

various ways in order to reduce the immunogenicity of the molecule to improve its therapeutic value while at the same time maintaining the toxin's ability to trigger cell death. The immunotoxin provides targeted cytotoxic delivery to cancer cells while sparing normal cells thereby resulting in therapies with fewer side effects.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted 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: April 2, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development & 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.

Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Final Rule, 42 CFR Part 51 (OMB No. 0930-0172)—Extension

These regulations meet the directive under 42 U.S.C. 10826(b) requiring the Secretary to promulgate final regulations to carry out the PAIMI Act. 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 designated by the governor of each State, including American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Mayor of the District of Columbia, and the tribal councils for the American Indian Consortium (the Hopi and Navajo Nations in the Four Corners region of the Southwest), to protect and advocate the rights of persons with developmental disabilities are eligible to receive PAIMI Program grants [the Act at 42 U.S.C. at 10802 (2)]. These grants are based on a formula prescribed by the Secretary [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 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 [42 CFR Part 51] mandate that each State P&A system may place restrictions on either its 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 they request a service [42 CFR 51.32(b)].

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 State P&A system's operations [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	11,482
51.8(8)(a)(8) Advisory Council Report	57	1	10.0	1570
51.10 Remedial Actions:				
Corrective Action Plans	7	1	8.0	56
Implementation Status Report	7	3	2.0	42
51.23(c) Reports, materials and fiscal data provided to the PAC	57	1	1.0	57

42 CFR Citation	Number of respondents	Responses per respondent	Burden per response (Hrs.)	Total annual burden
51.25(b)(2) Grievance Procedures	57	1	.5	29
Total	126	8	47.5	184

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

Written comments and recommendations concerning the proposed information collection should be sent by May 9, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202-395-7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,
Statistician.

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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

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

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.

CSAT monitors the performance of ATTC events. The ATTCs hold three types of events: technical assistance events, meetings, and trainings. An ATTC technical assistance event is defined as 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. An ATTC meeting is defined as an 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. An ATTC training is defined as an ATTC sponsored or co-sponsored event of at least three hours that focuses on the enhancement of knowledge and/or skills. Higher education classes are included in this definition with each course considered as one training event.

CSAT currently uses seven (7) instruments to monitor the performance and improve the quality of ATTC events. Two (2) of these forms, the Meeting Follow-up Form and the Technical Assistance Follow-up Form, are currently approved by the Office of Management and Budget (OMB) through approval for CSAT Government Performance and Results Act (GPRA) Customer Satisfaction instruments (OMB No. 0930-0197). CSAT is not seeking any action related to these two forms at this time. They are merely referenced here to provide clarity and context to the description of the forms CSAT uses to monitor the performance of the ATTCs.

The remaining five (5) instruments for program monitoring and quality improvement of ATTC events are

currently approved by the OMB (OMB No. 0930-0216) for use through April 30, 2013. These five forms are as follows: Event Description Form; Training Post Event Form; Training Follow-up Form; Meeting Post Event Form; and Technical Assistance Post Event Form. 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. At this time, CSAT is requesting approval to extend the use of these five forms as is, with no revisions. A description of each of these forms follows.

(1) Event Description Form (EDF). The EDF collects descriptive information about each of the events of the ATTC Network. This instrument asks approximately 10 questions of ATTC faculty/staff relating to the event focus and format, as well as publications to be used during the event. It allows the ATTC Network and CSAT to track the number and types of events held. There are no revisions to the form. CSAT is proposing to continue to use the form as is.

(2) Training Post Event Form. This form is distributed to training participants at the end of the training activity, and collected from them before they leave. For training events which take place over an extended period of time, this form is completed after the final session of training. The form asks approximately 30 questions of each individual that participated in the training. Training participants are asked to report demographic information, education, profession, field of study, status of certification or licensure, workplace role, employment setting, satisfaction with the quality of the training and training materials, and to assess their level of skills in the topic area. There are no revisions to the form. CSAT is proposing to continue to use the form as is.

(3) Training Follow-up Form. The Training Follow-up form, which is