine, is dispensed to patients in admitted to Opioid Treatment Programs (OTPs). The rule permits OTPs to dispense buprenorphine addiction treatment products to patients without requiring the patients to meet eligibility requirements relating to their length of treatment. This change will increase flexibility in treatment and is justified by the experience to date with buprenorphine addiction treatment products, together with buprenorphine's safety profile.

C. Costs and Benefits

The Secretary anticipates that there will be an overall reduction in societal costs if treatment is expanded under this final rule. The costs for OTPs to implement this regulatory change are negligible. The added flexibility will permit OTPs to dispense buprenorphine products more frequently. Insofar as there are costs associated with each dispensing activity, this change could lead to lower overall treatment costs for OTPs. The added flexibility will also benefit patients, who should be able to report to the OTP less frequently, while still benefitting from the counseling, medical, recovery and other services

OTPs provide. There may be additional diversion and abuse risks associated with the possible of expansion of treatment, but the Secretary believes that the benefits of increased flexibility and increased access to care in OTP settings outweighs these possible risks.

II. Background

Opioid Treatment Regulations—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 Controlled Substance Act (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. 290bb–2a.).

In a notice published in the **Federal Register** on 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). The authority citation for this rule is 21 U.S.C. 823; 42 U.S.C. 290bb–2a, 290aa(d), 290 dd–2, 300x–23, 300x–27(a), 300y–11.

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 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 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 notice was preceded by the FDA's approval of two buprenorphine products (Subutex® and Suboxone®) on October 8, 2002, and the DEA's 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 products 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 also 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, Pub. L. 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 under 21 U.S.C. 823(g) 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 FDA 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)). “DATA Waived” physicians are not permitted to prescribe the Schedule II medication methadone for addiction or dependence treatment.

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 authorization 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. 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 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. SAMHSA developed a system to accept, review, and verify that physicians fulfill the criteria under DATA to qualify for the waiver. The system assures that physicians complete qualifying training, that they have the necessary DEA registration, and that they are licensed. In addition, SAMHSA developed and issued an office-based treatment guideline, which was a requirement under DATA 2000. The DEA’s final regulation removed the regulatory prohibition on prescribing certain 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).

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 physicians). This

distinction is because, as explained elsewhere in this notice, OTPs are registered under 21 U.S.C. Section 823(g)(1) of the CSA as practitioner programs. Under this section, SAMHSA certifies and DEA registers “narcotic treatment programs” (not individual physicians) to dispense and administer (but not prescribe) approved opioid treatment medications for dependence or addiction treatment. As certified and registered programs with required staffing (physicians, counselors, other health professionals), OTPs are subject to extensive federal, state, and local regulation, including accreditation. OTP medical staffs are required to be licensed and qualified; however, there is no requirement that the OTP physicians, who are part of the treatment team, complete special training on methadone or buprenorphine treatment, or obtain waivers under DATA 2000. As noted elsewhere in this notice, even though it is not required that OTP program physicians obtain waivers to prescribe buprenorphine products, most OTP physicians have completed the training and obtained the waivers. The minority of physicians in OTPs who have not obtained waivers may be located in programs that currently do not use buprenorphine products. Unlike DATA-waivered physicians, federal law does not place a limit on how many patients OTPs treat with buprenorphine or methadone.

C. Comments Submitted in Response to Interim Final Rule—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 commenter believed that 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 and noted that 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. Commenters noted that 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 suggesting that 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.

D. Notice of Proposed Rulemaking—After considering the comments submitted in response to the Interim Final Rule, along with administrative considerations, the Secretary decided to not finalize the Interim Final Rule. Instead, the Secretary published a **Federal Register** Notice of Proposed Rulemaking. In the June 19 2009, Notice (74 FR 29153, June 19, 2009) the Secretary proposed to modify the dispensing regime for buprenorphine in OTPs. The proposed rule was based upon the information available 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. Schedule II is the most restrictive Schedule under the Controlled Substances Act, reserved for substances with high potential for abuse and accepted medical use. Substances controlled in Schedule III have a lower potential for abuse compared to Schedule II substances. These distinctions supported the establishment of a less restrictive distribution scheme for Schedule III

buprenorphine products approved to treat opioid dependence.

