provider in connection with your planning and/or scheduling an official conference or other group travel (as opposed to performing official travel yourself) are considered property of the Government, and you may only accept the benefits or materials on behalf of the Federal Government (*see* § 301–74.1(d) of this chapter).

■ 3. Revise § 301–53.3 to read as follows:

§ 301–53.3 How may I use promotional materials and frequent traveler benefits?

Promotional materials and frequent traveler benefits may be used as follows:

(a) You may use frequent traveler benefits earned on official travel to obtain travel services for a subsequent official travel assignment(s); however, you may also retain such benefits for your personal use, including upgrading to a higher class of service while on official travel.

(b) If you are offered such benefits as a result of your role as a conference planner or as a planner for other group travel, you may not retain such benefits for your personal use (*see* § 301–53.2 of this chapter). Rather, you may only accept such benefits on behalf of the Federal Government. Such accepted benefits may only be used for official Government business.

PART 301–74—CONFERENCE PLANNING

■ 4. The authority citation for 41 CFR part 301–74 continues to read as follows:

Authority: 5 U.S.C. 5707.

■ 5. Amend § 301–74.1 by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 301–74.1 What policies must we follow in planning a conference?

* * * * *

(d) Ensure that the conference planner or designee does not retain for personal use any promotional benefits or materials received from a travel service provider as a result of booking the conference (*see* §§ 301–53.2 and 301–53.3 of this chapter); and

* * * * *

[FR Doc. 03–12896 Filed 5–21–03; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

42 CFR Part 8

RIN 0910–AA52

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Addition of Buprenorphine and Buprenorphine Combination to List of Approved Opioid Treatment Medications

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

ACTION: Interim final rule.

SUMMARY: This interim final rule amends the Federal opioid treatment program regulations by adding buprenorphine and buprenorphine combination products to the list of approved opioid treatment medications that may be used in federally certified and registered opioid treatment programs. The Food and Drug Administration (FDA) recently approved Subutex® (buprenorphine) and Suboxone® (buprenorphine in fixed combination with naloxone) for the treatment of opiate dependence. These two products will join methadone and ORLAAM® as medications that may be used in opioid treatment programs for the maintenance and detoxification treatment of opioid dependence. Opioid treatment programs that choose to use these new products in the treatment of opioid dependence will adhere to the same Federal treatment standards established for methadone and ORLAAM®. The Secretary invites public comments on this action.

DATES: This interim final rule is effective May 22, 2003. This interim final rule is also being presented here for public comments. Written comments must be received by the Substance Abuse and Mental Health Services Administration (SAMHSA) on or before July 21, 2003.

ADDRESSES: Comments should be submitted to the Division of Pharmacologic Therapy, Center for Substance Abuse Treatment, Rockwall II, Room 6–18, 5600 Fishers Lane, Rockville, MD, 20857; Attention: DPT Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapy, SAMHSA, Rockwall II Room 6–18, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0457, email: *nreuter@samsha.gov.*

SUPPLEMENTARY INFORMATION:

Background

In a rule document published in the **Federal Register** of January 17, 2001 (66 FR 4076, January 17, 2001), the Substance Abuse and Mental Health Services Administration (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.

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 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.

On October 8, 2002, FDA approved two new opioid treatment medications, buprenorphine and buprenorphine combination for the treatment of opioid addiction. These medications are controlled under schedule III of the Controlled Substances Act (''CSA,'' 21 U.S.C. 812). *See* final rule published October 7, 2002 (67 FR 62354). By adding these two medications to the previous list of approved opioid treatment medications, the Secretary allows OTPs to use buprenorphine and buprenorphine combination for the treatment of opioid addiction. OTPs will apply the same treatment standards that were finalized on January 17, 2001, for methadone and ORLAAM®.

Summary of 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) (3)). (*See also* 42 U.S.C. 257a.)

This interim final rule does not 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, the rule provides for a minor amendment to subpart B, Certification and Treatment Standards. The rule amends only one section of subpart B, section 8.12(h)(2) Medication administration, dispensing, and use.

Under 42 CFR 8.12(h)(2), OTPs are limited to using only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355). This section notes that ''currently the following medications will be considered to be approved by the Food and Drug Administration for use in the treatment opioid addiction: (i) Methadone; and (ii) levomethadyl acetate (LAAM).'' The effect of this rule is to add buprenorphine and buprenorphine combination to this list by adding a new item (iii).

Justification for Interim Final Rule

The Administrative Procedure Act (5 U.S.C. 553) requires agencies to follow certain procedures for informal rulemaking, including publication of proposed rules in the **Federal Register** with an opportunity for public comment. Section 553(b)(B) allows agencies to dispense with prior notice and opportunity for public comment if the agency finds for good cause that use of such procedures is impracticable, unnecessary, or contrary to the public interest. Section 553(d)(3) permits the Secretary to waive the 30 day effective date if it is contrary to the public interest.

