Federal Register reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http:// www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Division of Dockets Management Internet site at http://www.fda.gov/ ohrms/dockets.

## IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collection(s) of information in this guidance were approved under OMB control number 0910–0577.

### V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 24, 2006.

### Jeffrey Shuren,

Assistant Commissioner for Policy.
[FR Doc. E6–6458 Filed 4–28–06; 8:45 am]
BILLING CODE 4160–01–8

# 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: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) is responsible for the Evaluation of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major national initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuserelated problems in communities; and, (3) build prevention capacity and infrastructure at the State/territory and community levels. Five steps comprise the SPF:

- Step 1: Profile population needs, resources, and readiness to address needs and gaps.
- Step 2: Mobilize and/or build capacity to address needs.
- Step 3: Develop a comprehensive strategic plan.
- Step 4: Implement evidence-based prevention programs, policies, and practices
- Step 5: Monitor, evaluate, sustain, and improve or replace those that fail.

Under a contract with CSAP, an evaluation team will implement a multimethod quasi-experimental evaluation at national, State, and community levels. Evaluation data will be collected from 26 states receiving grants in 2004

and 2005 and as many as 32 non-grantee states that will serve as a comparison group. The primary evaluation objective is to determine the impact of SPF SIG on the SAMHSA National Outcome Measures (NOMs).

This notice invites comment on statelevel and community-level data collection instruments. The instruments for assessing state-level change will be included in an OMB review package submitted immediately after the expiration of the comment period and are the main focus of this announcement. These instruments will be reviewed first by OMB to ensure that state-level data collection occurs as specified in the evaluation plan (on or before June 30, 2006). Because the states have not awarded community-level funding, the evaluators will not initiate community-level data collection until late in 2006. Thus, the community-level survey will be submitted as an addendum approximately one month after the comment period expires. However, the instrument is described in this notice and comments on the instrument are invited.

### **State-Level Data Collection**

Two instruments were developed for assessing state-level effects. Both instruments are guides for telephone interviews that will be conducted by trained interviewers three to four times over the life of the SPF SIG award. The Strategic Prevention Framework Index will be used to assess the relationship between SPF implementation and change in the national outcome measures. The State Infrastructure Index will capture data to assess infrastructure change and to test the relationship of this change to outcomes. Prevention infrastructure refers to the organizational features of the system that delivers prevention services, including all procedures related to planning, data management systems, workforce development, intervention implementation, evaluation and monitoring, financial management, and sustainability. The estimated annual burden for state-level data collection is displayed below in the table.

# STATE LEVEL BURDEN ESTIMATE [Year 1]

Interview guide	Content description	Number of respondents	Number of responses	Hourly burden per response	Total hourly burden
SPF Implementation Index.	SEW activities, indicators for each SPF step, including cultural competence throughout all five steps		1	3	78

# STATE LEVEL BURDEN ESTIMATE—Continued [Year 1]

Interview guide	Content description	Number of respondents	Number of responses	Hourly burden per response	Total hourly burden
State Infrastructure Index.	Assessment of a state's progress over time toward the implementation of these best practices.	26	1	6	156
Total State Level		26			234

### **Community-Level Data Collection**

The Community Level Index is a twopart, web-based survey for capturing information about SPF SIG implementation at the community level. Part 1 of the survey focuses on the five SPF SIG steps and efforts to ensure cultural competency throughout the SPF SIG process. Part 2 will capture data on the specific intervention(s) implemented at the community level including both individual-focused and environmental prevention strategies. Community partners receiving SPF SIG awards will be required to complete the survey every six months, using a secure

password system. The survey data will be analyzed in conjunction with state and community outcome data to determine the relationship, if any, between the SPF process and substance use outcomes. This survey will be submitted as an addendum to the forthcoming OMB package approximately one month after the expiration of the comment period. The estimated annual burden for community-level data collection is displayed below. Note that the total burden assumes an average of 15 community-level sub-grantees per state (a total of 390 respondents) and two

survey administrations per year. Note also that some questions will be addressed only once and the responses will be used to pre-fill subsequent surveys. In addition, as community partners work through the SPF steps, they will report only on step-related activities. For example, needs assessment activities will likely precede monitoring and evaluation activities. Thus, respondents will answer questions related to needs assessment in the first few reports but will not need to address monitoring and evaluation items until later in the implementation process.