In the June 19 2009, Notice (74 FR 29153, June 19, 2009), SAMHSA did not propose 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 proposed an amendment to Subpart B, Certification and Treatment Standards. SAMHSA proposed to amend only one Section of Subpart B, Section 8.12(i) regarding 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 intended to limit or reduce the potential for diversion of these medications to the illicit market. The proposed rule would remove the restrictions for dispensing buprenorphine and buprenorphine combination products for unsupervised or “take-home” use while retaining those requirements for methadone products. The 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).” As discussed throughout this notice, the Secretary believes that buprenorphine’s lower potential for abuse, and other factors, when compared to methadone, supports this change.

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, including buprenorphine products for unsupervised use set forth under 42 CFR 8.12(i)(2) and 8.12(i)(3). In addition, the provisions of DATA 2000 that limit the total number of patients an office-based physician could treat would not be applied to patients treated with buprenorphine products in OTPs.

In response to the June 19, 2009, proposed rule, the Secretary received 12 comments from patient advocacy groups, addiction treatment provider associations, addiction medicine treatment societies, state regulatory officials, and individuals not affiliated with any organizations. These comments have been considered and analyzed, as discussed below.

E. Discussion, Analyses of Comments. Most comments generally supported the proposed changes to the dispensing restrictions for buprenorphine addiction

treatment products in OTPs. A few comments opposed the change, while others either suggested changes to the OTP regulations, or changes to DATA 2000.

1. Those comments that support the modification to the rules stated that the change would significantly increase the use of a valuable treatment medication (buprenorphine) for opioid dependence and addiction through OTPs. They also noted that the change would make the regulations more consistent with DATA 2000. Commenters noted, for example, that “the analysis supplied by SAMHSA is very complete and accurately reflects the realities of the treatment experience of patients in both OTP’s and addiction physicians’ offices.” They note that there is extensive patient experience, including the hundreds of thousands of patients who have received buprenorphine prescriptions from physicians authorized under DATA 2000, that supports the safety and efficacy of buprenorphine addiction treatment products dispensed for unsupervised use. Another comment stated that the proposed rule will help ease the financial and staffing burden incurred with the daily supervised administration of buprenorphine in OTPs. This change may allow OTPs to increase their patient capacity to match the community’s needs. Other comments supported the change for its impact on patient access to treatment, particularly in rural settings.

2. Another comment supporting the proposed change urged SAMHSA to go further to implement harm reduction measures, including expanded access to substitution treatment and distribution of sterile injection equipment. The comment is based upon studies that indicate a higher prevalence of intravenous heroin and prescription opioid abuse in patients enrolling in OTPs compared to patients seeking treatment in office-based settings. According to the comment, the increased risk of intravenous drug abuse would also be present in OTP patients who receive buprenorphine products (combination or single entity) for addiction treatment. The commenter was concerned that the hypothetical increase in intravenous buprenorphine abuse would lead to increases in infectious disease transmission and other health issues.

As stated in the June 2009 NPRM, the Secretary anticipates that reducing the distribution restrictions for OTPs using buprenorphine products would increase the number of patients treated in OTPs, expanding access to medication assisted treatment. Although studies may show a higher prevalence of intravenous drug

abuse among individuals entering OTPs compared to office-based physicians, it is not clear that these patients would continue intravenous abuse once in treatment, or if they would increase the level of intravenous buprenorphine abuse. Indeed, the number of patients treated with buprenorphine products in OTPs has increased steadily since 2003. According to the 2010 National Survey on Substance Abuse Treatment Services (N-SSATS, a point prevalence, one day client count estimate), OTPs reported treating almost 6,500 patients with buprenorphine products (REF 1). Although a modest number when compared to the hundreds of thousands of patients who receive buprenorphine products from office-based DATA 2000 prescribers, it represents a 5-fold increase since 2005. The Secretary is not aware of a significant increase in intravenous buprenorphine abuse during this period. The Secretary will continue to monitor the treatment field to detect changes in rates of intravenous buprenorphine abuse.

3. One commenter supported the proposal to eliminate the take home restrictions for buprenorphine in OTPs but urged SAMHSA to “harmonize” the OTP use of buprenorphine with the requirements of DATA 2000, in particular, the patient limits. A different commenter, while supporting the proposed rule, suggested that the patient limit requirements of DATA 2000 be eliminated altogether. Finally, one comment supported the proposal, but stated that it did not go far enough. This commenter believed that the OTPs rules should be harmonized to eliminate all other requirements under 42 CFR part 8, so that there would be no differences in requirements for patients treated in OTP versus office-based DATA waived physicians.

These comments refer to the requirements under DATA 2000 that physicians adhere to patient limits. Under DATA 2000, a physician initially is limited to treating no more than 30 patients at any one time. DATA 2000 was modified by public law in 2005 to permit physicians to submit applications to treat up to 100 patients at any one time. Of the almost 22,000 physicians certified to prescribe buprenorphine products under DATA 2000, almost 5,200 submitted notifications necessary to treat up to 100 patients.

The Secretary does not intend to issue new rules to “harmonize” the use of buprenorphine in OTPs with the use of buprenorphine under DATA 2000 as the commenter suggests. The commenter is correct in noting that DATA 2000 physicians are subject to limits on how

many patients that they may treat with buprenorphine for addiction treatment at any one time, while OTPs are not subject to patient limits. It should be noted, however that under 42 CFR part 8, OTPs are required to provide counseling, medical, drug testing, and other services to each patient admitted to treatment. In addition, OTPs are subject to state laws and regulations, including, in some cases, patient limits. At this time, DATA waived physicians are not required under federal treatment regulations to provide counseling and other services to the patients they treat. The Secretary is not proposing to harmonize either the patient limits or the counseling and services requirements and will not be modifying patient limits in OTPs or for DATA Waived physicians at this time. In addition, the comment to remove most of the requirements set forth under 42 CFR part 8, for OTPs, goes well beyond the scope of changes proposed in the June 2009, NPRM. Additional changes to these regulations would need to be preceded by another notice and comment rulemaking process.

4. One comment urged SAMHSA to address concerns about buprenorphine abuse and diversion from OTPs by “working with the Drug Enforcement Administration and the Food and Drug Administration to develop a risk evaluation and mitigation strategy.” The strategy would include dose and quantity limits for buprenorphine, and require that patient demonstrate stability for an unspecified period of time before they are provided buprenorphine products for unsupervised use.

The Secretary notes that the FDA has established a Risk Evaluation and Mitigation Strategy (REMS) program for buprenorphine addiction treatment products.¹ In addition, FDA has established a REMS program for certain buprenorphine pain treatment products. These programs include components on prescriber education to address prescribing practices (including guidance on dosing) and other measures to help ensure that only appropriate patients receive the drug. Making sure that only an appropriate group of patients use the product has the effect of reducing the abuse and diversion of buprenorphine addiction and pain treatment products. SAMHSA has worked with FDA to make the buprenorphine addiction treatment

REMS program consistent with these rules. At this time, the Secretary does not believe that modifications to the REMS for buprenorphine addiction treatment products are necessary to ensure the benefits of the product outweigh the risks. In addition, the Secretary does not accept the recommendation that the regulations require OTP patients demonstrate stability for a period of time before receiving buprenorphine take homes. As discussed in the NPRM and throughout this final rule, the Secretary believes that there are adequate safeguards and controls in place to minimize buprenorphine abuse and diversion without applying the time in treatment requirements under 42 CFR 8.12. These include the requirements for patient stability assessments and criteria for stability set forth under 42 CFR 8.12 (i)(2). Under this rule, OTPs will continue to be required to assess patients before unsupervised use and they will continue to be required to provide counseling, which is not required of office-based settings. Finally, as stated elsewhere in this notice, SAMHSA will send a formal guidance letter to all OTP Medical Directors, encouraging them to complete buprenorphine training and obtain a waiver. In the letter, SAMHSA will provide links to Web sites where OTP physicians can complete on-line qualifying training and will offer to send the OTP physicians a CD-ROM to complete training.

5. One comment, representing addiction treatment professionals expressed great concern about “the potential negative effect the proposed change in regulation would have on the management of opioid dependence” provided by OTPs. Specifically, the comment stated that removing the restriction for dispensing buprenorphine and buprenorphine combination products in OTPs will lead to poorer treatment outcomes and increased diversion. This problem would arise because OTP patients are often in programs (as opposed to office-based physician settings) because “they require the structure offered in methadone maintenance (frequent dosing within the clinic environment, frequent contact with clinical staff).” The comment contends that “OTPs are a primary referral for patients receiving buprenorphine/naloxone in office-based treatment settings who have been unable to comply with treatment requirements or to discontinue illicit drug use.” In addition, the comment states that “patients in methadone maintenance/narcotic treatment

programs often have more severe illness (poly-substance abuse/dependence, co-occurring mental illness, antisocial behaviors associated with early drug abuse treatment).”