The Secretary has determined that good cause exists for publication of this rule without prior notice and opportunity for public comment and without a delayed effective date since such procedures are contrary to the public interest and unnecessary. It is contrary to the public interest to deny OTPs' access to this important new medication for the treatment of persons addicted to opioids. As compared to methadone and ORLAAM®, buprenorphine and buprenorphine combination are particularly useful in treating patients who have had a shorter course of addiction. Similarly, it would be contrary to the public interest to deny patients access to such prescription drugs from OTPs particularly in areas in which there are no physicians who have obtained a waiver under the Drug Addiction Treatment Act of 2000 (''DATA,'' section 3502 of Pub. L. 106–310).

To further elaborate, while OTPs may continue to use methadone and ORLAAM® for medicated assisted treatment, buprenorphine and buprenorphine combinations will provide OTPs with an important additional option for the treatment of addiction. Indeed, because of its ''partial'' agonist pharmacology, buprenorphine will provide programs with more flexibility in finding the most appropriate medication for each patient. It would thus be contrary to the public interest to delay the availability of buprenorphine products.

In addition to the public interest in having buprenorphine and buprenorphine combination products available for treatment use as soon as possible, prior notice and comment procedures are unnecessary. Currently, the rule states: ''OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration * * * for use in the treatment of opioid addiction * * *. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administation for use in the treatment of opioid addiction: (i) Methadone; and (ii) Levomethadyl acetate (LAAM).'' Because the buprenorphine products have been approved by the FDA as required by section 8.12(h)(2), the proposed modification is technical in nature in that it simply adds buprenorphine and buprenorphine combination to the list of FDA-approved medications that may be used by OTPs. Thus, comment is not necessary before finalizing this change to the regulation.

Although we are making the rule effective immediately without first obtaining public comment, we are providing for a 60-day comment period after publication. Specifically, we seek comments on the applicability of the existing OTP rules to these newly approved medications.

Analysis of Economic Impacts

The Secretary has examined the impact of this interim final rule under Executive Order 12866. Executive Order 12866 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 interim 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 recent 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.

The Secretary also finds that this rule is a not a significant regulatory action as defined by Executive Order 12866. The rule merely adds buprenorphine and buprenorphine combination products to the list of medications that may be used in the detoxification or maintenance treatment of opioid dependence. If opioid treatment programs choose to use the new medications, the new medications will be used in accordance with the standards set forth in the January 17, 2001, final rule (66 FR 4090). No new regulatory requirements are imposed by this interim final rule.

For the reasons outlined above, the Secretary has determined that this interim 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)). Therefore an initial regulatory flexibility analysis is not required for this interim final 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 of 1996 (SBREFA).

The Secretary has examined the impact of this rule under the Unfunded Mandates Reform Act of 1995 (UMRA)

(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 State, local, and tribal governments in the aggregate, or by the private sector, in any one 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 interim 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 interim final rule to modify minimally treatment regulations that provide for the use of approved opioid agonist treatment medications in the treatment of opiate addiction. The Narcotic Addict Treatment Act (the 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 interim final rule does not preempt State law. Accordingly, the Secretary has determined that this interim final rule does not contain policies that have federalism implications or that preempt State law.

Paperwork Reduction Act of 1995

This interim final rule adds buprenorphine and buprenorphine combination products to the list of approved medications that may be used in SAMHSA-certified opioid treatment programs. The interim final rule establishes no new reporting or recordkeeping requirements beyond those discussed in the January 17, 2001, final rule (66 FR 4076 at 4088). The Office of Management and Budget has 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'' 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 interim 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: May 5, 2003.

Tommy G. Thompson,

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 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; Sections 301(d), 543, and 1976 of the 42 U.S.C. 257a, 290aa(d), 290 dd–2, 300x–23, 300x–27(a), 300y–ll.

■ 2. Section 8.12(h) (2) is revised to read as follows:

§ 8.12 Federal opioid treatment standards.

* * * * *

(h)* * *

(2) OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid addiction. Currently the following opioid agonist treatment medications will be considered to be approved by the Food and Drug Administration for use in the treatment of opioid addiction:

(i) Methadone;

(ii) Levomethadyl acetate (LAAM); and

(iii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid addiction.

* * * * *

[FR Doc. 03–11469 Filed 5–21–03; 8:45 am]

BILLING CODE 4160–20–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03–1477; MB Docket No. 02–255; RM–10524]

Radio Broadcasting Services; Cottage Grove, Depoe Bay, Garibaldi, Toledo, and Veneta, OR

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document at the request of Alexandra Communications, Inc. licensee of Station KDEP(FM), Depoe Bay, Oregon, Signal Communications, Inc., licensee of Station KEUG, Inc., Cottage Grove, Oregon, and Agpal Broadcasting, Inc., licensee of Station KPPT(FM), Toledo, Oregon, substitutes channel 288A for channel 288C3 at Depoe Bay, Oregon, reallots channel 288A from Depoe Bay to Garibaldi, Oregon, and modifies the license of Station KDEP(FM) to specify the new community. It also substitutes channel 283C3 for Channel 288A at Cottage