

Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: March 13, 2000.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 4, 2000, 8 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the

Information Line for up-to-date information on this meeting.

Agenda: There will be a brief FDA presentation on the least burdensome provisions of the FDA Modernization Act of 1997. Subsequently, the committee is being asked to provide input to the agency regarding the design of clinical trials for the following: (1) Devices using spinal cord stimulation in the treatment of angina pectoris; (2) rate-responsive pacemakers, specifically, the evaluation of rate-adaptive features; and (3) devices used in the treatment of atrial fibrillation. Background information, questions for the panel, and a bibliography for each topic to be discussed by the committee are available to the public on the Internet at <http://www.fda.gov/cdrh/upadvmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 28, 2000. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 28, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the April 4, 2000, Circulatory System Devices Panel of the Medical Device Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Circulatory System Devices Panel were

available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 20, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2000 Funding Opportunities

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

ACTION: Notice of funding availability.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) announces the availability of FY 2000 funds for grants for the following activity. This activity is discussed in more detail under Section 3 of this notice. This notice is not a complete description of the activity; potential applicants must obtain a copy of the Program Announcement, including Part I, Programmatic Guidance for Grants to Expand Substance Abuse Treatment Capacity in Targeted Areas of Need, and Part II, General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements, before preparing an application.

Activity	Application deadline	Estimated funds available, FY 2000	Estimated No. of Awards	Project period
PRC Implementation Program	June 13, 2000	\$3,000,000	8-10	Up to 3 years.

The actual amount available for awards and their allocation may vary, depending on unanticipated program requirements and the number and quality of applications received. FY 2000 funds for the activity discussed in this announcement were appropriated by the Congress under Public Law No. 106-113. SAMHSA's policies and procedures for peer review and Advisory Council review of grant and cooperative agreement applications

were published in the **Federal Register** (Vol. 58, No. 126) on July 2, 1993.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The SAMHSA Centers' substance abuse and mental health services activities address issues related to Healthy People 2000 objectives of Mental Health and Mental Disorders;

Alcohol and Other Drugs; Clinical Preventive Services; HIV Infection; and Surveillance and Data Systems. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-512-1800).

SAMHSA will publish additional notices of available funding opportunities for FY 2000 in subsequent issues of the **Federal Register**.

General Instructions

Applicants must use application form PHS 5161-1 (Rev. 6/99; OMB No. 0920-0428). The application kit contains the two-part application materials (complete programmatic guidance and instructions for preparing and submitting applications), the PHS 5161-1 which includes Standard Form 424 (Face Page), and other documentation and forms. Application kits may be obtained from the organization specified for the activity covered by this notice (see Section 3).

When requesting an application kit, the applicant must specify the particular activity for which detailed information is desired. This is to ensure receipt of all necessary forms and information, including any specific program review and award criteria.

The PHS 5161-1 application form and the full text of the activity described in Section 4 are also available electronically via SAMHSA's World Wide Web Home Page (address: <http://www.samhsa.gov>).

Application Submission

Applications must be submitted to: SAMHSA Programs, Center for Scientific Review, National Institutes of Health, Suite 1040, 6701 Rockledge Drive MSC-7710, Bethesda, Maryland 20892-7710*, (* Applicants who wish to use express mail or courier service should change the zip code to 20817.)

Applications sent to an address other than the address specified above will be returned to the applicant without review.

Application Deadlines

The deadline for receipt of applications is listed in the table above. Competing applications must be received by the indicated receipt date to be accepted for review. An application received after the deadline may only be accepted if it carries a legible proof-of-mailing date assigned by the carrier and that date is not later than one week prior to the deadline date. Private metered postmarks are not acceptable as proof of timely mailing. Applications received after the deadline date will be returned to the applicant without review.

FOR FURTHER INFORMATION CONTACT: Requests for activity-specific technical information should be directed to the program contact person identified for the activity covered by this notice (see Section 3). Requests for information concerning business management issues

should be directed to the grants management contact person identified for the activity covered by this notice (see Section 3).

Programmatic Information

1. Program Background and Objectives

SAMHSA's mission within the Nation's health system is to improve the quality and availability of prevention, early intervention, treatment, and rehabilitation services for substance abuse and mental illnesses, including co-occurring disorders, in order to improve health and reduce illness, death, disability, and cost to society.

Reinventing government, with its emphases on redefining the role of Federal agencies and on improving customer service, has provided SAMHSA with a welcome opportunity to examine carefully its programs and activities. As a result of that process, SAMHSA moved assertively to create a renewed and strategic emphasis on using its resources to generate knowledge about ways to improve the prevention and treatment of substance abuse and mental illness and to work with State and local governments as well as providers, families, and consumers to effectively use that knowledge in everyday practice.

2. Criteria for Review and Funding

2.1 General Review Criteria

Competing applications requesting funding under the specific project activity in Section 3 will be reviewed for technical merit in accordance with established PHS/SAMHSA peer review procedures. Review criteria that will be used by the peer review groups are specified in the application guidance material.

2.2 Award Criteria for Scored Applications

Applications will be considered for funding on the basis of their overall technical merit as determined through the peer review group and the appropriate National Advisory Council review process. Availability of funds will also be an award criteria. Additional award criteria specific to the programmatic activity may be included in the application guidance materials.

3. Special FY 2000 SAMHSA Activities

Cooperative Agreement to Bridge the Gap: Phase II Implementation of Community-Based Practice/Research Collaboratives (Short Title: PRC Implementation Program) number TI 00-004.

- *Application Deadline:* June 13, 2000.

