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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

21 CFR Part 291

42 CFR Part 8

RIN 0910-AA52

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Repeal of Current Regulations and Issuance of New Regulations: Delay of Effective Date and Resultant Amendments to the Final Rule

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

ACTION: Final rule; delay of effective date and resultant amendments to the final rule.

SUMMARY: In accordance with the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled ``Regulatory Review Plan,'' published in the Federal Register on January 24, 2001, this action temporarily delays for 60 days the effective date of the rule entitled ``Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Repeal of Current Regulations and Issuance of New Regulations'' published in the Federal Register on January 17, 2001 (66 FR 4076). It also amends the final

rule published on January 17 to extend by 60 days the dates outlines in the rule for transitional certification of opioid treatment programs so as to be consistent with extending the effective date by that amount of time. That rule repealed the existing narcotic treatment regulations enforced by the Food and Drug Administration (FDA), and created a new regulatory system based on an accreditation model. It also shifted administrative responsibility and oversight of the program from FDA to SAMHSA.

DATES: This rule is effective March 18, 2001. The effective date of the ``Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction'' published in the Federal Register on January 17, 2001 (66 FR 4076), is delayed for 60 days, from March 19, 2001 to a new effective date of May 18, 2001.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), SAMHSA, Rockwell II, 5600 Fishers Lane, Rm 12-05, Rockville, MD 20857, 301-443-0457, email: nreuter@samsha.gov.

SUPPLEMENTARY INFORMATION: To the extent that 5 U.S.C. section 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. section 553(b)(A). Alternatively, the Department's implementation of this rule without opportunity for public comment, effective immediately upon publication today in the Federal Register, is based on the good cause exceptions in 5 U.S.C. section 553(b)(B) and 553(b)(3). Seeking public comment is impracticable, unnecessary and contrary to the public interest. The temporary 60-day delay in effective date is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President's memorandum of January 20, 2001. Given the imminence of the effective date, seeking prior public comment on this temporary delay would have been impractical, as well as contrary to the public interest in the orderly promulgation and implementation of regulations.

List of Subjects in 42 CFR Part 8

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

Dated: January 14, 2001.
Tommy G. Thompson,
Department of Health and Human Services.

For the reasons set forth above, Part 8 of Title 42 of the Code of Federal Regulations is amended as follows:

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

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-11.

2. Section 8.11(d) is revised to read as follows:

Sec. 8.11 Opioid treatment program certification.

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(d) Transitional certification. OTPs that before May 18, 2001 were the subject of a current, valid approval by FDA under 21 CFR, part 291 (contained in the 21 CFR parts 200 to 299 edition, revised as of July 1, 2000), are deemed to be the subject of a current valid certification
for purposes of paragraph (a)(11) of this section. Such ``transitional certification'' will expire on August 17, 2001 unless the OTP submits the information required by paragraph (b) of this section to SAMHSA on or before August 17, 2001. In addition to this application, OTPs must certify with a written statement signed by the program sponsor, that they will apply for accreditation within 90 days of the date SAMHSA approves the second accreditation body. Transitional certification, in that case, will expire on May 19, 2003. SAMHSA may extend the transitional certification of an OTP for up to one additional year provided the OTP demonstrates that it has applied for accreditation, that an accreditation survey has taken place or is scheduled to take place, and that an accreditation decision is expected within a reasonable period of time (e.g., within 90 days from the date of survey). Transitional certification under this section may be suspended

or revoked in accordance with Sec. 8.14.

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