

Matters To Be Considered

Summary Agenda

August 10, 2011 minutes—Open Session.

(No substantive discussion of the above items is anticipated. These matters will be resolved with a single vote unless a member of the ASC requests that an item be moved to the discussion agenda.)

Discussion Agenda

Appraisal Foundation May 2011 Grant Reimbursement Request.
Appraisal Subcommittee Fiscal Year 2012 Budget.

How to Attend and Observe an ASC Meeting

E-mail your name, organization and contact information to meetings@asc.gov.

You may also send a written request via U.S. Mail, fax or commercial carrier to the Executive Director of the ASC, 1401 H Street, NW., Ste. 760, Washington, DC 20005. The fax number is 202–289–4101. Your request must be received no later than 4:30 p.m., ET, on the Monday prior to the meeting. Attendees must have a valid government-issued photo ID and must agree to submit to reasonable security measures. The meeting space is intended to accommodate public attendees. However, if the space will not accommodate all requests, the ASC may refuse attendance on that reasonable basis. The use of any video or audio tape recording device, photographing device, or any other electronic or mechanical device designed for similar purposes is prohibited at ASC meetings.

Dated: September 12, 2011.

James R. Park,
Executive Director.

[FR Doc. 2011–23876 Filed 9–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Registry of Evidence-Based Programs and Practices

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

ACTION: Notice Regarding Substance Abuse and Mental Health Services Administration's National Registry of Evidence-based Programs and Practices (NREPP): Open Submission Period for Fiscal Year 2012.

SUMMARY: The mission of the Substance Abuse and Mental Health Services Administration (SAMHSA) is to reduce

the impact of substance abuse and mental illness on America's communities. Established in 1992, the Agency was directed by Congress to target effective substance abuse and mental health services to the people most in need, and to translate research in these areas more effectively and more rapidly into the general health care system. The National Registry of Evidence-based Programs and Practices (NREPP) is a key public resource SAMHSA has developed to help meet this directive. This notice announces NREPP's open submission period for Fiscal Year 2012, during which developers of interventions may submit an application for a potential review. The notice explains how submissions will be screened and selected, and provides guidance on the submission process. Potential applicants should be aware that this notice includes updated information relating to the eligibility of interventions and the review process that supersedes guidance provided in earlier **Federal Register** notices.

FOR FURTHER INFORMATION CONTACT:

Kevin D. Hennessy, Ph.D., Science to Service Coordinator, Center for Behavioral Health Statistics and Quality, SAMHSA, 1 Choke Cherry Road, Room 2–1017, Rockville, MD 20857, telephone 240–276–2234.

Rose Shannon,

Director, Division of Executive Correspondence.

Substance Abuse and Mental Health Services Administration's National Registry of Evidence-Based Programs and Practices (NREPP): Open Submission Period for Fiscal Year 2012

Background

The Substance Abuse and Mental Health Services Administration's (SAMHSA) National Registry of Evidence-based Programs and Practices (NREPP) is a voluntary rating system designed to provide the public with reliable information about interventions that promote mental health or prevent or treat mental disorders, substance abuse, substance use disorders, and/or co-occurring disorders. Programs and practices that are accepted for inclusion in the registry undergo two independent review processes in which their (1) Quality of research and (2) readiness for dissemination are evaluated and rated. The results of these reviews are published on the NREPP Web site (<http://nrepp.samhsa.gov>).

It should be noted that inclusion in NREPP does not constitute endorsement of an intervention by SAMHSA. Moreover, since NREPP has not reviewed all interventions, the use of

NREPP as an exclusive or exhaustive list of interventions is not appropriate. Policymakers and funders in particular are discouraged from limiting contracted providers and/or potential grantees to selecting only among NREPP interventions.

This notice announces the next open submission period during which SAMHSA will consider and accept new applications for review, describes the minimum requirements and other considerations that will be used in screening and selecting interventions, and provides guidance on the submission process.