The Secretary is not aware of evidence to support the assertion that OTPs serve as primary referral centers for non-compliant office-based patients and those office-based patients unable to discontinue drug use, or that OTP patients are more likely to have more severe illness compared to patients treated in office-based settings. The commenter did not provide evidence that removing the take home restrictions for buprenorphine products for patients treated in OTPs would interfere with the medical, drug testing, counseling, and other services that OTPs are required to provide to patients admitted to treatment. In addition, the proposal removes the time in treatment schedule for dispensing buprenorphine products but does not remove the requirement that every patient is assessed for stability before any buprenorphine products are dispensed by an OTP for unsupervised use. As discussed above, providers treating patients in OTPs with approved buprenorphine products are required under the Drug Addiction Treatment Act to provide counseling and other services to patients treated with buprenorphine products, and to assess and document patient suitability and stability before buprenorphine is prescribed for unsupervised use. Office-based buprenorphine providers are not required to provide counseling and to assess suitability and stability.

The same commenter suggested that patients in OTPs are dosed daily until stability is demonstrated. Permitting OTPs to dispense “buprenorphine products in up to 1-month prescriptions rapidly upon starting this therapy will result in patients losing that important component of their treatment * * * [and] will result in poorer treatment outcomes for this population as well as substantial increases in diversion of the drug.” The commenter believes that increases in buprenorphine diversion could jeopardize the availability of buprenorphine treatment modality. However, OTPs are not required to dispense a one month supply to every patient; programs are required to assess patients and dispense amounts that meet criteria for stability.

Taken together, the Secretary believes that the risk for buprenorphine diversion from buprenorphine dispensed by OTPs in accordance with this final rule will be less than the risk of diversion associated with office-based settings. Nonetheless, at least annually, SAMHSA will, in consultation with the

¹ The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require a Risk Evaluation and Mitigation Strategy (REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

Office of National Drug Control Policy (ONDCP) and relevant HHS agencies, review new data on buprenorphine diversion from OTPs and, if necessary, SAMHSA will take formal steps to address this diversion.

The same comment acknowledges that buprenorphine diversion is increasing now, but contends that the risk of diversion “will increase further should generic buprenorphine (without naloxone) become the preferred formulation used by narcotic treatment programs.” The comment states that generic single entity (“mono”) formulations will be less expensive than the fixed combination buprenorphine/naloxone products. OTPs seeking higher profit margins will dispense the less expensive and presumptively more abuseable mono formulation, contributing to an increase in abuse and diversion.

The Secretary acknowledges that generic versions of Subutex (a mono formulation of buprenorphine) were first approved in October 2009 and are priced nominally less than the combination (Suboxone product). Generic mono buprenorphine formulations have been available for almost two years. The amount of mono buprenorphine prescribed by office-based physicians has increased steadily in this period of time to almost 12 percent of the total number of patients receiving prescriptions in 2010 (REF 2). As discussed below, the Secretary is aware of reports on increasing buprenorphine abuse and diversion, including diversion in criminal justice settings (REF 3). The Secretary is not aware of compelling evidence to support the assertions that OTPs will predominantly dispense mono buprenorphine more than office-based physicians. Regardless, as noted above, the controls in place under the 42 CFR 8.12, will mitigate diversion issues in OTPs with either buprenorphine formulation.

6. One comment expressed concern that the availability of buprenorphine treatment through narcotic treatment programs “could discourage office-based practitioners from offering this treatment; particularly if third party payers encourage such treatment from narcotic treatment programs and introduce barriers to office-based treatment.”

The Secretary is not aware of any evidence to support the suggestion the regulatory changes on buprenorphine distribution in OTP settings would discourage office-based buprenorphine treatment, or that third party payers would react to by creating additional barriers to reimbursement for office-

based treatment under DATA 2000. Buprenorphine products have been available for office-based treatment and for use in OTPs since 2003. Buprenorphine treatment has been covered by public and private insurance providers in both OTP and office-based settings. It is unclear how changing the way buprenorphine products are dispensed by OTPs will have any direct or indirect impact on private or public reimbursement decisions, or on office-based physicians willingness to continue to treat patients in that setting.

7. One comment recommended that physicians in OTPs be required to obtain the waiver to prescribe buprenorphine under DATA 2000, and to complete the training that is one of the requirements under DATA 2000. The commenter “believes it would be irresponsible to simply permit uneducated physicians working in narcotic treatment programs to begin to prescribe this medication with no foundation as to its proper use.” The same comment recommended that non-physician OTP staff also be required to obtain education on buprenorphine.

