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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) 276-1112.

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 rule also includes requirements that OTPs and accreditation organizations disclose information. For example, 42 CFR 8.12(e)(1) requires that a physician explain the facts concerning the use of opioid drug treatment to each patient. This type of disclosure is considered to be consistent with the common medical practice and is not considered an additional burden. Further, the rule requires, under Sec. 8.4(i)(1) that accreditation organizations shall make public their fee structure; this type of disclosure is standard business practice and is not considered a burden.

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

Estimated Annual Reporting Requirement Burden for Accreditation Bodies

42 CFR Citation	**Purpose**	**No. of Respondents**	**Responses/ Respondent**	**Total Responses**	**Hours/ Response**	**Total Hours**
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	1	6.0	6
8.3(c)	Renewal of approval (SMA-163)	2	1	2	1.0	2
8.3(e)	Relinquishment notification	1	1	1	0.5	0.5

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.3(f)(2)	Non-renewal notification to accredited OTPs	1	90	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs	2	2	4	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	20	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request	6	5	30	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	450	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request	6	6	36	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA	6	5	30	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	300	0.5	150
8.4(e)	Notifications of Complaints	12	6	72	0.5	36
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs	1	185	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA	1	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status	1	185	185	0.3	55.0
				1,407		394.20

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
SUB TOTAL		54				

Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs

42 CFR Citation	Purpose	No. of Respondents	Responses/ Respondent	Total Responses	Hours/ Response	Total Hours
8.11(b)	Renewal of approval (SMA-162)	386	1	386	0.15	57.9
8.11(b)	Relocation of Program (SMA-162)	35	1	35	1.17	40.95
8.11(e)(1)	Application for provisional certification	42	1	42	1	42.00
8.11(e)(2)	Application for extension of provisional certification	30	1	30	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA-162)	60	1	60	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance	1	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exemption from 8.11 and 8.12 (including SMA-168)	1,200	20	24,000	0.07	1680
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA-162)	10	1	10	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance	1	20	20	0.33	6.6
8.24	Contents of Appellant Request for Review of	2	1	2	0.25	.50

	Suspension					
8.25(a)	Informal Review Request	2	1	2	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement	2	1	2	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review	2	1	2	1.00	2.00
8.28(c)	Appellant Review File and Written Statement	2	1	2	5.00	10.00
SUB TOTAL		1,775		24,594		1868.95
TOTAL		1,829		26,001		2,263.15

Send comments to Janet Heekin, SAMHSA Reports Clearance Officer, Room 15E21-B, 5600 Fishers Lane, Rockville, MD 20850 ***OR*** e-mail her a copy at **janet.heekin@samhsa.hhs.gov**. Written comments should be received within 60 days of this notice.

Date: June 6, 2019.

Carlos Castillo,
Committee Management Officer.
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