Dates of Open Submission Period

SAMHSA has established a 3-month period for receipt of NREPP submissions for Fiscal Year 2012 that will begin November 1, 2011, and end February 1, 2012. Interventions submitted after February 1, 2012, will not be considered during this submission cycle. Program developers, researchers, and others interested in submitting an intervention should read this notice for information about current minimum requirements, and examine the information provided on the NREPP Web site about the review process and criteria (<http://nrepp.samhsa.gov/Reviews.aspx>) and guidance for preparing an intervention for submission (<http://nrepp.samhsa.gov/SubmissionCourse.aspx>). The selection of interventions will take place after the closing of the open submission period, and applicants will be informed of their acceptance status at that time. The number of reviews conducted will depend on the availability of funds, with the final selection of interventions and the timing of reviews to be determined at the discretion of SAMHSA.

In submitting an intervention, applicants understand that the results of NREPP reviews are considered public information and will be posted on the NREPP Web site. Once a review is completed, the applicant will be provided with a summary document ("intervention summary") that presents ratings and descriptive information about the intervention. Anyone that consents to a review is expected to authorize publication of the intervention summary on the NREPP Web site. If a summary is completed and consent is not given to publish the summary, a statement to that effect will be posted on the NREPP Web site.

Applicants are encouraged to view examples of NREPP intervention summaries on the NREPP Web site to become familiar with the end product of the review process.

Minimum Requirements

To be considered for review, interventions must meet four minimum requirements:

1. The intervention has produced one or more positive behavioral outcomes ($p \leq .05$) in mental health, mental disorders, substance abuse, or substance use disorders among individuals, communities, or populations.

2. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. Experimental designs require random assignment, a control or comparison group, and pre- and postintervention assessments. Quasi-experimental designs do not require random assignment, but do

require a comparison or control group and pre- and postintervention assessments; this category includes longitudinal/multiple time series designs with at least three preintervention or baseline measurements and at least three postintervention or follow-up measurements. Studies that are based on single group, pre-/posttest designs do not meet this requirement.

3. The results of these studies have been published in a peer-reviewed journal or other professional publication, or documented in a comprehensive evaluation report. Comprehensive evaluation reports must include a review of the literature, theoretical framework, purpose,

methodology, findings/results with statistical analysis and p values for significant outcomes, discussion, and conclusions. Submissions must include information that can be rated according to the six Quality of Research criteria identified on the NREPP Web site.

4. Implementation materials, training and support resources, and quality assurance procedures have been developed and are ready for use by the public.

Applicants are required to provide documentation at the time of submission that demonstrates the intervention meets these minimum requirements. Table 1 lists examples of appropriate supporting documentation.

TABLE 1—DOCUMENTATION FOR DEMONSTRATING COMPLIANCE WITH MINIMUM REQUIREMENTS

| | Minimum requirement | Documentation |
|-----------------------------------|--|--|
| Quality of Research | <p>1. Intervention has produced one or more positive behavioral outcomes ($p \leq .05$) in mental health, mental disorders, substance abuse, or substance use disorders among individuals, communities, or populations.</p> <p>2. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design.</p> <p>3. Results of these studies have been published in a peer-reviewed journal or other publication or documented in a comprehensive evaluation report.</p> | <p>A list of significant behavioral outcomes that includes supporting citations (document/page number) for each outcome; <i>and</i></p> <p>A full-text copy of each article/report cited in the list of outcomes. Other research articles, published or unpublished evaluation reports, grant final reports, and replication studies may be submitted as additional supporting documentation.</p> <p>Note: Abstracts or URLs to partial articles are regarded as incomplete and will not be considered.</p> |
| Readiness for Dissemination | <p>4. Implementation materials, training and support resources, and quality assurance procedures have been developed and are ready for use by the public.</p> | <p>A brief narrative description and list of available materials, resources, and systems to support implementation (e.g., treatment manuals, information for administrators, tested training curricula, mechanisms for ongoing supervision and consultation, protocols for gathering process and outcome data, ongoing monitoring of intervention fidelity, processes for gathering feedback); <i>and</i></p> <p>A brief description of the method through which new implementation sites acquire the above materials.</p> |

The following types of interventions are not eligible for review and should not be submitted to NREPP:

1. Stand-alone pharmacologic treatments—The evidence base for pharmacologic treatments is reviewed and approved through the U.S. Food and Drug Administration (FDA). FDA-approved pharmacotherapy interventions (on-label use) are considered for NREPP review only when combined with one or more behavioral or psychosocial treatments.