Another comment, referring to DATA 2000 stated that “qualified physicians are authorized [to use buprenorphine in addiction treatment]—not programs.” The same commenter suggested allowing Nurse Practitioners to become qualified to treat these patients.

The Secretary has carefully considered this recommendation, but does not at this time believe that it is necessary to modify the Opioid Treatment Regulations to require all OTP physicians to complete training and obtain waivers under DATA 2000. The Drug Addiction Treatment Act (21 U.S.C. 823(g)(2)(F), did not establish any additional training or educational requirements for practitioners, including OTPs that dispense Schedule III–V narcotic drugs and are registered as treatment programs under 21 U.S.C. 823(g)(1). Indeed, DATA 2000 specifically authorized treatment programs registered under 21 U.S.C. 823(g)(1) to use Schedule III–V narcotic drugs for addiction and dependence treatment. In addition, 42 CFR 8.12 (d), requires “that each person engaged in the treatment of opioid addiction must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.” This requirement applies to OTP program physicians, who order both methadone and buprenorphine for patients admitted to OTPs. OTP program physicians have been authorized to order buprenorphine products for patients admitted to treatment since the interim final rule

was issued in 2003. Moreover, SAMHSA has analyzed its OTP Medical Director database and cross referenced it to the database of physicians with DATA waivers. This analysis indicates that as of October 2012 at least 80 percent of the Medical Directors in OTPs have sought and obtained DATA 2000 waivers to prescribe buprenorphine products in office-based or other settings.

As stated elsewhere in this notice, SAMHSA will send a formal guidance letter to all OTP Medical Directors, encouraging them to complete buprenorphine training and obtain a waiver. In the letter, SAMHSA will provide links to Web sites where OTP physicians can complete on-line qualifying training and will offer to send the OTP physicians a CD-ROM to complete training.

There are many other resources available to OTP staff on the use of buprenorphine in the treatment of opioid dependence. SAMHSA has issued two treatment improvement protocols (TIPs): “TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction” and “TIP 43: Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.” These treatment guidelines provide extensive evidence-based clinical guidelines on the use of buprenorphine, as well as methadone and other medications in treating opioid dependence. These guidelines are supplemented by the SAMHSA-funded Physician Clinical Support System which provides continuous assistance and training to OTP physicians who need more information on using buprenorphine in dependence treatment.

The Treatment Improvement Protocols, discussed above, are also available to non-physician OTP Staff. In addition, SAMHSA has developed specific guidance for nurses in OTPs or other practice settings such as “Technical Assistance Publication 30—Buprenorphine: A Guide for Nurses.” SAMHSA also sponsors continuing medical education seminars for nurses on using buprenorphine in OTPs (see www.dpt.samhsa.gov.)

There is also information available on buprenorphine treatment to counselors and other addiction treatment professionals. For example, the SAMHSA-supported network of Addiction Technology Transfer Centers (ATTCs) offers classroom training and other information on using buprenorphine in opioid dependence treatment, including treatment in adolescent populations. (See Short-

Term Opioid Withdrawal Using Buprenorphine: Findings and Strategies from a NIDA Clinical Trials Network (CTN) Study, <http://www.nattc.org/explore/priorityareas/science/blendinginitiative/bupdetox/>.

The Secretary believes that there are considerable education resources available to physicians and non-physician staff in OTPs and that these resources are being used. Finally, the Drug Addiction Treatment Act authority to prescribe buprenorphine addiction treatment products does not extend to practitioners such as nurse practitioners or physicians assistants.

8. One comment recommended that the regulations be modified to establish dose limits for patients treated with buprenorphine products in OTPs. Specifically, the OTP must document the need for any daily dose above 16 mg per day. The commenter provided references to support that 16 mg per day occupies 95 percent of the mu-opioid receptor, and any dose above that amount invites diversion.

The existing OTP regulations (42 CFR 8.12(h)(4)) require that "each opioid agonist treatment medication used by the program is administered and dispensed in accordance with its approved product labeling." Further, the current regulations require that any significant deviations from this labeling, including dosing deviations, are documented in the patient record. The Secretary notes that there are no daily dose limits applied to physicians who prescribe buprenorphine products under their DATA 2000 waiver authority. Accordingly, it is not clear whether establishing a specific 16 mg per day dose limit for buprenorphine dispensed by OTPs would have a measureable impact above the current regulatory requirements. As such, the Secretary declines the recommendation to establish buprenorphine dose limits for OTPs.

