REPORTING REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response	Total burden hours
17 Holders	5	78	12 Min	16
190 Schools	.4	78	10 Min	13
Total Reporting				29

NOTIFICATION REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response	Total burden hours
7,930 Borrowers	1	7,930	10 Min	1,322
17 Holders	7,910	134,470	10 Min	22,412
190 Schools	.89	170	14 Min	40
Total Notification				23,774

RECORDKEEPING REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response	Total burden hours
17 Holders	3,568	60,657	14 Min	14,153
190 Schools	257	48,822	15 Min	12,206
Total Recordkeeping				26,359
Total				50,162

E-mail comments to *paperwork@hrsa.gov* or mail to the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 4, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9–29827 Filed 12–14–09; 8:45 am]

BILLING CODE 4165–15–P

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.

Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930–0206)—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 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.

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

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR ACCREDITATION BODIES—Continued

42 CFR citation	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.4(b)(1)(ii)	Notification to SAMHSA for seriously non-compliant OTPs.	2	2	1.0	4
8.4(b)(1)(iii)	Notification to OTP for serious noncompliance	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	12	6	0.5	36
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
Total		6			394.20

ESTIMATED ANNUAL REPORTING REQUIREMENT BURDEN FOR OPIOID TREATMENT PROGRAMS

42 CFR citation	Purpose	No. of respondents	Responses/ respondent	Hours/response	Total hours
8.11(b)	Renewal of approval (SMA–162)	386	1	0.15	57.9
8.11(b)	Relocation of Program (SMA–162)	35	1	1.17	40.95
8.11(e)(1)	Application for provisional certification	42	1	1	42.00
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 Exemption from 8.11 and 8.12 (including SMA–168).	1,200	25	0.7	2,135.0
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		1,200			2,323.95

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.

Written comments and recommendations concerning the proposed information collection should be sent by January 14, 2010 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: 202–395–5806.

Dated: December 9, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–29768 Filed 12–14–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[30Day–10–09BK]

Agency Forms Undergoing Paperwork Reduction Act Review

Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC/ATSDR Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Registration of Individuals Displaced by the Hurricanes Katrina and Rita (Pilot Project)—New—Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

On August 29, 2005, Hurricane Katrina made landfall on the coast of the Gulf of Mexico near New Orleans, Louisiana, and became one of the most deadly and destructive storms in U.S. history. Also occurring in 2005, Hurricane Rita was the fourth-most intense Atlantic hurricane ever recorded and the most intense tropical cyclone ever observed in the Gulf of Mexico. Following the initial phase of the response, the Federal Emergency Management Agency (FEMA) assumed the primary role for housing displaced persons over the intermediate term. To support those needing temporary housing, FEMA provided over 143,000 travel trailers, park homes, and mobile homes for persons displaced by the above mentioned storms. However, some persons living in trailers complained of an odor or of eye or respiratory tract irritation.

FEMA entered into an Interagency Agreement with the Centers for Disease Control and Prevention (CDC)/ATSDR on August 16, 2007 to conduct a comprehensive public health assessment, based on objective and credible research, of air quality conditions present in FEMA housing units to guide FEMA policy makers and inform the public as to the actual conditions in the field and any actions required to better promote a safe and healthful environment for the disaster victims FEMA housed in the units. FEMA's agreement with the CDC includes an initial formaldehyde exposure assessment as well as a subsequent long-term study of the health effects among resident children. Formaldehyde testing conducted and evaluated by the CDC pursuant to the initial exposure assessment has identified the need to evaluate the feasibility of establishing a national registry to identify and monitor the health of disaster victims who occupied FEMA-provided temporary housing units. The establishment of such a registry would complement the long-term health effects study set forth in the FEMA-CDC Interagency Agreement.

The purpose of this study is to assess the feasibility of contacting and enrolling members of the targeted group in a registry; to provide a basis for budgeting and further planning for a comprehensive registry; and to test the acceptance of and response to a questionnaire composed of standardized health questions related to systemic and respiratory symptoms.

A pre-registration dataset will be created before enrollment. This dataset will be populated with contact information of the study population, gathered from two main sources: FEMA datasets (in the case of occupants of temporary housing units) and data provided by self-identified individuals who were displaced by the hurricanes but did not live in the FEMA temporary trailers.

A computer-assisted telephone interview (CATI) system based on a paper questionnaire will be used during all interviews to collect data for this project. The first part will consist of screening questions to determine eligibility for enrollment. The second part will contain contact information of the registrant and other household members, demographics, and health status questions, focusing on respiratory outcomes and cancer.

There will be two types of respondents included the registry: Temporary housing unit occupants and Non-temporary housing unit occupants. The three minute screening questionnaire will be administered to a total of 10,000 respondents (8,000 temporary housing unit occupants and 2,000 non-temporary housing unit occupants). Annualized over a two year period, 4,000 temporary housing unit respondents and 1,000 non-temporary housing unit respondents will be screened. The 45 minute main questionnaire will be administered to a total of 5,000 respondents (4,000 temporary housing unit occupants and 1,000 non-temporary housing unit occupants). Annualized over a two year period, 2,000 temporary housing unit occupants and 500 non-temporary housing unit occupants will complete the main questionnaire.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 2,125.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Temporary housing unit occupant	Screening questionnaire	4,000	1	3/60
	Main questionnaire	2,000	1	45/60
Non-Temporary housing unit occupant	Screening questionnaire	1,000	1	3/60
	Main questionnaire	500	1	45/60