The regulations contain information collection requirements. The Act authorizes funds to support activities on behalf of individuals with significant (severe) mental illness (adults) or emotional impairment (children/youth) [42 U.S.C. 10802(4)]. Only entities that are designated by the governor of each State, the five (5) territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands), the American Indian Consortium (the Hopi and Navajo Nations in the Southwest), and the Mayor of the District of Columbia to protect and advocate the rights of persons with developmental disabilities under Title I, Subtitle C—Protection and Advocacy of Individual Rights, the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 150041 et seq.) are eligible to receive PAIMI Program grants [42 U.S.C. at 10802(2)]. These grants are based on a formula prescribed by the Secretary at 42 U.S.C. at 10822(a)(1)(A).

On January 1, each eligible State protection and advocacy (P&A) system is required to prepare a report that describes its activities, accomplishments, and expenditures to protect the rights of individuals with mental illness supported with payments from PAIMI Program allotments during the most recently completed fiscal year. The PAIMI Act at 42 U.S.C. 10824(a) requires that each P&A system transmit a copy of its annual report to the Secretary (via SAMHSA/CMHS) and to the State Mental Health Agency where the system is located. These annual PAIMI Program Performance Reports (PPR) to the Secretary must include the following information:

- The number of (PAIMI-eligible) individuals with mental illness served;
- A description of the types of activities undertaken;
- A description of the types of facilities providing care or treatment to which such activities are undertaken;
- A description of the manner in which the activities are initiated;
- A description of the accomplishments resulting from such activities;
- A description of systems to protect and advocate the rights of individuals with mental illness supported with payments from PAIMI Program allotments;
- A description of activities conducted by States to protect and advocate such rights;
- A description of mechanisms established by residential facilities for individuals with mental illness to protect such rights; and
- A description of the coordination among such systems, activities and mechanisms;
- Specification of the number of systems that are public and nonprofit systems established with PAIMI Program allotments;
- Recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of the need for such activities and services that were not met by the State P&A systems established under the PAIMI Act due to resource or annual program priority limitations.

** [The PAIMI Rules at 42 CFR Part 51 at section 51.32(b), state that P&A systems may place restrictions on case or client acceptance criteria developed as part of its annual PAIMI priorities. Each P&A system is required to inform prospective clients of any such restrictions when he/she requests a service].

This PAIMI PPR summary must include a separate section, prepared by the PAIMI Advisory Council (PAC) that describes the council's activities and its assessment of the operations of the State P&A system at 42 U.S.C. 10805(7).

The burden estimate for the annual State P&A system reporting requirements for these regulations is as follows:

42 CFR citation	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total annual burden
51.(8)(a)(2) Program Performance Report	57	1	26.0	[1] 1,482
51.8(8)(a)(8) Advisory Council Report	57	1	10.0	[1] 570
51.10 Remedial Actions.				
Corrective Action Plans Implementation Status Report	6	1	8.0	56
	6	3	2.0	42
51.23(c) Reports, materials and fiscal data provided to the PAC	57	1	1.0	57
51.25(b)(2) Grievance Procedures	57	1	.5	29
Total	126			184

[1] Burden hours associated with these reports are approved under OMB Control No. 0930–0169.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: September 28, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–24019 Filed 10–5–09; 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.

Project: Addiction Technology Transfer Centers (ATTC) Network Program Monitoring (OMB No. 0930–0216)—Revision

The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) will continue to monitor program performance of its Addiction Technology Transfer Centers (ATTCs). The ATTCs disseminate current health services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Health Care Policy and Research, National Institute of Justice, and other sources, as well as other SAMHSA programs. To accomplish this, the ATTCs develop and update State-of-the-art, research-based curricula and professional development training.

Each of the forms is described below. SAMHSA/CSAT is proposing to revise the Event Description and Post-Event forms currently used by the ATTCs. The Follow-Up forms will not be changed. The Pre-Events forms currently in use will be eliminated.

Sixty percent of the forms are administered in person to participants at educational and training events, who complete the forms by paper and pencil. Ten percent of the training courses are online, and thus, those forms are administered online. The remaining thirty percent is made up of 30-day follow-up forms that are distributed to consenting participants via electronic mail using an online survey tool.

(1) The Event Description Form will be revised. The form collects event information. It includes questions regarding the SAMHSA priority areas and cross-cutting principles covered by the content of the event. SAMHSA's priority areas and cross-cutting principles have been revised since this form was approved, so the form will be revised to match the updated priorities and principles. In addition, the Event Description Form asks which of SAMHSA's Technical Assistance Publications (TAPs) and Treatment Improvement Protocols (TIPs) were used during the event. New TIPs and TAPs have been published since the form was approved. Those new TIPs and TAPs will be added to the form.

(2) The Pre-Event Form for meetings, technical assistance events, and training events will be eliminated. The demographic information that was collected on this form will be added to the Post-Event Forms. By incorporating this demographic information on the Post-Event Forms, the Pre-Event Form can be eliminated, thereby reducing the response burden for participants.