9. One comment recommended an increase in the required number of random urine toxicology screening tests within OTPs to at least twice monthly. According to the comment, this level of drug testing is necessary to demonstrate that drug use has ceased or has been at least reduced.

The current regulations require, at a minimum, that OTPs conduct at least 8 random drug tests each year. These tests must be adequate, and are used to monitor a patient's progress in treatment as well as to guide the OTP physician on appropriate take-home doses. The comment provided no evidence to support how increasing the frequency of drug testing in OTPs beyond the minimum of eight per year would

produce benefits that would outweigh the additional costs. The Secretary notes OTPs can conduct more frequent drug testing that can be tailored to individual patient needs and treatment status. Further, there is no federal regulatory requirement that a physician that prescribes buprenorphine products under DATA 2000 waivers conduct any drug testing with their patients. This final rule does not increase the number of required drug tests in OTPs.

After carefully analyzing the comments submitted in response to the June 2009 NPRM, together with additional information on buprenorphine abuse and diversion, the Secretary concludes that the OTP regulations should be modified as proposed in the 2009 NPRM. Specifically, the time in treatment restrictions are eliminated for buprenorphine products use in SAMHSA-certified OTPs.

There is now even more experience with buprenorphine in the treatment of opioid dependence. Since 2002, almost 22,000 physicians have sought and obtained the federal certification to prescribe buprenorphine products. According to the DEA Automated Reports Consolidated Orders System (ARCOS), over 190 million dosage units were distributed to pharmacies in 2010, a more than fourfold increase from the almost 40 million dosage units distributed in 2006. It should be noted that only 1.1 million dosage units were distributed to OTPs during 2010. In addition, almost 800,000 individuals received buprenorphine addiction treatment prescriptions from office-based physicians in 2010, increasing almost fivefold from the 150,000 estimated in 2006. (REF 4).

Although buprenorphine abuse and diversion has increased concomitantly with the increase in availability according to information from published literature reports and from long-standing monitoring systems maintained by FDA, SAMHSA, and DEA, the scope, extent, and nature of abuse and diversion, while a major concern, are considerably less—and qualitatively different than the scope, nature, and extent associated with methadone and other Schedule II and Schedule III opioid drug products. Nonetheless, there are initiatives underway to address escalating buprenorphine abuse and diversion, and its consequences. These include the FDA REMS initiative for buprenorphine, the Physician Clinical Support System, and the updated buprenorphine office-based physician training curriculum.

One 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 substantially less than other opioids in the class. According to the DAWN 2006 national tables, 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. The 2010 DAWN indicates that out of 1,173,654 drug-related ED visits involving nonmedical use of pharmaceuticals in 2010, there were an estimated 15,778 (95 percent confidence interval [CI] 10,815 to 20,741) visits involving buprenorphine/combinations. While the number of visits in DAWN for buprenorphine/combinations doubled between 2007 and 2009, the increase between 2009 and 2010 (1,522 more reports) was not significant at the p.05 level. The rates for buprenorphine/combinations in 2006 were 1.5 per 100,000 population and 5.1 per 100,000 population in 2009. Non-medical use of buprenorphine/combinations has increased almost fourfold since 2006. (REF 5). It should be noted that analyses of the increases in DAWN reports over the years should also factor in increases in the number of buprenorphine tablets sold per year. (REF 6).

Increasing buprenorphine abuse and misuse has been identified in other substance abuse surveillance instruments. For example, the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System is a prescription drug abuse, misuse and diversion surveillance system that collects timely product- and geographically-specific data. The RADARS System measures rates of abuse, misuse and diversion throughout the United States (U.S.). Recent information from the RADARS system indicates that abuse of the mono formulation of buprenorphine may be increasing. The same system suggests that intravenous abuse of the mono formulation has increased recently (REF 8).