- *Purpose:* The overall purpose of the PRC program is to improve the quality of substance abuse treatment by increasing interaction and knowledge exchange among key community based stakeholders, including substance abuse treatment providers, community-based organizations providing support services to substance abusers, researchers, and policy makers, including health plan managers and purchasers of substance abuse treatment. Prior to the Implementation Phase of the program, it is expected that the PRCs will have developed the necessary infrastructure and capacity to conduct knowledge development and application studies to be able to participate effectively in federally-funded research efforts. Through these efforts, the PRCs will be able, over time, to make significant contributions to the field's knowledge and understanding about substance abuse treatment.

In order to accomplish the goals of the Phase II PRC Implementation Program, applicants are required to have met the following criteria: (1) An operational, community based PRC has been established in which providers participate as full partners with researchers, policy makers and other stakeholder groups; (2) a formal organizational structure and statement of operating procedures, roles and responsibilities of stakeholder members and designated consumer representative has been developed and endorsed by stakeholder groups; (3) a formal needs assessment of PRC stakeholders has been conducted and utilized to establish a consensus based research and knowledge application agenda and implementation plan; and (4) stakeholders have endorsed the implementation plan.

- *Eligible Applicants:* Applications for Implementation Cooperative Agreements may be submitted by domestic public and private nonprofit and for-profit entities, such as community-based organizations, public or private universities, colleges, and hospitals, units of State or local government, and Indian Tribes and tribal organizations.

- *Amount:* It is estimated that \$3.0 million will be available to support approximately 8-10 Implementation awards under this program in FY 2000. Awards are expected to range from \$300,000-\$400,000 per year in total costs (direct+indirect).

- *Period of Support:* Support may be requested for a period of up to three years. Annual awards will be made subject to continued availability of funds and progress achieved.

- *Catalog of Federal Domestic Assistance Number: 93.230.*

- *Program Contact:* For questions concerning program issues, contact: Frances Cotter, Project Officer, Office of Managed Care, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, Rockwall II, Suite 740, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-8796.

- *For questions regarding grants management issues, contact:* Christine Chen, Grants Management Officer, Division of Grants Management, OPS, Substance Abuse and Mental Health Services Administration, Rockwall II, 6th Floor, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-8926.

- *Application kits are available from:* National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20847-2345, Telephone: 1-800-729-6686.

4. Public Health System Reporting Requirements

The Public Health System Impact Statement (PHSIS) is intended to keep State and local health officials apprised of proposed health services grant and cooperative agreement applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental service providers who are not transmitting their applications through the State must submit a PHSIS to the head(s) of the appropriate State and local health agencies in the area(s) to be affected not later than the pertinent receipt date for applications. This PHSIS consists of the following information:

- a. A copy of the face page of the application (Standard form 424).
- b. A summary of the project (PHSIS), not to exceed one page, which provides:
 - (1) A description of the population to be served.
 - (2) A summary of the services to be provided.
 - (3) A description of the coordination planned with the appropriate State or local health agencies.

State and local governments and Indian Tribal Authority applicants are not subject to the Public Health System Reporting Requirements.

Application guidance materials will specify if a particular FY 2000 activity is subject to the Public Health System Reporting Requirements.

5. PHS Non-Use of Tobacco Policy Statement

The PHS strongly encourages all grant and contract recipients to provide a

smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

6. Executive Order 12372

Applications submitted in response to the FY 2000 activity listed above are subject to the intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR part 100. E.O. 12372 sets up a system for State and local government review of applications for Federal financial assistance. Applicants (other than Federally recognized Indian tribal governments) should contact the State's Single Point of Contact (SPOC) as early as possible to alert them to the prospective application(s) and to receive any necessary instructions on the State's review process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC of each affected State. A current listing of SPOCs is included in the application guidance materials. The SPOC should send any State review process recommendations directly to: Division of Extramural Activities, Policy, and Review, Substance Abuse and Mental Health Services Administration, Parklawn Building, Room 17-89, 5600 Fishers Lane, Rockville, Maryland 20857.

The due date for State review process recommendations is no later than 60 days after the specified deadline date for the receipt of applications. SAMHSA does not guarantee to accommodate or explain SPOC comments that are received after the 60-day cut-off.

Dated: March 12, 2000.

Richard Kopanda,

Executive Officer, SAMHSA.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Grant Programs Technical Assistance Workshops; Notice of Meetings

AGENCY: Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Notice of Technical Assistance Sessions for Potential Applicants for the SAMHSA/CSAT Grant Program: TI 00-004—"Cooperative Agreement to Bridge the Gap: Phase II Implementation of Community-Based Practice/Research Collaboratives."

Notice is hereby given for the following technical assistance sessions to be provided to prospective applicants for SAMHSA/CSAT Guidance for Applicants (GFA) TI 00-004. The text of the grant announcement can be downloaded from the SAMHSA Web Site at www.samhsa.gov or ordered from the National Clearinghouse for Alcohol and Drug Information (NCADI) at (800) 729-6686.

The technical assistance sessions will be held as follows: Session I—April 5, 2000, 1-3 p.m., 7th Floor Conference Room, Rockwall II Building, Center for Substance Abuse Treatment, 5515 Security Lane, Rockville, MD 20852; Session II—April 12, 2000, 3-5 p.m., Hilton New Orleans Riverside, New Orleans, LA. Each two-hour session will follow the following format: (1) Presentation of the key components of the GFA, and (2) question and answer session.

Potential applicants are strongly encouraged to review the grant announcement prior to attending a technical assistance session to determine if they meet the capability criteria listed below for the implementation phase. Applications may be submitted by domestic public and private non-profit and for-profit entities such as community-based organizations, public or private universities, colleges, and hospitals, and units of State or local government. In order to accomplish the goals of the Phase II PRC Implementation Program, applicants are required to have met the following criteria: (1) An operational, community based PRC has been established in which providers participate as full partners with researchers, policy makers and other stakeholder groups; (2) a formal organizational structure and statement of operating procedures, roles and