

and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 21, 2006.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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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) 276-1243.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR part 8 (OMB No. 0930-0206)—Revision

This regulation 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-162 is used as the initial application to request certification of an OTP, to request renewal of certification and to change existing information regarding the program’s location, sponsor and medical director. This form collects information such as address, program name, contact information, sponsor name and address and medical director name and address. Attachments are required to complete this form regarding the OTPs accrediting status, organizational structure, and operating procedures. Form SMA-163 is used as an application to become a SAMHSA approved accrediting body. This form collects accrediting body name, address and contact information. Attachments are required to complete this form regarding the accrediting body’s operating procedures and standards and their staff’s education and experience. Form SMA-168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions. This form collects patient admission date, dosage amount, patient status, attendance schedule per week, dates of exception and justification.

The tables that follow summarize the annual reporting burden associated with the regulation, including burden associated with the forms.

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES

42 CFR citation	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
8.3(b)(1-11)	Initial approval (SMA-163)	1	1	6.0	6
8.3(c)	Renewal of approval (SMA-163)	2	1	1.0	2
8.3(e)	Relinquishment notification	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTPs.	1	90	0.1	9
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant OTPs.	2	2	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious non-compliance.	2	10	1.0	20
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	0.5	15
8.4(d)(2)	Accreditation survey to SAMHSA upon request.	6	75	0.02	9
8.4(d)(3)	List of surveys, surveyors to SAMHSA upon request.	6	6	0.2	7.2
8.4(d)(4)	Report of less than full accreditation to SAMHSA.	6	5	0.5	15
8.4(d)(5)	Summaries of Inspections	6	50	0.5	150
8.4(e)	Notifications of Complaints	6	6	0.5	18
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTPs.	1	185	0.3	55.5
8.6(b)	Submission of 90-day corrective plan to SAMHSA.	1	1	10	10.0
8.6(b)(1)	Notification to accredited OTPs of Probationary Status.	1	185	0.3	55.0

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES—Continued

42 CFR citation	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
Total	6	376.2

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/respondent	Hours/response	Total Hours
8.11(b)	Renewal of approval (SMA-162)	370	1	0.30	111.00
8.11(b)	Relocation of Program (SMA-162).	35	1	1.17	40.95
8.11(e)(1)	Application for provisional certification.	40	1	1	40.00
8.11(e)(2)	Application for extension of provisional certification.	30	1	0.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA-162).	60	1	0.1	6.00
8.11(g)(2)	Documentation to SAMHSA for interim maintenance.	1	1	1	1.00
8.11(h)	Request to SAMHSA for Exception from 8.11 and 8.12 (including SMA-168).	1150	30	0.07	2415.00
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA-162).	10	1	0.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	0.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	0.25	.50
8.25(a)	Informal Review Request	2	1	1.00	2.00
8.26(a)	Appellant's Review File and Written Statement.	2	1	5.00	10.00
8.28(a)	Appellant's Request for Expedited Review.	2	1	1.00	2.00
8.28(c)	Appellant Review File and Written Statement.	2	1	5.00	10.00
Total	1,150	2655.05

Written comments and recommendations concerning the proposed information collection should be sent by September 27, 2006 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: August 18, 2006.

Anna Marsh,

Director, Office of Program Services.

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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 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) 276-1243.

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: Targeted Capacity Expansion Grants for Jail Diversion Program Evaluation—Additional Trauma Measures—(OMB NO. 0930-0277)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) has implemented the Targeted Capacity Expansion Grants for Jail Diversion Programs. The Program currently collects client outcome measures from program participants