Increasing buprenorphine abuse, as measured by DAWN, is a concern, and there are measures underway to identify and mitigate this abuse. Buprenorphine DAWN reports must be considered in the context of DAWN non-medical use

reports for other opioids. In 2009 there were an estimated 14,266 (95 percent confidence interval [CI] 8,001 to 20,531) visits involving buprenorphine/ combinations. The DAWN non-medical use ED visits for other opioids for 2010 are as follows:

Oxycodone/combinations—146,355 visits (95 percent C.I. 106,109—186,602);

Hydrocodone/combinations—95,972 visits (95 percent C.I. 74,472—117,472);

Fentanyl/combinations—21,196 visits (95 percent C.I. 15,872—26,520);

Hydromorphone/combinations—17,666 (95 percent C.I. 12,502—22,830); and,

Methadone—65,945 (95 percent C.I. 52,085—79,806).

Buprenorphine diversion—NFLIS—The National Forensic Laboratory Information System (NFLIS) is a DEA, Office of Diversion Control program that collects drug identification results and associated information from drug cases analyzed by federal, state, and local forensic laboratories. These laboratories analyze substances secured in law enforcement operations. NFLIS From 2003 to 2008, the national estimated number of methadone items reported in NFLIS more than doubled from 4,967 items to 10,459 items ($p < 0.05$), while buprenorphine increased more than 250-fold from 21 items to 5,627 items ($p < 0.05$). The greatest increases in NFLIS items were in the Northeast U.S. where per capita distribution of buprenorphine is greatest (REF 7).

DEA STRIDE—The DEA's System to Retrieve Information from Drug Evidence II (STRIDE) collects the results of drug evidence analyzed at DEA laboratories across the country. STRIDE reflects evidence submitted by the DEA, other federal law enforcement agencies, and some local police agencies that was obtained during drug seizures, undercover drug buys, and other activities. STRIDE captures data on both domestic and international drug cases; however, the following results describe only those drugs obtained in the U.S. STRIDE data and their generalization are limited by inconsistent and underreporting at the state and local level. During 2008, a total of 51,022 drug exhibits or items were reported in STRIDE, about 3 percent of the estimated 1.8 million drug items analyzed by state and local laboratories during this period. In STRIDE, methadone and buprenorphine each represented less than 1 percent of total drug items reported in 2008. The number of methadone items reported in STRIDE increased from 97 items in 2003 to 159 in 2006, then fell to 130 in 2007 and rose to 165 in 2008. Buprenorphine

items increased from 8 items in 2003 to 53 items in 2008.

In sum, buprenorphine abuse and diversion are measurable and increasing. The levels of actual abuse (not adjusted for rate of use) and diversion are noticeably less than other opioids. The Secretary will continue to monitor abuse while applying the specific buprenorphine abuse reduction interventions discussed elsewhere in this notice. While cognizant of this abuse, the Secretary believes that eliminating the time in treatment restrictions for buprenorphine will result in more patients treated in structured opioid treatment programs, where controls and requirements can be applied to identify and address buprenorphine abuse and diversion.

Importantly, the consequences of buprenorphine abuse further distinguish buprenorphine from methadone and other opioids. Two recent review articles discuss buprenorphine toxicity. These articles include reports from the National Poison Control Centers of the American Association of Poison Control Centers. (REFS 8, 9). According to these reports, which covered years 2000 through 2008, there were fewer than nine buprenorphine associated deaths over the nine year period. During the same period of time, there were 654 methadone associated deaths. These reports, together with the discussion in the Proposed Rule, further distinguish buprenorphine from methadone in overall toxicity. One report highlights the risks and severe consequences associated with pediatric buprenorphine poisoning. (REF 9). That same article recommends special precautions and warnings to mitigate the risk of pediatric buprenorphine exposure. Finally, information is presented that contrasts buprenorphine and methadone safety concerns for treatment for opioid dependence during pregnancy. (REF 9).

These peer-reviewed articles support the concept that the consequences of buprenorphine abuse are fewer and less severe than those associated with methadone. Nonetheless, SAMHSA will continue to work with other federal agencies, including FDA with its REMS program, to develop strategies to minimize the consequences of buprenorphine abuse in OTP and office-based settings. In addition, at least annually, SAMHSA will, in consultation with ONDCP and relevant HHS agencies, review new data on buprenorphine diversion from OTPs and, if necessary, SAMHSA will take formal steps to address this diversion, including additional provider training or additional guidance on appropriate prescribing. As stated elsewhere in this

notice, SAMHSA will send a formal guidance letter to all OTP Medical Directors, encouraging them to complete buprenorphine training and obtain a waiver. In the letter, SAMHSA will provide links to Web sites where OTP physicians can complete on-line qualifying training and will offer to send the OTP physicians a CD-ROM to complete training.

