



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.

Project: Medications for the Treatment of Opioid Use Disorder --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 use disorder treatment under the federal opioid use disorder 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, medical care, 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 Medications for the Treatment of Opioid Use Disorder 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 OTP practitioners when there is a patient care situation in which the OTP practitioner must make a treatment decision that falls outside of the required standards delineated in 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 medical history, a care plan, any prenatal support provided the patient if applicable, the medical rationale for initial starting doses

above 50mg, the medical rationale for a patient's dosage schedule, and care decisions made as a result of follow-up medical examinations.

The tables that follow summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are minor changes to these forms to improve data collection, remove unnecessary questions, and align terms with the final 42 CFR Part 8 rule released February 2, 2024.

Form	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
<u>Estimated Annual Reporting Requirement Burden for Accreditation Bodies</u>					
SMA-163	54	26.055	1,407	0.28	394
<u>Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs</u>					
SMA-162	751.33	17.976	13,506	0.08	1,081
SMA-168	1,302.67	17.977	23,418	0.08	1,873
Subtotal	2,054	17.977	36,925	0.08	2,954
Total			38,332		3,348

Send comments to SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E45, Rockville, MD 20852 *OR* email a copy to samhsapra@samhsa.hhs.gov. Written comments should be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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