Contact Person: Carl D. Banner, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5212, MSC 7850, Bethesda, MD 20892, (301) 435–1251, *bannerc@drg.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Leprosy Immunity.

Date: August 27, 2003.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jean Hickman, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4194, MSC 7808, Bethesda, MD 20892, (301) 435–1146.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 24, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–19565 Filed 7–31–03; 8:45 am]

BILLING CODE 4140–01–M

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 (301) 443–7978.

Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Addiction—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–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions. Minor changes are being made to Form SMA–162 to account for newly approved opioid treatment drugs, to provide structures space on the form for required information and to make it more compatible with electronic submission.

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/ respondents	Hours/ response	Total hours
8.3(b)(1–11)	Initial approval (SMA–163	1	1	6.0	6.0
8.3(c)	Renewal of approval (SMA–163)	2	1	1.0	2.0
8.3(e)	Relinquishment notification	1	1	0.5	0.5
8.3(f)(2)	Non-renewal notification to accredited OTP's	1	90	0.1	9.0
8.4(b)(1)(ii)	Notification to SAMHSA for seriously noncompliant programs.	2	2	1.0	4.0
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	2	10	1.0	20.0
8.4(d)(1)	General documents and information to SAMHSA upon request.	6	5	0.5	15.0
8.4(d)(2)	Accreditation survey to SAMHSA upon request	6	75	0.02	9.0
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	15.0
8.4(d)(5)	Summaries of Inspections	6	50	0.5	150.0
8.4(e)	Notifications of Complaints	6	6	0.5	18.0
8.6(a)(2) and (b)(3)	Revocation notification to Accredited OTP's	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 OTP's of Probationary Status.	1	185	0.3	55.0
Total		7			376.2

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	Number of respondents	Responses/ respondents	Hours/ response	Total hours
8.11(b)	New programs approval (SMA–162)	75	1	1.50	112.50
8.11(b)	Renewal of approval (SMA–162)	370.00	1	1.00	370

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondents	Hours/ response	Total hours
8.11(b)	Relocation of Program (SMA–162)	35	1	1.17	40.95
8.11(d)	Application for transitional certification (SMA–162)*	0	0	0	0
8.11(e)(1)	Application for provisional certification	75	1	1	75.00
8.11(e)(2)	Application for extension of provisional certification	30	1	.25	7.50
8.11(f)(5)	Notification of sponsor or medical director change (SMA–162).	60	1	.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 Exemption from 8.11 and 18.12 (SMA–168).	1,110	7	.152	1181.04
8.11(i)(1)	Notification to SAMHSA Before Establishing Medication Units (SMA–162).	10	1	.25	2.5
8.12(j)(2)	Notification to State Health Officer When Patient Begins Interim Maintenance.	1	20	.33	6.6
8.24	Contents of Appellant Request for Review of Suspension.	2	1	.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		1,100			1827.6

*This is a one-time requirement that was fully met during the first three years of approval for the final rule.

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 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.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Allison Herron Eydt, 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: July 25, 2003.

Anna Marsh,

Acting Executive Officer, SAMHSA.

[FR Doc. 03–19586 Filed 7–31–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) published in the **Federal Register** on April 11, 1988 (53 FR 11970), and revised in the **Federal Register** on June 9, 1994 (59 FR 29908) and on September 30, 1997 (62 FR 51118). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from HHS' National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at *http://workplace.samhsa.gov* and *http://www.drugfreeworkplace.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2, Room 815, Rockville, Maryland 20857; 301–443–6014 (voice), 301–443–3031 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards that laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection.