

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

**Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs)—Extension**

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. "Certification" is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA-162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA-163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA-168),

which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The tables that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to the forms.

Form	Number of respondents	Responses/respondent	Total responses	Hours/response	Total hours
<b>Estimated Annual Reporting Requirement Burden for Accreditation Bodies</b>					
SMA-163 .....	54	26.055	1,407	0.28	394
<b>Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs</b>					
SMA-162 .....	651.33	17.976	11,708.91		
SMA-168 .....	1,302.67	17.977	23,418.09		
Subtotal .....	1,954	17.977	35,127	0.08	2,902
Total .....			36,534		3,296

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, Room 15-E57A, 5600 Fishers Lane, Rockville, MD 20850 OR email him a

copy at [carlos.graham@samhsa.hhs.gov](mailto:carlos.graham@samhsa.hhs.gov).

Written comments should be received within 60 days of this notice.

**Carlos Graham,**  
Statistician.

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