

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 Administration 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 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)