



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment

Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-0361.

Project: Medications for the Treatment of Opioid Use Disorder --42 CFR part 8 (OMB No. 0930-0206) and Opioid Treatment Programs (OTPs) - Revision

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, 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 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 8.11(h)* (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 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 table that follows 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
Estimated Annual Reporting Requirement Burden for Accreditation Bodies					
SMA-163	54	26.055	1,407	0.28	394
Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs					
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

Written comments and recommendations for the proposed information collection should be sent

within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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