(3) The Post-Event Form for all events will be revised. The five current demographic questions will be revised to reflect a more current understanding of the field, and five additional demographic questions will be included.

(4) The Follow-Up Form for all events will remain the same as the ones currently in use by the ATTCs.

Event Description: The event description form asks approximately 10 questions of the ATTC faculty/staff for each of the ATTC events. The approved form asks the event focus, format, and publications to be used in the event. As noted above, it will be revised to reflect updates to SAMHSA's priority areas and cross-cutting principles and the publication of new TIPs and TAPs.

Technical Assistance and Meeting Events Forms

The ATTCs provide technical assistance, which is a jointly planned consultation generally involving a series of contacts between the ATTC and an outside organization/institution during which the ATTC provides expertise and gives direction toward resolving a problem or improving conditions. The ATTCs hold meetings, which are ATTC sponsored or co-sponsored events in which a group of people representing one or more agencies other than the ATTC work cooperatively on a project, problem, and/or a policy. The ATTCs will collect satisfaction measures after each technical assistance and meeting event. The ATTCs will base the Post-Event Form on the approved CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB #0930–0197). The only revision to this GPRA form will be that the ATTCs will revise the five current demographic questions asked on this form and include five additional demographic questions. The ATTCs will collect satisfaction measures 30 days after each event by using the approved CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB #0930–0197). The ATTCs are eliminating the Technical Assistance and Meeting Pre-Event Forms currently in use.

Post-Event Form for Technical Assistance and Meetings: The Post-Event Information form for technical assistance and meetings asks approximately 25 questions of each individual that participated in the event. The current form asks the participants to report satisfaction with the quality of the event and event materials, and to assess their level of skills in the topic area. The five current demographic questions on the form will be revised to reflect a more current understanding of the field, and five additional demographic questions will be included. The form will ask participants to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, and employment setting.

30-Day Follow-Up Form for Technical Assistance and Meetings: The Follow-up Information Form for technical assistance and meetings asks about 20 questions of about 25% of consenting participants. The approved form asks the participants to report satisfaction with the quality of the event materials, to assess their level of skills in the topic area, and to report whether or not they have shared information from the event at their place of work. This form is already approved by OMB and will not be revised (OMB #0930–0197).

Training Forms

Trainings are defined as ATTC sponsored or co-sponsored events, mainly focusing on the enhancement of knowledge and/or skills of counselors and other professionals who work with individuals with substance use disorder-related problems. The ATTCs will collect information from training participants at the end of the training event by using a revised version of the currently approved Post-Event Form for training. The current approval for this form is under OMB #0930–0216. The only revision to this Post-Event Form will be that the ATTCs will revise the five current demographic questions asked and include five additional demographic questions. The ATTCs will collect information from training participants 30 days after the training event by using the same form currently approved for this purpose under OMB #0930–0216. The Pre-Event Form for training will be eliminated.

Post-Event Form for Training: The Post- Form for Training asks approximately 25 questions of each individual that participated in the training. The approved form asks the participants to report satisfaction with, usefulness of, and quality of the training and training materials as well as to assess their level of skills in the topic area. The five current demographic questions on the form will be revised to reflect a more current understanding of the field, and five additional

demographic questions will be included. The form will ask participants to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, and employment setting.

Follow-up Form for Training: The Follow-up Information Form for Training asks about 25 questions of about 25% of consenting participants. The approved form asks the participants to report satisfaction with, usefulness of, and quality of the training and training materials as well as to assess their level of skills in the topic area. The form also asks participants to report whether or not they have shared information from the event at their place of work and which, if any, barriers they have encountered to applying the information gained from the training. This form is already approved by OMB and will not be revised (OMB #0930–0216).

The information collected on the ATTC forms will assist CSAT in documenting the numbers and types of participants in ATTC events, describing the extent to which participants report improvement in their clinical competency, and which method is most effective in disseminating knowledge to various audiences. This type of information is crucial to support CSAT in complying with GPRA reporting requirements and will inform future development of knowledge dissemination activities.

The chart below summarizes the annualized burden for this project.

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total annual burden hours
Faculty/staff Event Description Form	250	1	.25	62.50
Meeting and Technical Assistance Participants:				
Post-Event Form	5,000	1	.12	600
Follow-up Form	Covered under CSAT Government Performance and Results Act (GPRA) Customer Satisfaction form (OMB #0930–0197)			
Training Participants:				
Post-Event Form	30,000	1	.16	4,800
Follow-up Form	7,500	1	.16	1,200
Total	42,750			6,662.50

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *and* e-mail her a copy at *summer.king@samhsa.hhs.gov*. Written comments should be received within 60 days of this notice.

Dated: September 28, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–24017 Filed 10–5–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance, Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 5, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB Control Number 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, *JonnaLynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Draft Guidance, Emergency Use Authorization of Medical Products—(OMB Control Number 0910–0595)—Extension

The draft guidance describes the agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108–276). The act permits the FDA Commissioner (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the act, the FDA Commissioner may establish conditions on the approval of an EUA. Section 564(e) requires the FDA Commissioner (to the extent practicable given the