### COMMUNITY LEVEL BURDEN ESTIMATE

Community-level instrument section/domain	Number of respondents	Responses per respondent	Burden per response	Total burden
Year 1				
Part I, 1–11 State Responses	26	1	0.08	2.08
Part I, 12–20 Contact Information and Reporting Period	390	1	0.08	31.20
Part I, 21–26 Organization Type and Funding	390	1	0.08	31.20
Part I, 27–33 Cultural Competence, Sustainability, and Framework	000		0.17	100.00
Progress Part I, 34–66 Needs and Resources Assessments	390 390	2 2	0.17 0.50	132.60 390.00
Part I, 67–159 Capacity Building Activities	390	2	0.50	390.00
Part I, 160–178 Strategic Plan Development	390	2	0.50	390.00
Part I, 198–216 Systems and Contextual Factors and Closing Questions	390	2	1.00	780.00
Part I, subform 217–231 Coalition Organizational Information	390	1	0.17	66.30
Part II 1–40; 45 Intervention Specific Information and Adaptations	390	3	1.00	1,170.00
Review of past responses	390	2	0.50	390.00
Preparation and gathering of supporting materials	390	2	2.00	1,560.00
State Review of Community Responses	26	2	1.00	52.00
Total Year 1 Burden—State-level	26			54.08
Total Year 1 Burden—Community-level	390			5,331
Year 2				
Part I, 27–33 Cultural Competence, Sustainability, and Framework				
Progress	390	2	0.17	132.60
Part I, 67–15 Capacity Building Activities	390	2	0.50	390.00
Part I, 160–178 Strategic Plan Development	390	2	0.50	390.00
Part I, 179–184 Intervention Implementation	390	2	0.17	132.60
Part I, 198–216 Systems and Contextual Factors and Closing Questions	390	2	1.00	780.00
Part II 1–40; 45 Intervention Specific Information and Adaptations	390	3	1.00	1,170.00
Part II 41–44 Intervention Outcomes	390	6	0.17	397.80
Part II subforms Intervention Component Information	390	6	1.00	2,340.00
Review of past responses	390	2	0.50	390.00
Preparation and gathering of supporting materials	390 26	2	2.00 1.00	1,560.00 52.00
Total Year 2 Burden—State-level	26 26		1.00	52.00 52.00
Total Total 2 Buildon Otalo 10401	20			32.00

### COMMUNITY LEVEL BURDEN ESTIMATE—Continued

Community-level instrument section/domain	Number of respondents	Responses per respondent	Burden per response	Total burden
Total Year 2 Burden—Community-level	390			7,683
Year 3				
Part I, 27–33 Cultural Competence, Sustainability, and Framework Progress  Part I, 67–159 Capacity Building Activities  Part I, 179–184 Intervention Implementation  Part I, 185–197 Monitoring and Evaluation  Part I, 198–216 Systems and Contextual Factors and Closing Questions  Part II 1–40; 45 Intervention Specific Information and Adaptations  Part II 41–44 Intervention Outcomes  Part II subforms Intervention Component Information  Review of past responses  Preparation and gathering of supporting materials  State Review of Community Responses	390 390 390 390 390 390 390 390 390	2 2 2 2 3 6 6 2 2 2	0.17 0.50 0.17 0.33 1.00 1.00 0.17 1.00 0.50 2.00 1.00	132.60 390.00 132.60 257.40 780.00 1,170.00 397.80 2,340.00 390.00 1,560.00 52.00
Total Year 3 Burden—State-level  Total Year 3 Burden—Community-level	26 390			52.00 7,550.00
Total Average Annual Burden—Slate-level	26			53.00
Total Average Annual Burden—Community-level	390			6,855.00

Written comments and recommendations concerning the proposed information collection should be sent by May 31, 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: April 24, 2006.

### Anna Marsh,

Director, Office of Program Services.
[FR Doc. E6–6493 Filed 4–28–06; 8:45 am]
BILLING CODE 4162–20–P

# 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– 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: Opioid Treatment Data Systems for Disaster Planning Project (Pilot)—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Substance Abuse Treatment (CSAT), has identified a critical need for Opioid Treatment Programs (OTPs, also commonly known as Methadone Clinics) to be able to access limited but specific patient dosage data for patients displaced due to service disruptions affecting the OTP from which they regularly receive treatment (the patient's 'Home OTP'). Service disruptions in home OTPs have ranged in cause from events such as the

September 11th terrorist attacks or more recently, Hurricanes Katrina and Rita, to more common events such as snow storms or electrical black-outs

The proposed system will ensure that, in such circumstances, patients displaced from their home OTPs will still be able to obtain safe and effective treatment at an alternative OTP (referred to in this project as a 'Guest OTP'). In reviewing past events involving OTP service disruptions and their impact on patients, SAMHSA, in tandem with numerous stakeholders, established four basic principles that would guide creation of a deliberately simple, centralized Web-based system to house patient data. Such a system would facilitate guest OTPs in providing safe and effective continuity of treatment for patients temporarily unable to obtain treatment from their Home OTPs due to any form of service disruption. The proposed centralized data system is known as the Opioid Treatment Data Systems for Disaster. Subsequently, in a small sample study of five (5) OTPs, SAMHSA tested a protocol and data collection instrument for use in determining functional requirements for the proposed system. In Fall 2005, SAMHSA provided funding for the current project, to support creation of the necessary infrastructure for a pilot system, to be followed by testing on a regional basis. This pilot project will focus on creating the means by which vital dosage data for OTP patients can be made accessible to guest OTPs called