The Secretary notes that state entities have also initiated programs to inform prescribers on buprenorphine and pediatric exposures. Under the OTP regulations, all take-home doses dispensed by OTPs must be in dispensed in "packages designed to reduce the risk of accidental ingestion, including child proof containers." (see 42 CFR 8.12(i)(5)). Finally, OTPs have considerable experience in treating pregnant patients. This final rule will increase the flexibility in how OTPs can dispense buprenorphine products, and permit programs to expand treatment to this population.

The Secretary concludes that there is adequate information in the administrative record for this rulemaking to eliminate the take-home dispensing schedule for buprenorphine products as set forth in Section IV.

III. References

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Methadone Abuse: What Do We Know?, *The American Journal on Addictions*, 19: 73–88, 2009.

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IV. Summary of Final 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. 290bb–2a.)

SAMHSA is not changing 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 finalizing an amendment to Subpart B, Certification and Treatment Standards. If finalized, the rule would amend only one section of Subpart B, Section 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 intended to limit or reduce the potential for diversion of these medications to the illicit market. The effect of this final 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 change will 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 are still 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).

V. Regulatory Impact and Notices

Executive Orders 13563 and 12866

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review), explicitly states that our “regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” Consistent with this mandate, Executive Order 13563 requires agencies to tailor “regulations to impose the least burden on society, consistent with obtaining regulatory objectives.” Executive Order 13563 also requires agencies to “identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice” while selecting “those approaches that maximize net benefits.” This final rule sets forth a regulatory approach that will reduce burdens to providers and to consumers, while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of this final 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 final 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 notice 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.

While this is a significant regulatory action as defined by Executive Order 12866, the Secretary finds that it does not confer significant costs to regulated entities warranting a regulatory flexibility analysis. See the Regulatory Flexibility discussion below. The rule

permits OTPs to dispense buprenorphine and buprenorphine combination products for take home use. 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 final 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 final rule. The costs for OTPs to implement this regulatory change are negligible. The added flexibility will permit OTPs to dispense buprenorphine products more frequently. Insofar as there are costs associated with each dispensing activity, this change could lead to lower overall treatment costs for OTPs. The added flexibility will also benefit patients, who should be able to report to the OTP less frequently, while still benefitting from the counseling, medical, recovery and other services OTPs provide. There may be additional diversion and abuse risks associated with the possible of expansion of treatment, but the Secretary believes that the benefits of increased flexibility and increased access to care in OTP settings outweigh these possible risks.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that this final 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)). The flexibility added by this final rule will not require additional expenditures by OTPs. Therefore, an initial regulatory flexibility analysis is not required for this final Rule.

As mentioned in the section on Executive Orders 13563 and 12866, the Secretary anticipates that there will be an overall reduction in societal costs if treatment is expanded under this final rule. The costs for OTPs to implement this change to regulation are negligible. The added flexibility will permit OTPs to dispense buprenorphine products more frequently. Insofar as there are costs associated with each dispensing activity, this could lead to lower overall treatment costs for OTPs. The added flexibility will also benefit patients, who should be able to report to the OTP less frequently, while still benefitting from the counseling, medical, recovery and other services OTPs will provide.

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.

Unfunded Mandates

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 final 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" refer 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 final 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 final rule does not preempt State law. Accordingly, the Secretary has determined that this final rule does not contain policies that have federalism implications or that preempt state law.

Paperwork Reduction Act of 1995

This final 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 final rule establishes no new reporting or recordkeeping requirements beyond those discussed in the January 17, 2001, Final Rule (66 FR 4076 at 4088). On March 7, 2010, the Office of Management and Budget approved the information collection requirements of the Final Rule under control number 0930-0206.

Privacy Act

SAMHSA has determined that the Opioid Treatment Waiver Notification System (OTWNS) constitutes a system of records under the Privacy Act. The **Federal Register** notice announcing establishment of the buprenorphine waiver notification system as a system of records was published on April 25, 2002 (67 FR 20543, April 25, 2002). That system was assigned the identification number 09-30-0052

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 final 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: February 23, 2012.

Pamela S. Hyde,

Administrator, SAMHSA.

Dated: March 8, 2012.

Kathleen Sebelius,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on November 30, 2012.

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 amended as follows:

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

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

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

■ 2. Section 8.12(i)(3) 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 paragraph (h)(2)(iii) of this section.

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