2. To remain consistent with SAMHSA's mission ("to reduce the impact of substance abuse and mental illness on American communities"), NREPP will not accept for review, or otherwise include on the NREPP Web site, any interventions that have been

developed or evaluated with funds or other support—either partially or wholly—from organizations whose goals or activities are determined to be inconsistent with SAMHSA's mission.

Selection of Interventions for Review

All submissions meeting the minimum requirements will be considered eligible for review. In selecting interventions for review, SAMHSA may choose to give special consideration to interventions that meet one or more of the following conditions:

- The original investigator(s) or an independent party has used the same protocol with an identical or similar target population, and/or has used a slightly modified protocol based on a slightly modified population, where

results are consistent with positive findings from the original evaluation.

- Implementation materials (e.g., program manuals, training guides, measurement instruments, implementation fidelity guides) are available to the public at no cost.

- The intervention targets underserved populations (e.g., minority populations, elderly, young adults, individuals who are incarcerated).

- The intervention contributes to a content area where there are currently limited evidence-based interventions.

Interventions that are not selected for review may be resubmitted by the applicant in a future open submission period.

Instructions for Submitting an Intervention

To submit an intervention, individuals should send a written statement to NREPP expressing their interest along with documentation that demonstrates the intervention meets the minimum requirements as described above. All submissions must be made either by a principal investigator (PI) who has conducted research on the intervention, a project director (PD) who has worked with an evaluator of the intervention, or a formally authorized delegate of the PI or PD. For information on where to submit materials, please call 1-866-436-7377. Electronic submissions are preferred, but materials may be sent to NREPP in hard copy via postal mail or fax. To be eligible for consideration, submissions must be received no later than 11:59 p.m. E.S.T. on February 1, 2012; those received before November 1, 2011, will be disregarded.

For each intervention that is accepted, the Principal (the individual, usually the PI, formally designated as the intervention's point of contact and decisionmaking authority during the review process) will be asked to submit additional documentation to be used in the review. This additional documentation includes full-text copies of all articles and reports that provide evidence of significant outcomes ($p \leq .05$) as well as copies of selected dissemination materials in the format they are provided to the public (e.g., hard copies or electronic versions of manuals, training presentations, tools, quality assurance protocols; URLs for interactive Web-based resources).

The Principal continues to work with NREPP staff throughout the review and is responsible for approval of the final intervention summary that is developed by NREPP staff once the review has been completed.

Contact Information

Individuals who have questions about the information contained in this notice may write to NREPP staff at nrepp@samhsa.hhs.gov or call 1-866-436-7377.

[FR Doc. 2011-23757 Filed 9-15-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

Correction: This notice was published in the **Federal Register** on September 8, 2011, Volume 76, Number 174, Page 55678. The correct time should be 1 p.m.–3:30 p.m.

Contact Person for More Information: Drue Barrett, Ph.D., Designated Federal Officer, ACD, CDC—ES, CDC, 1600 Clifton Road, NE., M/S D-50, Atlanta, Georgia 30333. Telephone (404) 639-4690. E-mail: dbarrett@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 12, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011-23767 Filed 9-15-11; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10398]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function;

(2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Generic Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions; *Use:* CMS is requesting a generic PRA clearance for a body of forms necessary to conduct ongoing business with State partners in the implementation of Medicaid and the Children's Health Insurance Program (CHIP). Examples of the types of forms to be produced in this collection include State plan amendment templates, waiver and demonstration templates, and reporting templates. The development of streamlined submission forms is critical for States to implement timely health reform initiatives in Medicaid and CHIP state plans, demonstrations, and waivers, including legislative requirements enacted by the Affordable Care Act. The development of streamlined submissions forms enhances the collaboration and partnership between States and CMS by documenting CMS policy for States to use as they are developing program changes. Streamlined forms improve efficiency of administration by creating a common and user-friendly understanding of the information needed by CMS to quickly process requests for State plan amendments, waivers, and demonstration, as well as ongoing reporting.; *Form Number:* CMS-10398 (OMB #0938-NEW); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1120; *Total Annual Hours:* 28,747. (For policy questions regarding this collection contact Candice Payne at 410-786-4453. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must